

Effectiveness of Artificial Intelligence-Based Health Education Accurately Linking System (AI- HEALS) for Type 2 Diabetes Mellitus Self-Management: A Cluster Randomized Clinical Trial

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Abstract

Background

Type 2 diabetes mellitus (T2DM) requires sustained self-management, for which digital health interventions offer scalable support. However, evidence on their long-term effectiveness in real-world primary care remains limited. We evaluated the effectiveness of the Artificial Intelligence-based Health Education Accurately Linking System (AI-HEALS), an AI-driven platform delivering personalized T2DM self-management support.

Methods

In this cluster-randomized controlled trial (July 2023–July 2024), 45 community health centres in Beijing, China, were randomly allocated 1:1 to AI-HEALS plus treatment-as-usual (TAU) or TAU alone, enrolling 406 adults with T2DM aged 18–75 years. Proactive intervention delivery occurred over the first 3 months. The primary outcome was change in glycated haemoglobin (HbA_{1c}); secondary outcomes included self-management behaviours, diabetes-related skills, and psychological measures, assessed at 3, 6, 12, and 18 months. Outcomes were analysed using linear mixed-effects models, reporting adjusted between-group differences at each time point and overall across follow-up.

Results

Of 406 participants randomized, 391 were included in the analysis (AI-HEALS, $n = 202$; TAU, $n = 189$). HbA_{1c} declined in both arms, with no significant between-group difference at 18 months (adjusted mean difference, -0.22% ; 95% CI, -0.54 to 0.10) or overall across follow-up (-0.21% ; 95% CI, -0.48 to 0.06). AI-HEALS was associated with a small overall improvement in diabetes-related skills (1.69 points; 95% CI, 0.05 to 3.33) and higher dietary adherence at 6 and 12 months, though neither dietary adherence nor self-care activity showed a significant sustained overall effect. Medication adherence, self-efficacy, sleep quality, perceived stress, and quality of life did not differ significantly between groups.

Conclusions

AI-assisted personalized health education improved selected self-management behaviours, most consistently diabetes-related skills, but did not yield a sustained glycaemic benefit beyond usual care over 18 months. AI-HEALS offers a scalable digital health approach for community diabetes care, though durable metabolic benefit may require more sustained or adaptive interactive support.

Trial registration

Introduction

Diabetes is one of the four major chronic noncommunicable diseases worldwide and poses a significant public health challenge. According to the International Diabetes Federation (IDF), the global prevalence of diabetes has reached 537 million and is projected to increase to 643 million by 2030, with low- and middle-income countries bearing three-quarters of the burden[1]. China leads globally with 141 million patients, over 90% of whom have type 2 diabetes mellitus (T2DM), and the age of onset is trending significantly younger [2]. The burden of disability-adjusted life years (DALYs) associated with T2DM and its complications has increased substantially [3]. A 24-year follow-up of the United Kingdom Prospective Diabetes Study demonstrated that early diagnosis and immediate intensive glycaemic control are critical for minimizing the lifetime risk of diabetes-related complications [4]. Therefore, preventing and managing diabetes and controlling its risk factors should be a public health priority worldwide.

T2DM is a chronic, progressive condition that requires lifelong self-management, including regular physical activity, dietary modification, and adequate sleep [5]. Yet in China, treatment and glycemic control rates remain persistently low [6], underscoring a longstanding gap between clinical recommendations and their translation into sustained behavior change. Conventional clinic-based health education, delivered within brief and infrequent consultations, is poorly positioned to close this gap. Sustained self-management instead depends on individualized guidance: education patients can act on day to day, clinicians who translate evidence-based recommendations into practical, person-specific advice, and ongoing collaboration that allows care to be adjusted as circumstances change [7, 8]. These are precisely the conditions that episodic, in-person visits struggle to sustain. Digital health technologies offer one way to extend such support beyond the clinic walls, at a scale conventional care cannot match.

Digital health interventions (DHIs), including mobile applications, text messaging, and chatbots, may extend access to self-management support for adults with T2DM [9–11], yet evidence for sustained, longer-term benefit remains inconsistent [12–14]. Chatbot-based tools in particular have expanded rapidly and show promise for improving glycemic control, but the evidence base remains largely limited to system-design and pilot-stage work, with few randomized trials to date [15]. Most existing systems also remain rule-driven, offering limited structured medical knowledge or adaptive dialogue [16], and are rarely grounded in a behavior-change theory. These constraints may together limit the specificity and durability of their effects [17].

We developed the AI-based Health Education Accurately Linking System (AI-HEALS) to address these gaps. The system is grounded in the multi-theory model (MTM) of health behavior change, which has shown utility in explaining and predicting behavior [18] and in guiding intervention design [19], and integrates a knowledge graph to structure the underlying diabetes self-management knowledge base, paired with natural language processing to support flexible recognition of varied user phrasings. The system further combines a reactive AI-driven chatbot with proactive, personalized health education push

notifications, enabling tailored, on-demand, and continuous self-management support. We hypothesize that individuals with T2DM using AI-HEALS will achieve better glycemic control and greater self-management capacity than those receiving usual care.

Methods

Study design

This was a multicentre, parallel-group, cluster-randomised controlled trial conducted at 45 community health centres in Daxing and Shunyi Districts of Beijing, China, from July 1, 2023 to December 31, 2024. The trial was prospectively registered (ChiCTR2300068952) on March 2, 2023. The study was approved by the Biomedical Ethics Committee of Peking University (IRB00001052-22058), and all procedures were conducted in accordance with the Declaration of Helsinki. All participants provided written informed consent. This trial is reported in accordance with the CONSORT 2010 statement and the extension for cluster randomised trials.

Study Participants

Participants were eligible if they had a diagnosis of T2DM according to the WHO criteria (fasting plasma glucose ≥ 7.0 mmol/L, 2-hour postprandial glucose ≥ 11.1 mmol/L, or glycated haemoglobin [20] $\geq 6.5\%$). Inclusion criteria were age between 18 and 75 years; permanent residency in Beijing; ability to use a smartphone and the WeChat application; and capacity to receive systematic medical care and intervention for diabetes. Participants were also required to have no history of psychotropic medication use, no concurrent participation in other studies, and a willingness to comply with study procedures. Exclusion criteria included a diagnosis of type 1 diabetes, gestational or secondary diabetes; presence of severe diabetic complications; history of radiotherapy or chemotherapy within the past 6 months; any severe comorbidities or major systemic illnesses confirmed by medical history or examination; and any serious psychiatric disorders. Sex was confirmed on-site and recorded as either male or female. All participants provided written informed consent prior to enrolment.

