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RESEARCH

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SEM model analysis of diabetic patients' acceptance of artificial intelligence for diabetic retinopathy

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Abstract

Aims This study aimed to investigate diabetic patients' acceptance of artificial intelligence (AI) devices for diabetic retinopathy screening and the related influencing factors.

Methods An integrated model was proposed, and structural equation modeling was used to evaluate items and construct reliability and validity via confirmatory factor analysis. The model's path effects, significance, goodness of fit, and mediation and moderation effects were analyzed.

Results Intention to Use (IU) is significantly affected by Subjective Norms (SN), Resistance Bias (RB), and Uniqueness Neglect (UN). Perceived Usefulness (PU) and Perceived Ease of Use (PEOU) were significant mediators between IU and other variables. The moderating effect of trust (TR) is non-significant on the path of PU to IU.

Conclusions The significant positive impact of SN may be caused by China's collectivist and authoritarian cultures. Both PU and PEOU had a significant mediation effect, which suggests that impressions influence acceptance. Although the moderating effect of TR was not significant, the unstandardized factor loading remained positive in this study. We presume that this may be due to an insufficient sample size, and the public was unfamiliar with AI medical devices.

Keywords Diabetic retinopathy, Artificial intelligence, SEM model, TAM model, TPB theory, Dual factor theory

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Introduction

Background

Diabetes is one of the chronic diseases with the highest number of patients and the fastest-growing prevalence rate in China, the prevalence rate ranging from 0.67 to 11.2% within 40 years [1]. Currently, China has 116 million people with diabetes, which is more than any other country in the World [2]. Diabetic Retinopathy (DR) is a common complication of diabetes, occurring in approximately 30–40% of diabetic patients [3], and is a leading cause of blindness and visual impairment [4]. The frequency of DR examination in diabetic patients varies from 3 months to 2 years, depending on the severity of DR [1]. However, interpreting these photographs requires expertise and experience in diabetic eye disease. The long-term management of DR requires more medical resources; however, the existing medical resources are not sufficient to meet these demands. The medical system and financial costs will face great challenges [5], and the application of Artificial Intelligence (AI) medical devices may be a solution to these challenges [6].

In April 2018, the U.S. Food and Drug Administration approved the AI algorithm (IDx-DR) for DR screening and diagnosis, which announced the first clinical AI device for DR screening [7]. Using AI automatic fundus screening technology, the sensitivity of DR diagnosis ranges from 90.5 to 100%, and the specificity ranges from 91.1 to 91.6% [8]. In China, the work by Dai et al. introduced a DL system called DeepDR, which performs real-time image quality assessment, lesion detection and segmentation, and DR grading. For DR grading, the system demonstrated excellent performance across all stages, with AUCs ranging from 0.943 to 0.972 for mild, moderate, severe, and proliferative DR. This multi-task approach provides detailed information to assisting clinicians in diagnosis and treatment planning, while also offering real-time feedback on image quality to improve screening efficiency [9]. By analyzing vast amounts of patient data (e.g., genetic information, lifestyle factors, treatment histories), AI can identify patterns and predict individual patient responses to interventions. These predictive capabilities may enable early intervention and improve resource allocation in clinics [10]. Under these circumstances, China urgently needs AI devices for DR Screening as an effective supplement to primary health care, further improving medical efficiency and reducing financial costs. From the perspective of patients, the application of AI also helps patients to make early diagnosis, early interventional treatment, and achieve the purpose of cure or delay the course of disease.

However, for patients, the application of AI also has more or less obstacles, including the doctor-patient trust issue, the AI-transparency problem and the problem of psychological loss of control.

Although this study examined patient trust in AI devices, doctor-patient trust as a core background variable for medical AI adoption has not been fully explored. Studies have shown that patients' trust in doctors may transfer to AI systems, especially when doctors explicitly recommend AI technology [11]. On the other hand, if the doctor-patient relationship is tense (such as the current background of medical disputes in China [12]), patients may indirectly resist AI devices due to their distrust of doctors.

The "black box" nature of medical AI may exacerbate patients' perceived risk. Patients' demand for transparency in AI diagnosis process is significantly related to their education level and disease severity [13]. Therefore, in the screening scenario of diabetic retinopathy, providing visual explanations can effectively reduce perceived risk and increase usage intention [14]. These findings suggest that algorithmic transparency may be an important antecedent of perceived usefulness and that future research needs to develop targeted measurement tools.

