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Effectiveness of DiaWell, an artificial intelligence–based smartphone application, on glycaemic control and quality of life among patients with type 2 diabetes mellitus: a quasi-experimental study from South India

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Abstract

Background

Type 2 diabetes mellitus (T2DM) imposes a major and rising burden in India, where suboptimal follow-up in routine care exposes patients to poor glycaemic control and diminished quality of life (QOL). Advanced closed-loop digital systems remain unaffordable for most patients in Indian public and tertiary care settings. We developed DiaWell, a locally adapted artificial intelligence (AI)–assisted smartphone application, and evaluated its effectiveness on glycaemic control and QOL.

Methods

A quasi-experimental study was conducted over 18 months at a tertiary care hospital in Mysuru, South India. Using purposive sampling, 360 adults with T2DM were allocated to an experimental group (n = 180) that used DiaWell alongside standard care and a control group (n = 180) that received standard care alone, for six months. Glycated haemoglobin (HbA1c) was measured in the laboratory and QOL was assessed using the WHOQOL-BREF instrument at baseline and endline. Within-group HbA1c change was tested using the paired t test, between-group change using the independent t test; QOL domains were compared using the Wilcoxon signed-rank and Mann–Whitney U tests.

Results

Both groups achieved a significant within-group reduction in mean HbA1c. The experimental group declined from 8.80% to 7.44% (mean reduction 1.36%; $t = 7.129$, $p < 0.001$) and the control group from 8.45% to 7.60% (mean reduction 0.85%; $t = 4.487$, $p < 0.001$). The post-intervention between-group difference was not significant (7.44% vs 7.60%; $t = -0.827$, $p = 0.409$). The experimental group showed statistically significant improvements across all four WHOQOL-BREF domains (physical $p = 0.001$, psychological $p = 0.022$, social $p = 0.037$, environmental $p = 0.003$), whereas the control group showed no significant change in any domain. Notably, the experimental group achieved this parity despite a more severe baseline profile (older age, higher insulin dependency, greater familial burden, and lower baseline QOL).

Conclusions

DiaWell was an effective adjunct to standard T2DM care, enabling a more severely affected cohort to reach glycaemic parity with a healthier control group and producing comprehensive gains in quality of life. Accessible, locally adapted mHealth applications can strengthen self-management and well-being for T2DM patients in resource-constrained settings.

Background

Diabetes mellitus is a chronic metabolic disorder defined by persistent hyperglycaemia arising from defects in insulin secretion, insulin action, or both, and it represents one of the most rapidly escalating global public health emergencies of the twenty-first century [1]. In 2021, more than 537 million adults were living with diabetes worldwide, and over three-quarters of them resided in low- and middle-income countries [2]. India is among the epicentres of this epidemic, with an estimated 101 million people affected as of 2021—the second highest national figure globally—driven by genetic susceptibility interacting with rapid urbanisation, sedentary behaviour, and dietary transition [3].

Within this national landscape, the state of Karnataka and the rapidly urbanising district of Mysuru demonstrate a substantial and expanding metabolic disease burden, with high vulnerability to microvascular and macrovascular sequelae [4, 5]. Chronic uncontrolled diabetes increases the risk of nephropathy, retinopathy, neuropathy, diabetic foot ulcers, and cardiomyopathy. Achieving target glycaemic control, quantified primarily through glycated haemoglobin (HbA1c), remains the cornerstone of reducing this multi-organ morbidity. However, structured self-management education and routine clinical follow-up are frequently suboptimal in regional health facilities, exposing patients to erratic glycaemic excursions and accelerated target-organ damage [5, 6].

Type 2 diabetes also erodes patients' quality of life (QOL) across physical, psychological, social, and environmental dimensions [7, 8]. Prior work from the Mysuru clinical context has shown that structured, technology-enabled interventions can meaningfully elevate patient-reported outcomes across the domains of the WHOQOL-BREF instrument, underscoring the potential of non-traditional supportive frameworks [9, 10].