Randomisation and blinding

Forty-five primary healthcare institutions across two districts of Beijing—25 in Shunyi District and 20 in Daxing District—were cluster-randomized by an independent statistician using Excel-generated random numbers (RAND function): institutions with a value < 0.5 were allocated to the AI-HEALS group, and those with a value ≥ 0.5 to the treatment-as-usual (TAU) group. This yielded 23 intervention and 22 control institutions; all patients recruited at a given institution were assigned accordingly.

Three groups remained blinded to allocation: institutional clinicians, who recruited patients, scheduled visits, and collected physiological and biochemical measurements; field investigators, whose role was

limited to one-on-one data collection with no other study involvement; and data analysts, who received outcome data coded only as Group A and Group B.

Blinding of patients and of personnel delivering the intervention was not feasible. Field supervisors introduced intervention-group patients to the AI-HEALS WeChat platform and demonstrated its use, while control-group patients received no such materials; system administrators delivered personalised content exclusively to intervention-group participants.

Procedures

Participants in the AI-HEALS group received standard diabetes primary care (SDPC) supplemented by a personalised digital intervention delivered via the WeChat platform “PKU Diabetes Butler”. The intervention incorporated an AI chatbot deployed through API integration and designed to provide automated information retrieval and structured responses based on a predefined question–answer library (Fig. 1). Specifically, the research team co-developed 1,124 standardised high-frequency T2DM self-management questions, each mapped to three to six alternative phrasings to enhance coverage and flexibility in natural language input recognition. The question library covered key domains of diabetes self-management, including dietary management, physical activity, medication use, and general diabetes knowledge. The dietary module comprised 40 recipe recommendations (tailored according to participants’ body mass index), 105 diet-related educational questions, and 246 food-related questions; the physical activity module included 30 exercise recommendation schemes and 44 exercise-related questions; the medication module encompassed 595 medication-related questions and 40 detailed explanations for injectable therapies; and the diabetes knowledge module contained 24 questions addressing fundamental aspects of diabetes management. The chatbot was implemented using a knowledge graph–driven dialogue framework (Appendix 1 PP 3). In addition, the chatbot incorporated non-clinical, gamified auxiliary features, including simple interactive functions such as time inquiries, reminders, calculators, weather information, storytelling, idiom-based word games, and scripted humour-related interactions. These features were available on demand or triggered by user-initiated inputs and were designed to support platform usability, without providing medical advice or behavioural counselling.

The intervention also included a blood glucose monitoring reminder function, which allowed participants to set individualized reminder times and receive automated notifications to facilitate timely self-monitoring of blood glucose. In addition, a personalized self-management message delivery system was implemented (Fig. 2). The research team developed and reviewed 98 original diabetes health education materials covering dietary guidance, physical activity, medication management, diabetes treatment and care, complication prevention, and general diabetes-related knowledge (Appendix 1 PP 4). These materials were provided in text, video, and audio formats and were automatically delivered based on participants' baseline characteristics, recorded blood glucose values, and content preferences. During the first three months of the intervention, participants received at least one message per day, with an operational guide provided during the first week. Proactive message delivery was limited to this initial

period, as sustained high-frequency messaging can induce message fatigue and reactance, thereby undermining persuasive effectiveness [21]; after three months, proactive delivery was discontinued, though participants retained full access to the interactive chatbot, educational resources, and blood glucose recording functions throughout the remainder of the 18-month study period.

To support onboarding and platform usability, brief phone contacts were conducted only during the first month of the intervention (weeks 1, 2, and 4) and were limited to technical support, including account registration, navigation guidance, and troubleshooting. Although no equivalent phone contacts were scheduled for the TAU group, participants in this group received routine human contact through standard community-based care, including scheduled consultations and basic preventive health services provided by community physicians. AI-HEALS provided general medication education and adherence support but did not offer individualized dose adjustment recommendations; medication management and clinical decision-making remained under physician care.

All participants were assessed at baseline and at 3, 6, 9, 12 and 18 months after enrolment. Assessments included physiological and biochemical measurements as well as standardised questionnaire-based evaluations.

Outcomes

The primary outcome was the absolute change in HbA_{1c} levels from baseline, measured using fasting venous blood samples at each follow-up assessment.

Secondary outcomes included diabetes self-management behaviours, comprising self-care activities assessed using the 11-item Summary of Diabetes Self-Care Activities (score range, 0–77), dietary adherence assessed using the 22-item Diabetes Dietary Adherence Scale (score range, 22–110), and medication adherence assessed using the 7-item diabetes-specific Adherence to Refills and Medications Scale (ARMS; score range, 0–21). Additional secondary outcomes included self-efficacy (16-item scale; score range, 0–64), diabetes-related skills (12-item scale; score range, 0–48), perceived stress assessed using the 4-item Perceived Stress Scale (PSS-4; score range, 0–16), and sleep quality assessed using the Brief Pittsburgh Sleep Quality Index (B-PSQI; score range, 0–15). Health-related quality of life was assessed using the EQ-5D-5L utility index, derived from the 5-level EuroQol 5-dimension questionnaire using the Chinese value set, and the EQ visual analogue scale (EQ VAS; range, 0–100). Except for the ARMS, PSS-4, and B-PSQI, higher scores indicated better outcomes. Platform-use data during the 3-month active intervention phase included chatbot session initiation, chatbot interaction frequency and duration, timing and interval of use, and engagement with educational articles, including access and clicks by content category. Further details of outcome measures and scales are provided in Appendix 1 (PP 7–9).

Post hoc outcomes included the proportion of participants achieving prespecified glycaemic targets at 18 months. Across the entire cohort, two prespecified HbA_{1c} thresholds (< 7.0% and < 6.5%) were

evaluated. Separately, subgroup analyses were conducted using individualised glycaemic targets based on expert consensus for Chinese adults with T2DM. [22] Participants were stratified into four groups according to age and comorbidity status: (1) aged 18–44 years without comorbidities (target < 6.5%), (2) aged 45–59 years or aged 18–44 years with comorbidities (target < 7.0%), (3) aged ≥ 60 years without comorbidities (target < 7.5%), and (4) aged ≥ 60 years with comorbidities (target < 8.0%).

Safety and adverse events were monitored throughout the 18-month follow-up period. Participants were encouraged to report any health issues or unexpected events, which were documented and reviewed by the study team.