The automation of medical AI may raise patients' concerns about the "transfer of decision-making authority." Due to the interaction between perceived control and perceived ease of use, when patients perceive AI as overly replacing human labor, their usage intention may decrease even if the system is easy to use [15].

The promotion of AI screening for DR is not only involved in new medical technologies but also in management science [16]. From the perspective of management, consumer acceptance of a new technology is one of the most important premises for new products to explore the market [17]. Therefore, we assume that the public acceptance of AI medical devices is an urgent issue to be solved.

Objective

The primary objective of this study is to develop and validate a conceptual model within the cultural context of China to investigate public acceptance of AI devices for DR screening and diagnosis. Furthermore, we seek to identify critical determinants influencing the acceptance of AI devices for DR screening and diagnosis, and elucidate the interplay mechanisms among these factors.

Beyond theoretical research, this study aims to inform evidence-based policymaking by providing actionable insights for governmental health authorities and hospital administrators. Due to interest and research from various stakeholders in the use of AI have not fully translated to widespread adoption in practice [18]. In this case, our findings are designed to facilitate the formulation of clinical implementation guidelines that accelerate AI integration into routine care workflows. This dual-focused strategy targets: (1) enhancing patient accessibility to convenient, cost-effective early screening solutions; and (2) optimizing healthcare institutional resource allocation efficiency.

Theoretical background and hypothesis development

In management studies, scholars have proposed multiple technical models to explain consumer acceptance of new technologies and have evaluated the variables that may affect consumer acceptance. For example, the Technology Acceptance Model (TAM), Planned Behavior Theory (TPB), and Unified Theory of Technology Acceptance and Use (UTAUT) and etc. Many researchers have modified these models, and carried out research in the fields of telemedicine [19], clinical decision system [20], electronic medical record [21], mobile medical information system [22] and so on. However, empirical study revealing that UTAUT's uniform treatment of "social influence" may oversimplify cultural heterogeneity [23]. UTAUT's " Performance Expectancy" highly overlaps with TAM's "PU", but the latter puts more emphasis on individual's direct assessment of technical functions. Although the "Effort Expectancy" of UTAUT is similar to PEOU, it does not cover the dynamic response of SN and PBC to social and cultural environment in TPB. In this case, this study choose not to integrate UTAUT into the SEM model.

The successful application of AI devices in healthcare depends on the understanding and acceptance of its application by users, including medical professionals and patients. This understanding helps build trust in AI systems, promotes their effective use, and helps address ethical and regulatory challenges. When implementing generative AI in healthcare, the TAM model and Network Adoption and Sustainability Systems Model (NASSS) frameworks need to consider the following components: Perceived usefulness, Perceived ease of use, Attitude towards using, Behavioural intention to use and Actual system use [24]. Therefore, this study intends to use the following theories to assess influencing factors and promote the application of AI in primary healthcare based on the TAM model.

Technology acceptance model

TAM model is one of the most widely applied models for studying consumer acceptance of new technology. The original model revealed that PU (defined as the perception that using a system leads to enhanced job performance) and Perceived Ease of Use PEOU (defined as the perception that using a system will be free of effort) are two basic determinants of consumers' acceptance of new technology. PU and PEOU influence consumers' impressions towards new technology and further influence their Intention to Use (IU) [25].

However, many studies found that both PU and PEOU had a direct impact on IU, and impression had no mediating effect [26]. Therefore, this impression is deleted in the following TAMs. Although the purpose was to investigate the public's acceptance of AI devices in China, considering that AI devices for DR screening are still not available in most primary health care centers, the final dependent variable was adjusted to IU, rather than the actual use of AI devices for DR screening. IU as the final dependent variable is now commonly used to refer to acceptance, and is considered a reliable predictor of actual use [27].

Studies have shown that PU and PEOU have a positive influence on IU, while PEOU has a positive effect on PU [15, 17].

Therefore we proposed the following hypotheses:

H1 PU positively affects the IU of AI devices used for DR screening.

H2a PEOU positively affects the IU of AI devices used for DR screening.

H2b PEOU positively affects the PU of AI devices used for DR screening.