To address these deficiencies, clinical attention has shifted towards digital and artificial intelligence (AI)–enabled optimisation of care. The application of AI in diabetes has expanded rapidly, encompassing continuous glucose monitoring, decision support, and mobile self-management platforms [11, 12]. Systematic reviews and meta-analyses consistently report that mobile phone applications, used as an adjunct to medical therapy, improve glycaemic control, with mean HbA1c reductions of approximately 0.5% and enhanced effect when healthcare professional feedback is incorporated [13, 14]. Our group has previously demonstrated, in randomised and longitudinal studies in Mysuru, that smartphone- and web-based interventions improve both glycaemic control and quality of life among T2DM patients [9, 10, 15, 16, 17].

Despite this progress, a distinct research gap persists in Tier-II Indian cities. Highly autonomous closed-loop systems and continuous sensors common in high-resource Western settings remain prohibitively expensive for most patients attending public or tertiary care hospitals in India. There is a lack of locally validated evidence on the effectiveness of accessible, smartphone-integrated, AI-based applications tailored to the sociocultural, linguistic, and economic realities of South Indian T2DM cohorts. We therefore developed DiaWell, a locally adapted AI-assisted mobile application, and evaluated its

effectiveness on glycaemic control and quality of life among adults with T2DM attending a tertiary care hospital in Mysuru.

Methods

Study design and setting

This quasi-experimental study was conducted over a period of 18 months at the Department of Community Medicine and General Medicine, JSS Medical College and Hospital, Mysuru, a tertiary care teaching hospital in South India whose diabetic clinic registers approximately 2,500 patients on regular follow-up. The study was carried out in three phases: development of the DiaWell application, a pilot validation phase, and a six-month formal intervention.

Participants and eligibility

Adults aged more than 18 years with a diagnosis of T2DM of at least one year's duration, who were willing to participate and had access to an Android smartphone and the internet, were eligible. Patients who were bedridden, had neuropsychiatric disorders, had gestational diabetes mellitus, or had severe complications were excluded.

Sample size and sampling

Expecting a minimum difference of 0.81 units between groups (based on Chen et al., 2011), with a pooled standard deviation of 1.95 units, 90% power, and a 95% confidence level, a minimum of 139 subjects per group was required, rounded to 150. Anticipating a dropout of up to 20%, the sample was rounded to 180 per group, giving a total of 360 participants. Purposive sampling was used to recruit patients attending the diabetic clinic until the required sample size was reached.

The DiaWell application

DiaWell is a locally developed diabetes self-management application supporting two user roles—patient and doctor. For patients, it enables secure registration, recording and monitoring of blood glucose, blood pressure, body mass index and weight, food logging with AI-assisted calorie estimation, medication reminders, upload of prescriptions and laboratory reports, foot-image capture, health tips, and generation of health reports. For doctors, it provides a dashboard to view patient records, identify high-risk patients, generate digital prescriptions, and review health trends. The application follows a client–server architecture with a React Native (Expo) frontend and a Node.js/Express.js backend exposing RESTful APIs secured through JSON Web Token authentication. A dual-layer database design (local AsyncStorage plus a centralised server database) supports offline data entry with automatic synchronisation once connectivity is restored. The backend was deployed on a cloud service provider

and the client distributed as an Android application. The application was designed, developed, tested, and refined iteratively using an agile prototyping approach informed by focus groups and interviews with diabetic patients, caregivers, and medical experts.

Intervention

For six months, the experimental group used the DiaWell application alongside their standard medical care, enabling them to log diet, track daily blood glucose, and receive medication reminders, while physicians monitored their progress remotely. The control group continued their routine treatment without the application. A structured questionnaire was administered to both groups.

Outcomes and measurement

The primary outcome was glycaemic control, measured as HbA1c using an automated laboratory analyser. The secondary outcome was quality of life, assessed using the validated WHOQOL-BREF instrument [18], a previously published and internationally validated tool comprising 26 items covering four domains (physical, psychological, social relationships, and environmental) plus two general items; domain scores were transformed to a 0–100 scale. Both outcomes were assessed at baseline and after six months in both groups. In addition, a semi-structured questionnaire developed by the investigators for this study captured sociodemographic profile, anthropometry, and diabetes-related details; the full English-language version of this study-specific questionnaire is provided as Additional file 1.