Sample size

Sample size was prespecified for the primary outcome of HbA_{1c}. The calculation assumed a mean HbA_{1c} of 7.13%, a standard deviation of 1.60%, and an expected reduction to 6.50%, corresponding to a between-group difference of 0.63%. With a two-sided significance level of 0.05, 90% power, an intracluster correlation coefficient of 0.002, and a 1:1 cluster-randomized design, 157 participants per group were required before accounting for potential loss to follow-up. The target sample size was increased to 200 participants per group, yielding a total target sample size of 400 participants.

Statistical Analysis

All analyses followed the intention-to-treat principle. Continuous variables with normal distribution were summarized as means with standard deviations and compared using independent t tests; categorical variables were analyzed using χ^2 or Fisher exact tests, as appropriate. The primary outcome (HbA_{1c}) and secondary continuous outcomes (self-care activities, dietary adherence, medication adherence, diabetes-related skills, sleep quality, perceived stress, and health-related quality of life) were analysed using linear mixed-effects models to estimate between-group differences over time. Models included fixed effects for treatment group, time, and the group-by-time interaction, with time specified as a categorical variable representing four prespecified follow-up assessments (3, 6, 12 and 18 months). Random intercepts were included at both the participant and CHCs levels to account for within-participant correlation and clustering within CHCs. All models were adjusted for age and the baseline value of the corresponding outcome, and parameters were estimated using maximum likelihood (*lme4 package*). For continuous outcomes, intervention effects were expressed as adjusted mean differences between groups at each follow-up time point and as an overall difference across all follow-up assessments, with 95% confidence intervals (*emmeans package*).

For post hoc binary outcomes at 18 months, HbA_{1c} target achievement was defined according to prespecified glycaemic targets for each subgroup. Between-group differences in achievement rates were summarised as absolute risk differences with 95% confidence intervals calculated using score methods. These analyses were based on observed 18-month HbA_{1c} and were considered descriptive and exploratory. Sensitivity analyses for the primary outcome were performed using multiple imputation by chained equations with the *mice* package. All statistical tests were two-sided, with a significance level of

0.05. Because multiple secondary outcomes were evaluated, findings for secondary endpoints should be interpreted as exploratory. All analyses were conducted in R, version 4.4.1.

Results

A total of 406 participants were randomized (205 to AI-HEALS and 201 to TAU), and 391 contributed postbaseline data to the primary analysis (Fig. 3). Participants in the AI-HEALS group were younger than those in the TAU group (mean [SD] age, 56.6 [11.2] vs 58.9 [10.8] years; $P = 0.043$), whereas other baseline characteristics were generally similar (Table 1).

Table 1
Demographics and Baseline Characteristics of Study Participants

Variable	No. (%)		t/ χ^2	P value
	AI(n = 202)	TAU (n = 189)		
Sex			3.19	0.073
Male	95(47.0)	72(38.1)		
Female	107(53.0)	117(61.9)		
Age, years (M $\pm$ SD)	56.6 $\pm$ 11.2	58.9 $\pm$ 10.8	-2.04	0.043
BMI, kg/m ²			1.95	0.578
Underweight(<18.5)	1(0.5)	2(1.1)		
Normal weight (18.5–24.9)	57(28.2)	60(31.7)		
Overweight (25.0-29.9)	81(40.1)	64(33.9)		
Obese($\geq$ 30)	63(31.2)	63(33.3)		
Waist, cm			1.49	0.473
Normalcy(<80)	11(5.4)	16(8.5)		
Exceeding standard (80–94)	96(47.5)	84(44.4)		
Obese (>94)	95(47.0)	89(47.1)		
Disease duration, years			4.62	0.202
$\leq$ 5	57(28.2)	44(23.3)		
6–10	70(34.7)	56(29.6)		
11–20	58(28.7)	64(33.9)		
$\geq$ 21	17(8.4)	25(13.2)		
Diabetes Management			7.20	0.066
Diet	11(5.4)	11(5.8)		
OADs	142(70.3)	149(78.9)		
Injectable insulin	4(2.0)	0(0.0)		
OADs + Injectable Insulin	45(22.3)	29(15.3)		
Per capita monthly income, RMB			0.22	0.887
<3,000	58(28.7)	59(30.7)		

Variable	No. (%)		t/ χ^2	P value
	AI(n = 202)	TAU (n = 189)		
3,000–9,000	114(56.4)	105(55.6)		
>9,000	30(14.9)	26(13.8)		
Educational attainment			1.85	0.397
Junior high school and below	77(38.1)	82(43.4)		
High school and secondary school	48(23.8)	47(24.9)		
College and above	77(38.1)	60(31.7)		
Occupational status			4.14	0.126
Incumbency	93(46.0)	89(47.1)		
Separation/retirement	75(37.1)	81(42.9)		
Irregularly employed and Inactive/unemployed/unemployed	34(16.8)	19(10.1)		
Occupation			3.94	0.268
Management and professional and technical staff	74(36.6)	73(38.6)		
Services and manual labour	58(28.7)	67(35.4)		
Flexible employment and part-time workers	49(24.3)	34(18.0)		
Not involved in major economic activities	21(10.4)	15(7.9)		
Marital status			3.02	0.082
Unmarried, divorced or widowed	15(7.4)	24(12.7)		
Married	187(92.6)	165(87.3)		
Other diseases			3.17	0.214
0	44(21.8)	50(26.5)		
1	49(24.3)	54(28.6)		
≥2	109(54.0)	85(45.0)		
Family history of diabetes			0.04	0.844
None	93(46.0)	89(47.1)		
Yes	109(54.0)	100(52.9)		
Smoking status			3.75	0.153

Variable	No. (%)		t/ χ^2	P value
	AI(n = 202)	TAU (n = 189)		
Non-smoker	139(68.3)	124(65.6)		
Former smoker (quit)	10(5.0)	19(10.1)		
Current smoker	54(26.7)	46(24.3)		
Alcohol consumption status			0.68	0.882
Non-drinker	117(57.9)	112(59.3)		
Former drinker (quit)	18(8.9)	15(7.9)		
Current drinker	67(33.1)	62(32.8)		

Note: Data are mean (SD); n (%), unless otherwise specified.

Abbreviations: AI: artificial intelligence. TAU: treatment as usual. BMI: Body mass index. OADs: Oral antidiabetic drugs

HbA_{1c} declined in both groups over 18 months, from 7.20% at baseline to 7.09% in the AI-HEALS group and from 7.51% to 7.40% in the TAU group (Table 2 and Fig. 4). At 18 months, no statistically significant between-group difference in HbA_{1c} was observed (mean difference, – 0.22%; 95% CI, – 0.54 to 0.10; *P* = 0.181). The overall intervention effect across follow-up was also not statistically significant (mean difference, – 0.21%; 95% CI, – 0.48 to 0.06; *P* = 0.121).