Theory of planned behavior

The theory of Planned Behavior (TPB) is an extension of the Theory of Rational Behavior, and it indicates that individual behavioral intention (similar to IU in TAM) is influenced by attitudes (ATT, defined as individuals' subjective evaluation of specific objects and their resulting behavioral tendencies), Perceived Behavior Control (PBC, defined as the extent to which people have control over engaging in the behavior), and Subjective Norms(SN, defined as the perception of whether others think they should engage in a certain behavior). Ultimately, individual behavioral intention affects individual behaviors [28].

TPB allows us to examine the influence of social circumstances other than individual determinants on IU [29], and we propose a strong influence from SN to IU in China due to the local collectivist culture. In addition to its direct positive influence on IU, SN usually indirectly influences IU through PEOU in the integration model with the TAM model [30]. Similarly, PBC exerts a direct positive influence on IU in the TPB model and indirectly influences IU through PEOU in the integration model with the TAM [31].

Therefore, we proposed the following integrated hypotheses:

H3a SN is expected to strongly affect IU due to China's collectivist culture.

H3b SN positively affects public PEOU of AI devices for DR screening.

H4a PBC positively affects the public IU of AI devices used for DR screening.

H4b PBC positively affects public PEOU of AI devices for DR screening.

H5 ATT positively affects the public's PU of AI device for DR screening.

Dual factor theory

The above behavioral theories (TAM and TPB) mostly focused on consumers' positive (enabling) perception of new technology, yet ignored negative (inhibiting) factors. Therefore, we intend to integrate the dual-factor theory (DFT) into the model to ensure its integrity. Within DFT, potential consumers are influenced by both enabling and inhibiting factors when considering the use of new technology [32]. The existence of inhibiting factors hinders consumers' acceptance of new technology, but the absence of inhibiting factors does not necessarily improve consumers' acceptance of new technology.

Therefore, inhibiting and enabling factors are not completely opposite but are independent factors that can coexist. In this study, inhibiting factors, including Perceived Risk, Status Quo Bias, Resistance to Change and Uniqueness Neglect, were integrated into the model as variables.

Perceived risk

Perceived Risk (PR) refers to the combination of uncertainty and the seriousness of an outcome in relation to performance, safety, and psychological or social uncertainties that negatively impact IU and create further disincentives for consumer use of new technologies [33].

H6 PR negatively affects the IU of AI devices used for DR screening.

Status Quo Bias and resistance to change

Status Quo Bias theory aims to explain the public's preference for maintaining the status quo, and resistance to new technologies in the existing system. The two main inhibitors of the Status Quo Bias theory are regret avoidance (lessons from the past failures to avoid future regrettable consequences) and inertia (individual's attachment to the comfort zone, even better alternatives are provided) [34].

Resistance to Change refers to people's attempts to maintain their daily behaviors or habits that are related to their past experiences when facing change, and it has proven to be a major obstacle to the adoption of electronic and mobile health [35]. We combined these factors into an inhibiting factor, Resistance Bias (RB), defined as the resistance to using new technology because of biases such as regret avoidance, inertia, and resistance to change.

H7 RB negatively affects the IU of AI devices used for DR screening.

Uniqueness neglect

Uniqueness Neglect (UN) refers to the concern that AI devices are less able than humans to take into account the unique characteristics and situations of consumers. Previous studies have confirmed that UN drives consumer resistance to AI healthcare, with resistance being stronger among consumers who perceive themselves as more unique and special than others [36].

H8 UN negatively affects the IU of AI devices used for DR screening.

Trust (TR) as a moderator in the Chinese social context

Trust (TR) is defined as the belief that someone or something is honest, reliable, kind, and effective. TR is essential for the increasing popularity of AI applications in daily life because it is likely to be a critical factor in the acceptance of consumer products such as home automation, personal robots, and automotive automation [37].

In previous studies, TR was often regarded as a variable that directly or indirectly affected IU [38]. Meanwhile, it has also been proven that TR has a direct or indirect moderating effect on user intentions or the adoption of new technologies [39]. Due to continuously declining patients' trust over the past two decades, and resulting in a relatively tense physician-patient relationship in China [40], we assume that TR may play a more complicated role as a moderator in the model [41]. Therefore, we propose the following hypotheses:

H9 TR in AI devices moderates the path on PU to IU.

Our model is shown in Fig. 1.

In this study, we integrate the Technology Acceptance Model (TAM), Theory of Planned Behavior (TPB), and Dual Factor Theory (DFT) to construct a multidimensional analytical framework, which systematically examines both enablers and inhibitors through structural equation modeling (SEM). We seek to identify critical determinants influencing the acceptance of AI devices for DR screening and diagnosis, and elucidate the interplay mechanisms among these factors.