Statistical analysis

Data were entered in Microsoft Excel and analysed using SPSS version 30. Categorical variables were summarised as frequencies and percentages, and quantitative variables as mean and standard deviation. Normality was assessed using the Kolmogorov–Smirnov test. The paired t test was used to compare mean HbA1c before and after the intervention within groups, and the independent t test for between-group comparison. As QOL domain scores were not normally distributed, the Wilcoxon signed-rank test was used for within-group and the Mann–Whitney U test for between-group comparisons. A p value < 0.05 was considered statistically significant. All reported statistics were independently re-verified against the raw dataset.

Ethics

The study was approved by the Institutional Ethical Committee, JSS Medical College (JSS/MC/PG/23–24/2023-24). Written informed consent was obtained from all participants, and confidentiality of personal and medical details was maintained throughout.

Results

A total of 360 participants completed the study with no loss to follow-up—180 in the experimental (DiaWell) group and 180 in the control group. Both groups comprised an equal number of males and females (50% each). The mean age was 60.83 ± 9.2 years in the experimental group and 56.28 ± 10.7 years in the control group, indicating an older experimental cohort. The experimental group also carried a more severe baseline profile: a higher proportion with a family history of diabetes (83.3% vs 57.2%), greater insulin dependency (35.6% on insulin and 20.0% on combination therapy vs 8.3% and 4.5% in controls), more frequent self-monitoring of blood glucose, and lower baseline quality of life. Grade I obesity was highly prevalent in both groups (75.6% experimental, 71.1% control), with an overall mean body mass index of 26.25 ± 2.64 kg/m². The baseline sociodemographic and clinical characteristics of both groups are summarised in Table 1.

Table 1
Baseline sociodemographic and clinical characteristics of participants.

Characteristic	Experimental (n = 180)	Control (n = 180)
Male / Female, n	90 / 90	90 / 90
Mean age, years (SD)	60.83 (9.2)	56.28 (10.7)
Residence: rural / urban, n (%)	91 (50.6) / 89 (49.4)	73 (40.6) / 107 (59.4)
Family history of diabetes, n (%)	150 (83.3)	103 (57.2)
Current treatment — oral, n (%)	75 (41.7)	139 (77.2)
Current treatment — insulin, n (%)	64 (35.6)	15 (8.3)
Current treatment — both, n (%)	36 (20.0)	8 (4.5)
Current treatment — none, n (%)	5 (2.7)	18 (10.0)
Grade I obesity, n (%)	136 (75.6)	128 (71.1)
Mean BMI, kg/m² (SD)	26.23 (2.65)	26.26 (2.63)
Uncontrolled diabetes at baseline, n (%)	150 (83.3)	135 (75.0)

Glycaemic control

Both groups achieved a statistically significant within-group reduction in mean HbA1c after six months (Table 2, Fig. 1). In the experimental group, HbA1c declined from 8.80 ± 1.77% to 7.44 ± 1.81%, a mean reduction of 1.36% ($t = 7.129$, $p < 0.001$). The control group declined from 8.45 ± 1.90% to 7.60 ± 1.73%, a mean reduction of 0.85% ($t = 4.487$, $p < 0.001$). The between-group comparison showed no statistically significant difference at baseline ($t = 1.803$, $p = 0.072$) or after the intervention ($t = -0.827$, $p = 0.409$) (Table 3). Although the post-intervention difference was not significant, the experimental group—starting from a more severe, insulin-dependent baseline—achieved glycaemic parity with the healthier control group by endline.

Table 2
Comparison of mean HbA1c levels before and after intervention (within groups).

Mean HbA1c (%)	Experimental (n = 180)	Control (n = 180)
Before intervention	8.80 ± 1.77	8.45 ± 1.90
After intervention	7.44 ± 1.81	7.60 ± 1.73
Mean difference	1.36	0.85
t value	7.129	4.487
p value	< 0.001*	< 0.001*

*Values expressed as mean ± standard deviation. Paired t test. *p < 0.05 considered statistically significant.*

Table 3
Intergroup comparison of mean HbA1c levels before and after intervention.