Table 2
Estimates of Clinical Efficacy for Primary and Secondary Outcomes.

Outcome	AI		TAU		Treatment effect, mean (95% CI) ^a	P value
	Mean (SD)	No. of participants	Mean (SD)	No. of participants		
Primary outcome						
HbA _{1c} , %						
Baseline	7.20 (1.61)	202	7.51 (1.52)	189		
3-mo Follow-up	7.12 (1.34)	202	7.39 (1.65)	187	-0.12 (-0.42 to 0.19)	0.444
6-mo Follow-up	7.03 (1.21)	201	7.39 (1.64)	187	-0.28 (-0.58 to 0.02)	0.072
12-mo Follow-up	6.91 (1.26)	173	7.25 (1.62)	163	-0.23 (-0.54 to 0.09)	0.154
18-mo Follow-up	7.09 (1.23)	154	7.40 (1.60)	137	-0.22 (-0.54 to 0.10)	0.181
Overall intervention effect ^b					-0.21 (-0.48 to 0.06)	0.121
Secondary outcomes						
Self-Care Activities ^c						
Baseline	36.06 (14.38)	202	35.56 (14.91)	189		
3-mo Follow-up	42.01 (14.81)	196	42.51 (16.19)	180	-0.59 (-4.76 to 3.58)	0.780
6-mo Follow-up	46.70 (17.43)	190	44.54 (16.99)	172	2.00 (-2.21 to 6.21)	0.350
12-mo Follow-up	50.68 (16.73)	186	44.65 (16.00)	171	5.79 (1.56 to 10.01)	0.008
18-mo Follow-up	46.68 (12.78)	152	42.92 (15.16)	118	2.66 (-1.94 to 7.26)	0.256
Overall intervention effect					2.47 (-1.01 to 5.94)	0.163
Dietary adherence ^d						

Outcome	AI		TAU		Treatment effect, mean (95% CI) ^a	P value
	Mean (SD)	No. of participants	Mean (SD)	No. of participants		
Baseline	55.88 (16.31)	202	56.77 (17.99)	189		
3-mo Follow-up	82.81 (14.83)	196	84.46 (15.49)	180	-1.54 (-5.61 to 2.54)	0.458
6-mo Follow-up	91.49 (14.61)	190	86.87 (15.36)	172	4.83 (0.71 to 8.94)	0.022
12-mo Follow-up	93.66 (14.82)	186	86.84 (16.58)	171	6.91 (2.78 to 11.05)	0.001
18-mo Follow-up	87.86 (15.44)	152	85.73 (17.73)	118	1.24 (-3.27 to 5.75)	0.589
Overall intervention effect					2.86 (-0.50 to 6.22)	0.094
Medication adherence ^e						
Baseline	5.74 (5.18)	202	5.94 (4.94)	189		
3-mo Follow-up	3.59 (3.25)	196	3.24 (3.25)	180	0.37 (-0.41 to 1.15)	0.349
6-mo Follow-up	3.40 (3.32)	190	3.45 (2.80)	172	-0.01 (-0.80 to 0.78)	0.349
12-mo Follow-up	3.84 (4.02)	186	4.20 (3.87)	171	-0.28 (-1.08 to 0.51)	0.485
18-mo Follow-up	2.01 (3.59)	152	4.01 (3.33)	118	-1.80 (-2.70 to -0.90)	<0.0001
Overall intervention effect					-0.43 (-0.10 to 0.13)	0.129
Diabetes-related skills ^f						
Baseline	28.11 (9.86)	202	30.17 (10.17)	189		
3-mo Follow-up	31.87 (9.87)	196	32.58 (9.10)	180	-0.91 (-3.19 to 1.37)	0.434
6-mo Follow-up	37.56 (9.93)	190	34.58 (10.29)	172	2.82 (0.50 to 5.13)	0.017
12-mo Follow-up	39.17 (9.57)	186	34.59 (10.30)	171	4.42 (2.09 to 6.74)	<0.0001

Outcome	AI		TAU		Treatment effect, mean (95% CI) ^a	P value
	Mean (SD)	No. of participants	Mean (SD)	No. of participants		
18-mo Follow-up	34.05 (10.20)	152	33.11 (10.48)	118	0.43 (-2.20 to 3.06)	0.747
Overall intervention effect					1.69 (0.05 to 3.33)	0.043
Self-efficacy ^g						
Baseline	38.05 (16.11)	202	38.06 (15.25)	189		
3-mo Follow-up	43.36 (14.31)	196	45.07 (12.38)	180	-2.01 (-5.39 to 1.38)	0.245
6-mo Follow-up	47.11 (17.21)	190	46.97 (15.37)	172	-0.11 (-3.46 to 3.23)	0.946
12-mo Follow-up	52.77 (13.39)	186	44.64 (13.66)	171	7.74 (4.29 to 11.19)	<0.0001
18-mo Follow-up	46.94 (12.41)	152	46.16 (14.11)	118	0.01 (-3.87 to 3.88)	0.996
Overall intervention effect					1.41(-1.04 to 3.85)	0.256
Sleep quality ^h						
Baseline	5.54 (3.48)	202	4.88 (3.46)	189		
3-mo Follow-up	4.94 (2.91)	196	4.02 (3.01)	180	0.67 (-0.99 to 2.32)	0.427
6-mo Follow-up	4.58 (3.25)	190	4.85 (3.36)	172	-0.13 (-1.83 to 1.58)	0.882
12-mo Follow-up	4.23 (3.35)	186	4.68 (3.36)	171	-0.30 (-2.00 to 1.40)	0.727
18-mo Follow-up	4.16 (3.33)	152	4.19 (3.52)	118	-0.68 (-2.63 to 1.27)	0.492
Overall intervention effect					-0.11 (-1.47 to 1.25)	0.870
Perceived stress ⁱ						