Methods

Prerequisites and methods of sample collection

The respondents of this questionnaire survey had to meet the following prerequisites: (1) patients with diabetes and (2) could read and write in Chinese. Team members went to two major hospitals in Chengdu to recruit respondents. The collection process began in November 2023 and ended in March 2024. The research team calculated the required number of respondents based on a sample size rule of thumb for structural equation modeling of 10 times the number of participants as items [42]. As our survey had 36 items, the minimum number of respondents was 360.

The first page of the questionnaire provides the background and purpose of the study and includes the informed consent form. On the second page of the questionnaire, we briefly introduced the AI screening DR,

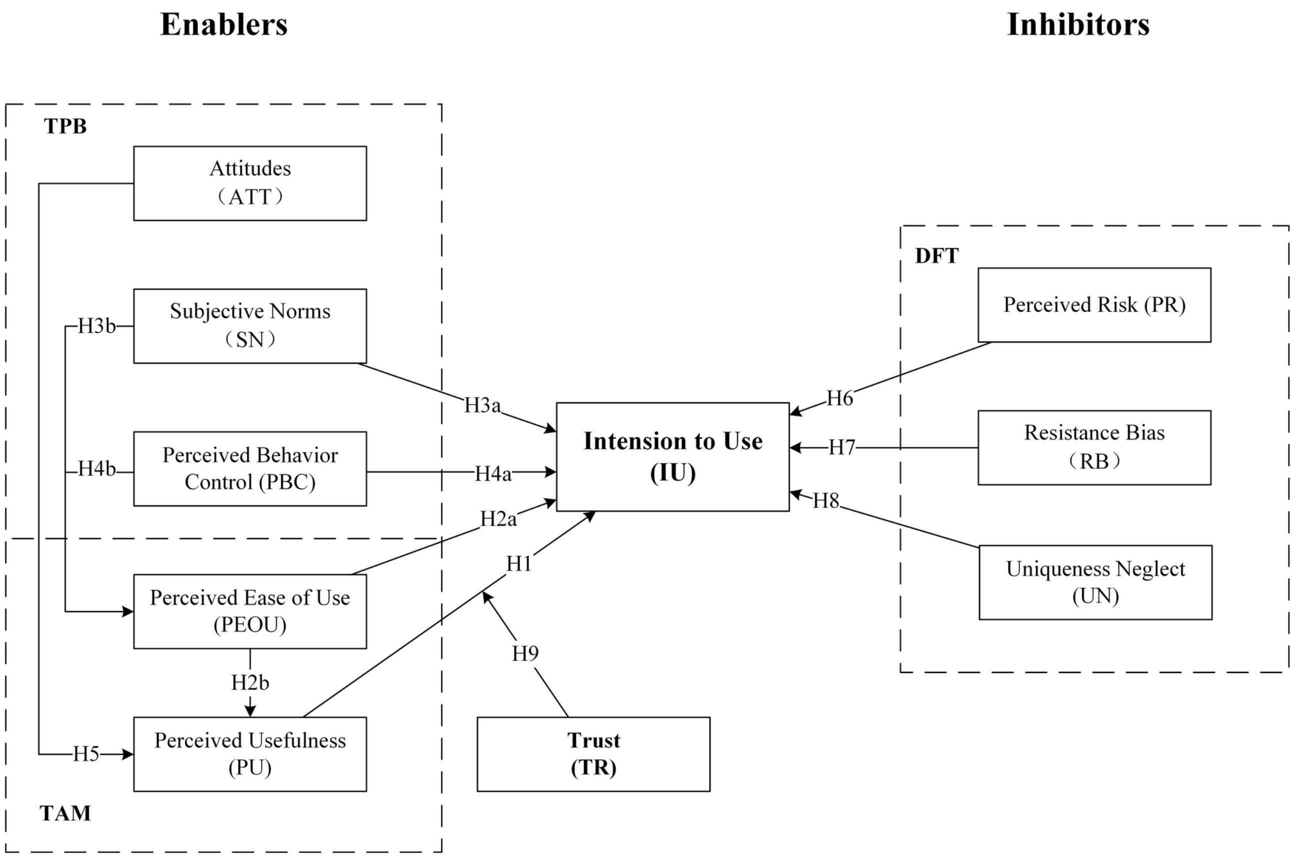

Fig. 1 Variables from relevant theories and development of our model for acceptance of AI devices for DR screening

Table 1 Demographic results

Characteristics	Values, *n* (%)
Gender	
Male	224 (43.2)
Female	295 (56.8)
Age (Years)	
30 and below	2(0.4)
31 ~ 40	18(3.5)
41 ~ 50	32(6.2)
51 ~ 60	246(47.4)
61 ~ 70	158(30.4)
71 ~ 80	51(9.8)
81 and above	12(2.3)

including the general functions and operational procedures, with pictures to help guide participants.