Mean HbA1c (%)	Experimental (n = 180)	Control (n = 180)	t value	p value
Before intervention	8.80 ± 1.77	8.45 ± 1.90	1.803	0.072
After intervention	7.44 ± 1.81	7.60 ± 1.73	−0.827	0.409

Values expressed as mean ± standard deviation. Independent t test. p < 0.05 considered statistically significant.

Quality of life

At baseline, the control group reported significantly higher WHOQOL-BREF scores than the experimental group across all four domains (physical p < 0.001, psychological p = 0.002, social p = 0.001, environmental p = 0.030), reflecting a substantial baseline well-being deficit in the experimental arm (Table 4). Following the intervention, the between-group differences were no longer significant in any domain (physical p = 0.478, psychological p = 0.851, social p = 0.488, environmental p = 0.971), indicating that the experimental group had closed the gap (Table 5).

Table 4
Comparison of WHOQOL-BREF domain scores between groups before intervention.

Domain	Experimental median (IQR)	Control median (IQR)	p value
Physical	56 (12)	56 (13)	< 0.001*
Psychological	50 (17.25)	56 (19)	0.002*
Social relationship	50 (25)	50 (25)	0.001*
Environmental	50 (19)	56 (25)	0.030*

*Values expressed as median and interquartile range (IQR). Mann–Whitney U test. *p < 0.05 considered statistically significant.*

Table 5
Comparison of WHOQOL-BREF domain scores between groups after intervention.

Domain	Experimental median (IQR)	Control median (IQR)	p value
Physical	56 (31)	56 (31)	0.478
Psychological	56 (43)	56 (43)	0.851
Social relationship	50 (50)	56 (44)	0.488
Environmental	56 (50)	63 (43)	0.971

Values expressed as median and interquartile range (IQR). Mann–Whitney U test. $p < 0.05$ considered statistically significant.

Within-group analysis confirmed that this convergence was driven by improvement in the experimental group (Table 6, Fig. 2). The experimental group showed statistically significant gains across all four domains (physical p = 0.001, psychological p = 0.022, social p = 0.037, environmental p = 0.003). By contrast, the control group showed no statistically significant change in any domain (physical p = 0.339, psychological p = 0.557, social p = 0.460, environmental p = 0.244) (Table 7).

Table 6
Comparison of WHOQOL-BREF domain scores before and after intervention (experimental group).

Domain	Before median (IQR)	After median (IQR)	p value
Physical	56 (12)	56 (31)	0.001*
Psychological	50 (17.25)	56 (43)	0.022*
Social relationship	50 (25)	50 (50)	0.037*
Environmental	50 (19)	56 (50)	0.003*

*Values expressed as median and interquartile range (IQR). Wilcoxon signed-rank test. *$p < 0.05$ considered statistically significant.*

Table 7
Comparison of WHOQOL-BREF domain scores before and after intervention (control group).

Domain	Before median (IQR)	After median (IQR)	p value
Physical	56 (13)	56 (31)	0.339
Psychological	56 (19)	56 (43)	0.557
Social relationship	50 (25)	56 (44)	0.460
Environmental	56 (25)	63 (43)	0.244

Values expressed as median and interquartile range (IQR). Wilcoxon signed-rank test. $p < 0.05$ considered statistically significant.

Discussion

In this quasi-experimental study of 360 adults with T2DM, the AI-assisted DiaWell application functioned as an effective adjunct to standard care. It produced a larger within-group reduction in HbA1c (1.36% vs 0.85%) and enabled a more severely affected experimental cohort—older, more insulin-dependent, with a greater familial burden and lower baseline quality of life—to achieve glycaemic and psychosocial parity with a healthier control group. Improvements in quality of life were comprehensive and statistically significant across all four WHOQOL-BREF domains in the experimental group, while the control group showed no significant change.

These glycaemic findings align with global meta-analyses reporting that mobile phone applications, used as an adjunct to medical therapy, improve glycaemic control by roughly 0.5% HbA1c, with effect sizes enhanced by younger age and healthcare professional feedback [13, 14]. They are also consistent with our group's prior randomised and longitudinal work in Mysuru, in which smartphone- and web-based interventions improved glycaemic control among T2DM patients [15, 16]. The non-significant between-group difference after intervention should be interpreted in light of the experimental group's substantially more severe baseline disease profile and the likely operation of a Hawthorne effect within the control arm in a tertiary care research setting; the more meaningful signal is the experimental group's capacity to overcome a marked baseline disadvantage.