Outcome	AI		TAU		Treatment effect, mean (95% CI) ^a	P value
	Mean (SD)	No. of participants	Mean (SD)	No. of participants		
Baseline	8.26 (3.03)	202	8.31 (3.15)	189		
3-mo Follow-up	8.31 (3.06)	196	7.89 (3.04)	180	-1.31 (-2.57 to -0.04)	0.043
6-mo Follow-up	6.92 (3.38)	190	7.01 (3.36)	172	0.13 (-1.20 to 1.45)	0.852
12-mo Follow-up	7.30 (3.68)	186	8.06 (3.52)	171	0.00 (-1.35 to 1.34)	0.998
18-mo Follow-up	7.64 (3.28)	152	8.41 (3.38)	118	-0.81 (-2.50 to 0.87)	0.342
Overall intervention effect					-0.50 (-1.25 to 0.26)	0.187
Quality of life (EQ-5D-5L) ^j						
Baseline	0.93 (0.10)	202	0.95 (0.08)	189		
3-mo Follow-up	0.97 (0.07)	196	0.97 (0.12)	180	0.01 (-0.01 to 0.03)	0.365
6-mo Follow-up	0.97 (0.06)	190	0.96 (0.11)	172	0.01 (-0.00 to 0.03)	0.115
12-mo Follow-up	0.98 (0.05)	186	0.97 (0.07)	171	0.01 (-0.01 to 0.03)	0.321
18-mo Follow-up	0.95 (0.08)	152	0.95 (0.10)	118	0.00 (-0.02 to 0.02)	0.874
Overall intervention effect					0.01 (-0.00 to 0.02)	0.165
Quality of life (0-100) ^k						
Baseline	77.84 (13.59)	202	78.25 (13.14)	189		
3-mo Follow-up	74.66 (20.65)	196	76.01 (18.92)	180	-1.56 (-7.12 to 3.99)	0.579
6-mo Follow-up	80.48 (12.67)	190	76.94 (12.14)	172	3.29 (-2.51 to 9.10)	0.264
12-mo Follow-up	81.91 (12.96)	186	79.03 (12.00)	171	3.60 (-2.27 to 9.48)	0.228

Outcome	AI		TAU		Treatment effect, mean (95% CI) ^a	P value
	Mean (SD)	No. of participants	Mean (SD)	No. of participants		
18-mo Follow-up	81.09 (10.94)	152	80.54 (12.87)	118	-1.62 (-8.86 to 5.61)	0.66
Overall intervention effect					0.93 (-2.88 to 4.74)	0.624

Note: Data are mean difference (95% CI), unless otherwise specified.

a The average treatment effect was derived from a linear mixed-effects model, which implicitly controlled for baseline values of the outcome and the age.

b P value is from a mixed effects model, comparing between-group differences over the entire 18-mo trial.

c Measures diabetes self-care activities, with scores ranging from 0 to 77. Higher scores indicate stronger self-management ability.

d Measures dietary adherence in diabetes patients, with scores ranging from 22 to 110. Higher scores indicate better adherence.

e Measures medication adherence and refill adherence in diabetes patients, with scores ranging from 0 to 21. Higher scores indicate poorer adherence to medication and refills.

f Measures the ability of diabetes patients to acquire relevant skills, with scores ranging from 0 to 48. Higher scores indicate stronger skills.

g Measures self-efficacy in managing dietary control for diabetes, with scores ranging from 0 to 64. Higher scores indicate greater confidence.

h Measures sleep quality, with scores ranging from 0 to 15. Higher scores indicate poorer sleep quality.

i Measures psychological stress levels over the past month, with scores ranging from 0 to 16. Higher scores indicate higher levels of psychological stress.

j Measures health-related quality of life using the EQ-5D-5L utility index, derived from EQ-5D-5L responses using the Chinese value set. Higher values indicate better health-related quality of life.

k Measures self-rated health on the EQ visual analogue scale, ranging from 0 to 100, with higher scores indicating better perceived health status.

Abbreviations: AI: artificial intelligence. TAU: treatment as usual. HbA_{1c}: glycated haemoglobin.

Compared with TAU, participants in the AI-HEALS group demonstrated greater improvements in several secondary outcomes. Diabetes self-care activity scores were higher at 12 months (between-group difference, 5.79 points [95% CI, 1.56 to 10.01]), although the overall intervention effect across follow-up was not statistically significant. Dietary adherence was higher at 6 months (4.83 points [95% CI, 0.71 to 8.94]; $P = 0.022$) and 12 months (6.91 points [95% CI, 2.78 to 11.05]; $P = 0.001$), but the overall intervention effect across follow-up was not statistically significant ($P = 0.094$). Diabetes-related skills improved more in the AI-HEALS group at 6 and 12 months (Table 2 and Fig. 4), with a small but statistically significant overall effect (1.69 points [0.05 to 3.33]; $P = 0.043$). Medication adherence, self-efficacy, sleep quality, perceived stress, and health-related quality of life, assessed by both the EQ-5D-5L utility index and EQ VAS, did not differ significantly between groups across follow-up. Sensitivity analyses yielded results consistent with the primary analysis (Appendix 2 Table 1).

During the 3-month active intervention phase, 158 of 202 participants (78.2%) initiated at least 1 AI-chatbot session. Interaction frequency was concentrated at low to moderate levels, with the largest groups using the chatbot 1 to 5 times or 6 to 10 times, whereas relatively few participants used it more than 10 times. Average session length was generally short, most often 1 to 10 minutes, and more than half of participants used the system at intervals of less than 1 week. Educational articles were accessed by 84% of participants and received 3192 total clicks, with the highest use in the general diabetes knowledge and dietary guidance modules.

In post hoc analyses at 18 months, 59.1% of participants in the AI-HEALS group and 48.9% in the TAU group achieved $\text{HbA}_{1c} < 7.0\%$, corresponding to an absolute risk difference of 10.2 percentage points (95% CI, -1.3 to 21.4). The corresponding proportions for $\text{HbA}_{1c} < 6.5\%$ were 36.4% and 35.0%, yielding an absolute risk difference of 1.3 percentage points (95% CI, -9.7 to 12.3). Across individualised glycaemic target strata, attainment rates were numerically higher in the AI-HEALS group, although confidence intervals were wide (Table 3).

Table 3
Post hoc HbA1c target achievement at 18 months

Outcome	AI	TAU	Absolute risk difference, % (95% CI) ^b
	Achieved/Observed, n/N (%) ^a	Achieved/Observed, n/N (%)	
HbA _{1c} achievement rate at 18 months (all people)			
Target 6.5% group	56/154 (36.4%)	48/137 (35.0%)	1.3% (-9.7% to 12.3%)
Target 7.0% group	91/154 (59.1%)	67/137 (48.9%)	10.2% (-1.3% to 21.4%)
HbA _{1c} achievement rate at 18 months (target achievement subgroup)			
Target 6.5% group	3/6 (50.0%)	4/7 (57.1%)	-7.1% (-54.7% to 43.6%)
Target 7.0% group	43/85 (50.6%)	26/58 (44.8%)	5.8% (-10.9% to 22.0%)
Target 7.5% group	8/11 (72.7%)	8/16 (50.0%)	22.7% (-15.7% to 53.9%)
Target 8.0% group	45/52 (86.5%)	43/56 (76.8%)	9.8% (-5.2% to 24.5%)
Note: a: Data are presented as n/N (%). b: Absolute risk differences are expressed as AI-HEALS minus TAU.			
Abbreviations: AI, artificial intelligence; TAU, treatment as usual; HbA1c, glycated haemoglobin.			