Measurement and data analysis strategy

Ten variables were constructed in the model and were measured using 36 questionnaire items. Each variable contained at least three questions, as shown in Appendix 1. All items were measured using a 5-point Likert scale ranging from (1) strongly disagree to (5) strongly agree.

SPSS 23 was used to analyze the descriptive statistics and single-factor analysis. In addition, Amos 26 was used to evaluate the reliability and validity of the measurement model and to further evaluate the significance and regression coefficient of each variable, as well as the mediation and moderation effects of the model.

Results

Demographic results of collected samples

The team member collected 550 questionnaire surveys, of which 31 were invalid because there was no signature on the informed consent. Participants' demographic characteristics are shown in Table 1.

Among the 519 participants, 224 were male and 295 were female. The results showed that there was no significant difference (P=.686) in the acceptance of AI devices for DR screening between male (M = 3.81,SD = 0.80) and female (M = 3.78,SD = 0.77).

Data analysis results

Public acceptance of AI devices for DR screening

The average scores were 3.682 for IU1, 3.850 for IU2, 3.854 for IU3 and 3.795for IU. All IU items were measured in 5-point Likert scale, ranging from (1) strongly disagree to (5) strongly agree. Therefore, the average values of individual IU items and IU in general show that the public has a general acceptance of AI screening for DR.

Measurement model analysis

Before the SEM analysis, the reliability and validity of the variables involved in this questionnaire were tested to ensure the internal consistency of the questionnaire items. Then, we tested the model fit to ensure that the model had a good fit. After completing the reliability, validity, and model fit tests, the SEM model analysis was implemented. The analysis is divided into three parts: the first part acquires the path coefficient and significance level of each variable to IU, after which the mediation effect is tested; finally, the moderation effect of TR on the PU to IU path will be tested.

Reliability and validity evaluation of the measurement model

Maximum likelihood estimation was used to test the factor loadings, measurement reliability, convergent validity, and discriminant validity. Table 2 presents a summary of the significance tests, item reliability, composite reliability, and convergent validity.

The standardized factor loadings of the items were between 0.416 and 0.990, indicating good item reliability. The Composite Reliability values of the ten variables ranged from 0.737 to 0.893. All CR values were greater than 0.7, and acceptable internal consistency was proven [43]. The average variance extracted (AVE) value of all variables was higher than the threshold of 0.4, which confirmed the constructs' convergent validity [44].

In Table 3, the square roots of the AVE values are higher than the numbers in the off-diagonal direction (correlations between a particular construct in the same column and other constructs in different rows) in the corresponding columns, indicating that the discriminant validity of all constructs meets the criteria of Fornell and Larcker [45].

Model fit analysis

Table 4 shows the model fit analysis, the normed Chi-square (χ^2 */df)* is 1.766, located between 1 and 3; The root mean squared error of approximation (RMESA) and the standardized root mean square residual (SRMR) are 0.038 and 0.062, respectively, and both are smaller than 0.08; The comparative fit index (CFI) and goodness-of-fit index (GFI) are 0.950 and 0.897, respectively, and they are either greater or very close to 0.9; the adjusted goodness-of-fit index (AGFI) was 0.879, and it was greater than 0.8.

The model fit indicators satisfied most of the criteria and the combination rule, indicating that the hypothesized model had a good fit to the data.