The quality-of-life findings extend earlier evidence that technology-enabled diabetes interventions enhance patient-reported outcomes across all WHOQOL-BREF domains [9, 10, 17]. The ubiquitous improvement in the experimental group is consistent with a psychosocial mechanism in which continuous educational nudges and automated reminders foster self-efficacy and reduce diabetes-related distress, contrasting with earlier concerns that digital hyper-monitoring might induce anxiety. Because both HbA1c and QOL improved, yet the well-documented weak correlation between clinical and patient-reported outcomes persists [19], participants likely felt better through the empowerment and self-efficacy gained from the tool rather than through the reduction in HbA1c alone.

From a health-systems perspective, DiaWell is a scalable, low-marginal-cost intervention capable of democratising continuous, structured diabetes support for resource-constrained settings. Its effectiveness in an older, less-educated, and rural-inclusive experimental cohort suggests that simplified visual interfaces, automated alerts, and localised design can bypass traditional literacy and access barriers. Wider integration of such mHealth applications into routine diabetes care could improve self-management, reduce avoidable hospital visits, and optimise resource utilisation.

Strengths and limitations

Strengths of this study include a large sample of 360 participants with no loss to follow-up, an equal sex distribution reducing gender-related bias, the use of validated tools (WHOQOL-BREF and laboratory HbA1c), the balanced rural–urban composition of the experimental group, and independent re-verification of all statistical results against the raw dataset. The study also addresses an important gap

by developing and evaluating a regionally adapted AI-based application for a Tier-II Indian setting. Limitations include the quasi-experimental design with purposive, non-random allocation, which introduced a baseline mismatch between cohorts (the experimental group being older, with a higher familial burden and lower baseline QOL); the potential for a Hawthorne effect; the absence of an interim follow-up before six months; and reliance on self-reported data through both the application and the subjective WHOQOL-BREF instrument. A randomised controlled trial with longer follow-up would further clarify effectiveness while reducing confounding.

Conclusions

The AI-assisted DiaWell application was an effective adjunct to standard T2DM care. Despite commencing with significant health and psychosocial disadvantages, patients using the application achieved robust glycaemic control and comprehensive, statistically significant improvements in quality of life, reaching parity with a healthier control group. Accessible, locally adapted mobile health applications can empower patients, strengthen continuous self-management, and enhance overall well-being, and merit wider integration into routine diabetes care in resource-constrained settings.

Abbreviations

AI
Artificial intelligence
HbA1c
Glycated haemoglobin
QOL
Quality of life
T2DM
Type 2 diabetes mellitus
WHOQOL-BREF
World Health Organization Quality of Life – BREF instrument
API
Application programming interface
SPSS
Statistical Package for the Social Sciences
ICMR
Indian Council of Medical Research
DHR
Department of Health Research
IQR
Interquartile range
SD
Standard deviation.

Declarations

Clinical trial number

Not applicable. This was a quasi-experimental study with non-randomized, purposive allocation to groups and did not constitute a registered clinical trial.

Ethics approval and consent to participate

The study was approved by the Institutional Ethical Committee of JSS Medical College, JSS Academy of Higher Education & Research, Mysuru (approval number JSS/MC/PG/23–24/2023-24). Written informed consent was obtained from all participants prior to enrolment. All methods were carried out in accordance with the Declaration of Helsinki and relevant institutional guidelines and regulations.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Funding

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Author Contribution

K.M. and S.K.D. conceived and designed the study. K.M. collected the data and coordinated development of the DiaWell application. A.G. performed and verified the statistical analysis. K.M. and S.K.D. drafted the main manuscript text. A.G. and L.S.A. critically revised the manuscript for important intellectual content. S.K.D. supervised the study as corresponding author. All authors reviewed and approved the final manuscript.