During the 18-month follow-up period, one hospitalisation due to respiratory infection was reported in the AI-HEALS group. In the TAU group, one hospitalisation due to malignancy and two deaths, attributed to pulmonary infection and myocardial infarction, respectively, were reported. All serious adverse events were reviewed by the investigators and were considered unlikely to be related to the intervention.

Discussion

In this cluster-randomized trial involving 406 participants with T2DM in community primary care, AI-HEALS was not associated with a statistically significant improvement in HbA_{1c} relative to treatment as usual over 18 months (between-group difference, - 0.22%; 95% CI, - 0.54 to 0.10), despite favorable numerical trends at several intermediate time points. Secondary outcomes showed a more differentiated pattern: diabetes-related skills improved modestly but consistently across follow-up, whereas gains in dietary adherence and self-care activity were evident at intermediate time points but not sustained overall. Taken together, these findings suggest that AI-assisted personalized health education can

strengthen disease-related knowledge and skills in a real-world primary care setting, but that this alone was insufficient to produce a durable glycemic benefit beyond usual care.

To our knowledge, this is among the few studies evaluating an AI-assisted diabetes self-management intervention implemented in routine community primary care with follow-up to 18 months [23–26]. The between-group difference in HbA_{1c} was smaller than pooled effects reported in recent meta-analyses of DHIs for T2DM [27]. This more modest glycemic effect may reflect the relatively good baseline HbA_{1c} control in our cohort, which limited room for further reduction, and the low-intensity design of AI-HEALS, which emphasized self-management support rather than structured medication adjustment or more intensive clinical management. Prior evidence suggests that larger HbA_{1c} reductions are more often observed in interventions incorporating responsive coaching or closer clinical integration and in populations with poorer baseline glycemic control [20, 28–32].

Improvements were more evident in diabetes-related skills than in dietary adherence over follow-up. Skills such as understanding the relationship between diet and glycaemia, interpreting health information, and applying diabetes knowledge to everyday decisions may be more directly responsive to structured education and informational support, and therefore more readily improved through low-intensity digital interventions [33]; as with other secondary endpoints, this finding is exploratory given the number of outcomes assessed and warrants confirmation. By contrast, dietary behaviours are shaped by broader contextual, social, and environmental influences and are harder to sustain over time [14]. This dissociation between improved knowledge and unsustained behavioural or glycaemic change reflects the well-recognised knowledge–behaviour gap in chronic disease self-management, which informational support alone is often insufficient to bridge [34]. Notably, dietary adherence also improved in the control group, consistent with the effects of routine primary care, repeated assessments, and greater attention to lifestyle behaviours in a pragmatic trial setting [35, 36]; AI-HEALS was associated with additional dietary gains at 6 and 12 months, but this effect was not sustained overall. Together, these findings suggest that future digital self-management interventions may need to pair educational content with structured behaviour-change techniques—such as personalized goal-setting, feedback on self-monitored glucose, or clinician-triggered support for patients showing early signs of non-response—rather than relying on content delivery alone.

These outcome patterns were mirrored in how participants used the platform. Educational articles were accessed by 84% of participants, whereas chatbot use, though initiated by 78.2%, was typically shallow, with most participants engaging only one to five times and in brief sessions, and it tailed off after proactive messaging ended at three months. Participants thus gravitated toward low-effort, content-consumption features rather than the interactive components that require sustained, active input. This preference is not unique to our platform; disengagement from the more demanding elements of digital health tools is common and tends to accelerate once external prompts are withdrawn [37, 38]. For an education-centred intervention such as AI-HEALS, this creates a specific design tension, in that the components most readily adopted are also those least able to drive behaviour change on their own. Sustaining benefit beyond the active phase may therefore require lowering the effort barrier to interactive

features and integrating self-regulatory techniques—such as goal-setting, self-monitoring, and feedback on recorded glucose—into routinely used content [39].

The intervention was evaluated in community health centers, which strengthens the relevance of the findings to routine primary care delivery. The cluster-randomized design reduced the risk of contamination across centers, and the 18-month follow-up allowed assessment of whether early effects were sustained beyond the 3-month active intervention phase. Platform-use data also provided additional context on how participants used different components of AI-HEALS during the active phase.

Several limitations should be considered. First, blinding of participants and outcome assessors was not feasible because of the nature of the intervention, and reliance on self-reported measures may have introduced reporting or social desirability bias. Second, participants were recruited from community health centres in Beijing; differences in healthcare resources, digital infrastructure, socioeconomic context, and patterns of technology use may limit generalisability to other regions, particularly rural or resource-limited settings. Third, although AI-HEALS was designed as a low-cost, scalable intervention, its predominantly text-based delivery may have limited accessibility for individuals with lower literacy, cognitive impairment, or reduced digital access. In addition, all AI-HEALS content was drawn from a predefined, expert-reviewed repository based on national and international diabetes guidelines; however, formal quantitative assessment of information quality was beyond the scope of this trial. Finally, system usage data were available only during the active intervention phase, limiting inference about longer-term engagement and its relationship with sustained outcomes.

Conclusions

In summary, this cluster-randomised trial suggests that AI-HEALS was associated with modest improvements in glycaemic control, without a sustained overall effect on HbA_{1c} at 18 months. More consistent benefits were observed for selected behavioural outcomes, particularly diabetes-related skills, whereas improvements in dietary adherence were time-limited. These findings indicate that AI-assisted, personalised health education can support key components of diabetes self-management in routine community primary care, while durable metabolic benefit may require greater intervention intensity or sustained engagement.

Abbreviations

T2DM

Type 2 diabetes mellitus

DHIs

Digital health interventions

AI-HEALS

Artificial Intelligence-based Health Education Accurately Linking System

TAU

Treatment-as-usual
SDPC
Standard diabetes primary care
HbA_{1c}
Glycated haemoglobin

Declarations

Competing Interests

We declare no competing interests.

Data Availability

De-identified individual participant data, a defining data dictionary, and the statistical analysis code are available from the corresponding author (xysun@bjmu.edu.cn) upon reasonable request. Access is subject to approval by the AI-HEALS steering committee and must comply with institutional data governance and participant privacy requirements.

Author Contribution

XS served as the principal investigator, securing funding and designing the AI-HEALS trial. YW and YN contributed equally to the trial implementation, results analysis, and manuscript drafting. HH, YY, and YJ contributed to the design of the AI-HEALS trial. PL provided technical support for AI-HEALS, while AM coordinated the entire multicenter trial in Beijing, China. HM, YJ, PC, YG, ML, and XZ designed and prepared the content for the AI-HEALS intervention and contributed to the development of personalized measures. AM and XS verified the adjusted assessment measures. YW, XG, and BK participated in sample collection and data management. AM and XS directly accessed and verified the underlying data reported in the manuscript. All authors participated in the rigorous revision and final approval of the manuscript, and all authors had full access to all study data and bear final responsibility for the decision to submit the manuscript for publication.

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Figures

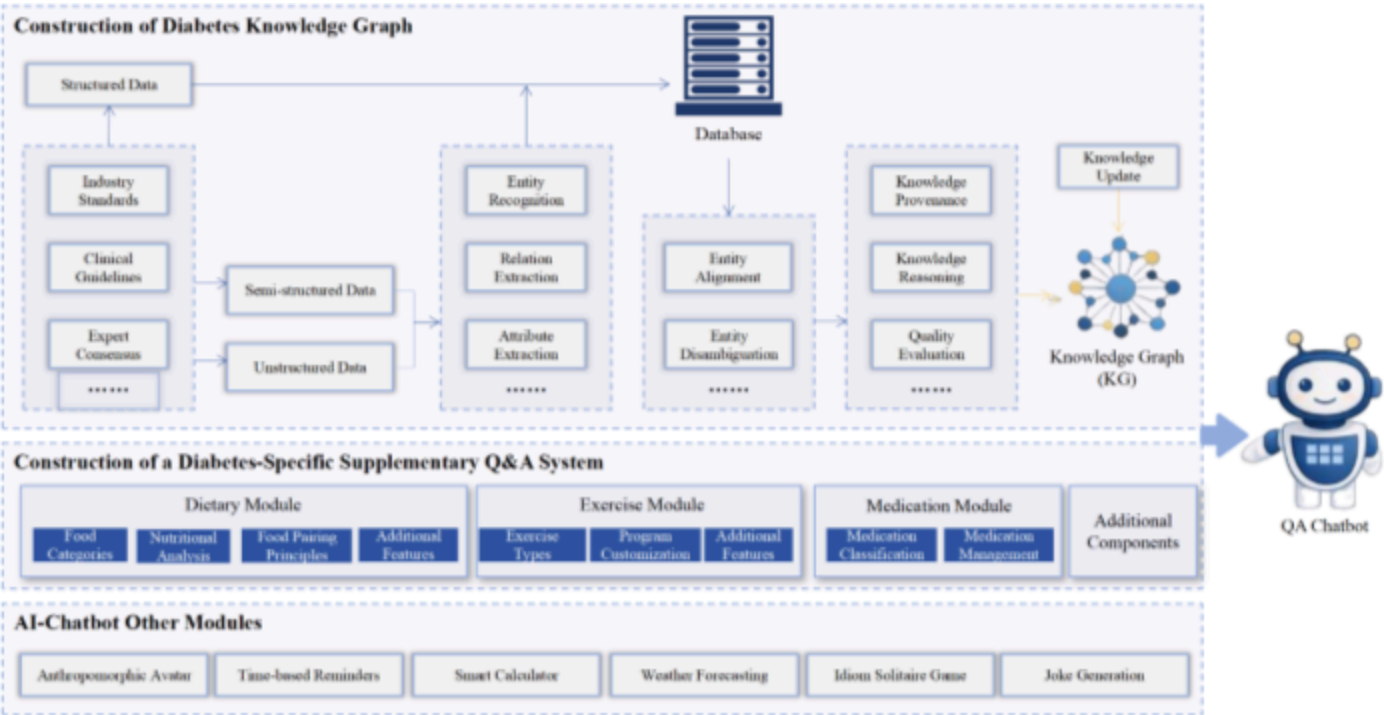


Figure 5

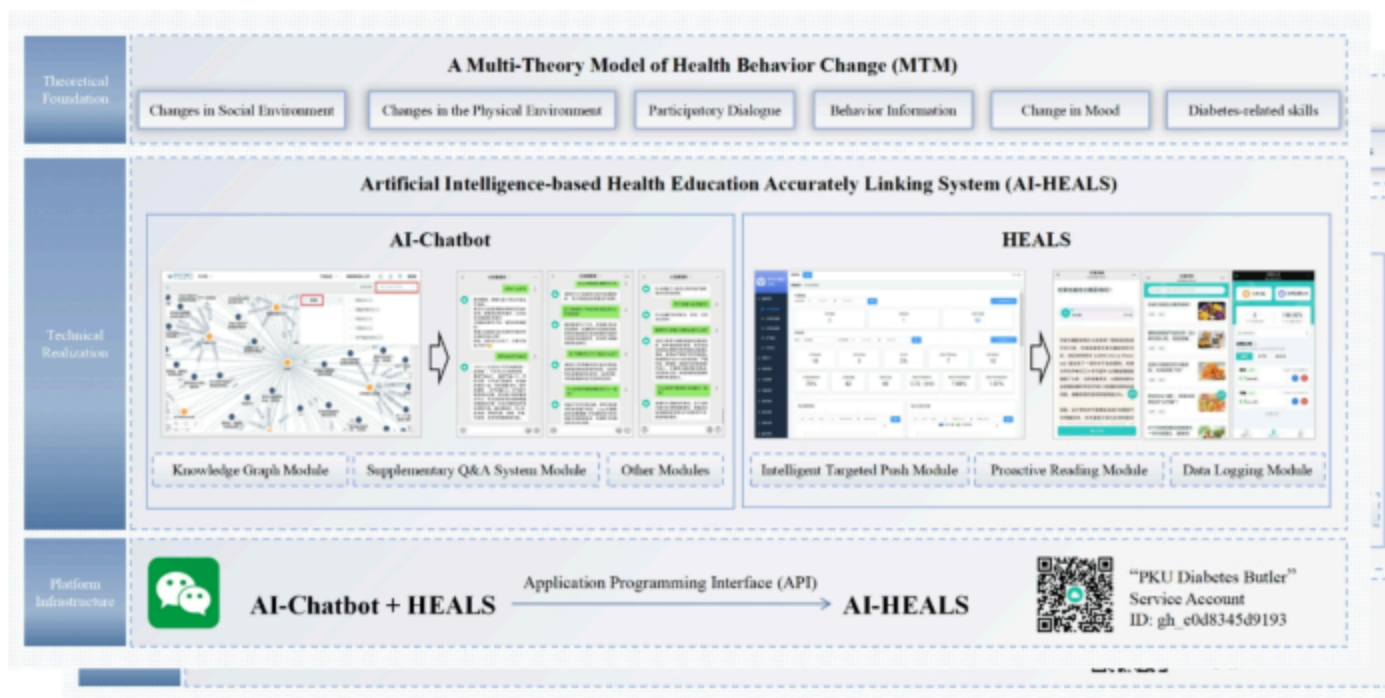


Figure 6

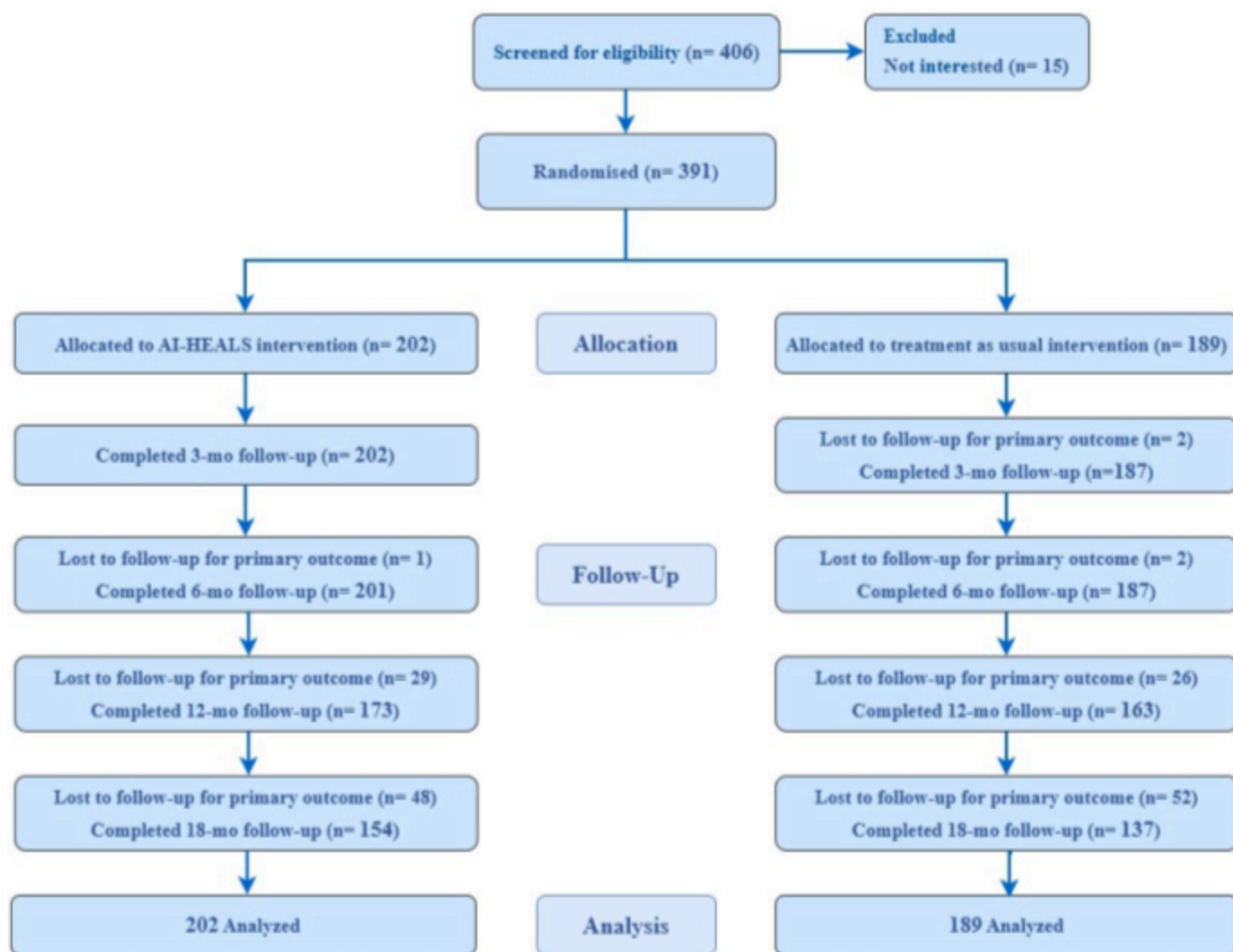


Figure 7

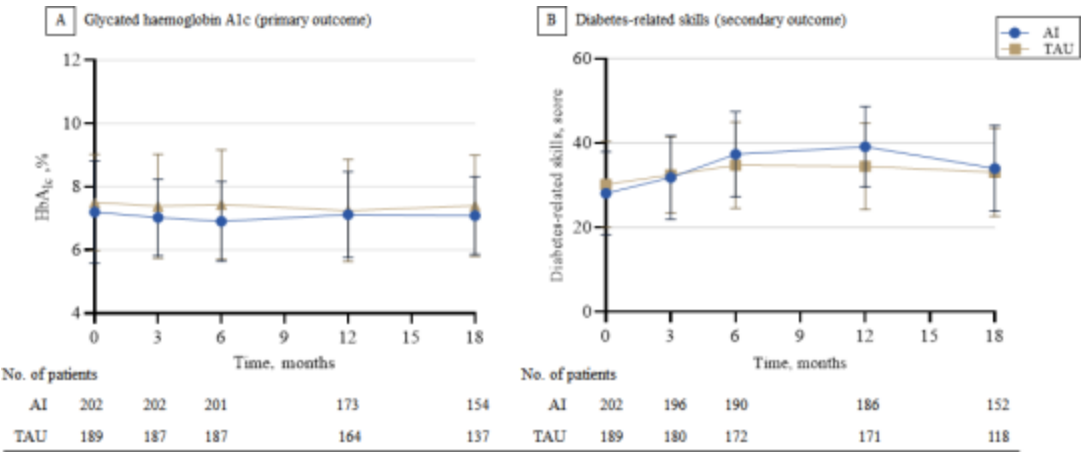


Figure 8

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