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Data Availability

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

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Figures

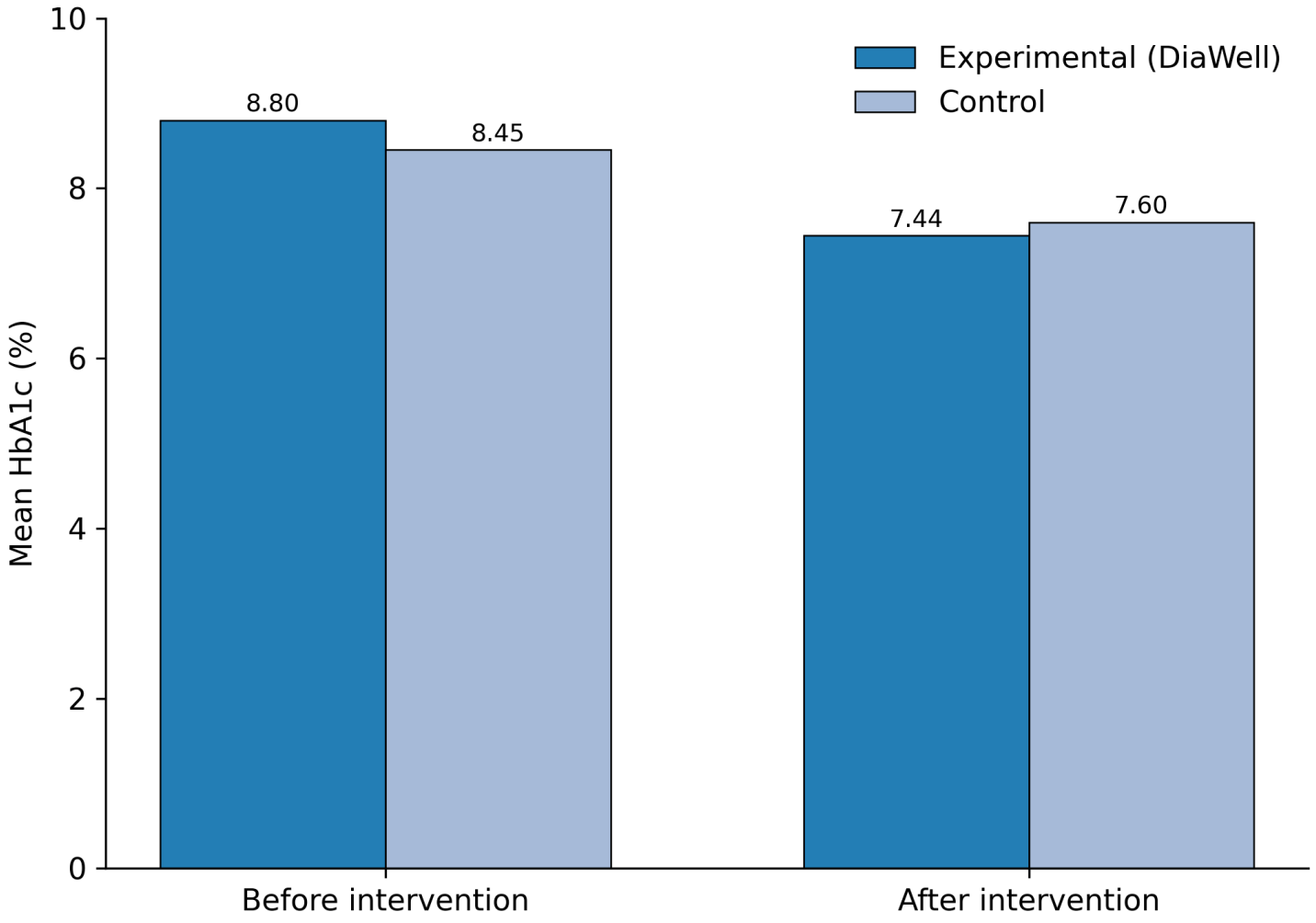


Figure 1

Comparison of mean HbA1c levels before and after the intervention in the experimental (DiaWell) and control groups. Both groups showed a statistically significant within-group reduction; the experimental group achieved a larger mean reduction (1.36% vs 0.85%).

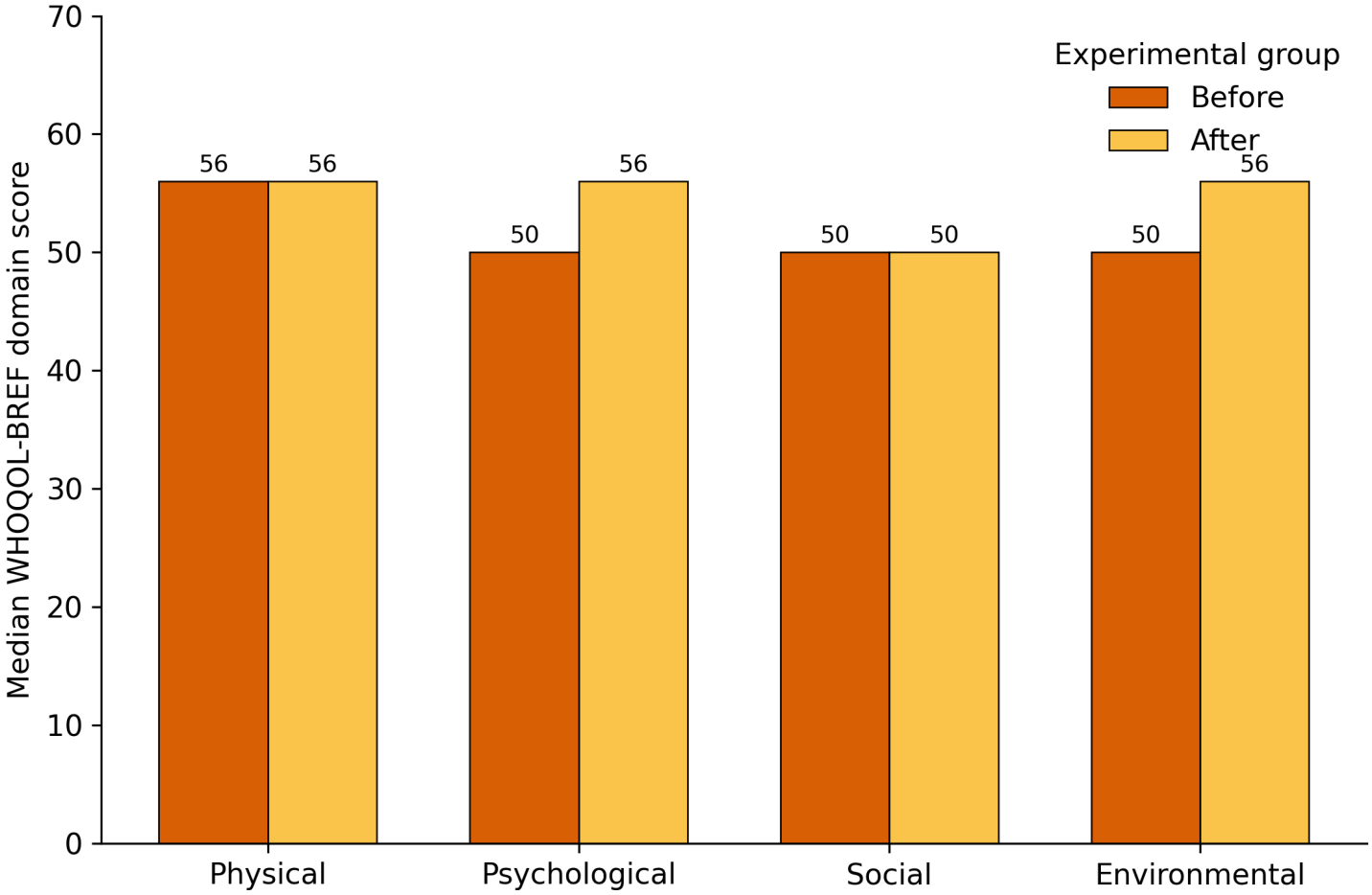


Figure 2

Median WHOQOL-BREF domain scores before and after the intervention in the experimental group. Statistically significant improvement was observed across all four domains (physical, psychological, social relationships, and environmental).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Additionalfile1Questionnaire.docx