Structural equation modeling analysis

Table 5 lists the numerical results of the path coefficients. IU was significantly affected by PU (beta = 0.149; P = .038), SN (beta = 0.323; P < .001), RB (beta = –0.215; P = .002) and UN (beta = 0.124; P = .030). PEOU (beta = 0.060, P = .428), PBC (beta = 0.010, P = .885), and PR (beta=-0.098, P = .234) do not significantly affect IU. PU was significantly affected by ATT (beta = 0.378; P = .004) and PEOU was significantly affected by SN (beta = 0.084; P = .004). R^2 value for IU, PU and PEOU are greater than the minimum threshold of 0.1, indicating that the model exhibits a good degree of fitting accuracy. VIF values for all latent variables ranged from 1.078 to 1.572, all well below the threshold of 5, indicating no significant multicollinearity problems in the model. For those which has a significance on path coefficients, the F^2 values for PU→IU is smaller than the threshold of 0.02. We assume there are might two reasons to explain. First, the large sample size enhances the test, so that the significance level can be reached even if the actual effect is small; Second, PU has a weak effect on IU, which may be due to respondents paying more attention to ATT or SN. We believe that although the effect size of PU is small, it should still be retained because it fits the theoretical framework and may be stronger in other contexts (such as different populations or technology types).

Analysis of mediation and moderation effects

We conducted a bootstrapping test based on 5000 samples. Table 6 presents the results of the mediation and moderation tests. PU was a significant mediator between ATT and IU (beta = 0.070, lower = 0.030, upper = 0.132) and between PEOU and IU (beta = 0.042, lower = 0.004, upper = 0.098), whereas PEOU was a significant mediator between SN and IU (beta = 0.025, lower = 0.005, upper = 0.052) and between PBC and IU (beta = 0.019, lower = 0.003, upper = 0.044). As for the moderation effects, the P-value of PU*TR is 0.165, which suggests that trust moderation is not significant and TR does not moderate the path from PU to IU.

Discussion

Major findings

The major findings are as follows: (1) both ATT and SN play important roles in the model; they could positively impact IU either directly or indirectly; (2) RB of new technology reduces public IU, UN increases the public IU, whereas PR does not have an effect on public IU; and (3) both PU and PEOU were significant mediators. (4) The moderating effect of TR was not significant for PU to IU. The results are discussed in detail below:

Both ATT and SN play important roles in the model

In most studies, ATT was not included in the model as an independent variable, but was incorporated into PU. However, we assume that it would be better to separate ATT as an independent variable towards PU when an AI medical device is involved in the research. This is because a positive attitude towards an industry should be the

Table 2 Descriptive statistics of variables, items, and convergent validity

	Significant test of parameter estimation				Item reliability		Composite reliability, CR	Convergence validity, AVE
	Unstd.	**S.E.**	**t-value**	***P***	**STD**	**SMC**		
Perceived usefulness (PU)							0.832	0.416
PU1	1.000				0.771	0.594		
PU2	0.829	0.058	14.213	<0.001	0.673	0.453		
PU3	0.819	0.064	12.811	<0.001	0.595	0.354		
PU4	0.791	0.065	12.245	<0.001	0.568	0.323		
PU5	1.013	0.069	14.607	<0.001	0.679	0.461		
PU6	0.922	0.066	13.981	<0.001	0.641	0.411		
PU7	0.827	0.069	12.033	<0.001	0.564	0.318		
Perceived ease of use (PEOU)							0.878	0.726
PEOU1	1.000				0.438	0.192		
PEOU2	2.511	0.225	11.155	<0.001	1.008	1.016		
PEOU3	2.419	0.215	11.226	<0.001	0.985	0.970		
Perceived behavioral control (PBC)							0.842	0.663
PBC1	1.000				0.416	0.173		
PBC2	2.292	0.232	9.873	<0.001	0.969	0.939		
PBC3	2.267	0.227	10.007	<0.001	0.937	0.878		
Subjective norms (SN)							0.747	0.497
SN1	1.000				0.642	0.412		
SN2	1.091	0.094	11.627	<0.001	0.760	0.578		
SN3	1.007	0.087	11.625	<0.001	0.707	0.500		
Trust (TR)							0.741	0.488
TR1	1.000				0.692	0.479		
TR2	1.109	0.093	11.865	<0.001	0.720	0.518		
TR3	1.066	0.090	11.909	<0.001	0.684	0.468		
Resistance bias (RB)							0.742	0.489
RB1	1.000				0.666	0.444		
RB2	0.906	0.071	12.687	<0.001	0.722	0.521		
RB3	1.038	0.084	12.370	<0.001	0.709	0.503		
Attitude (ATT)							0.737	0.484
ATT1	1.000				0.701	0.491		
ATT2	1.026	0.078	13.174	<0.001	0.704	0.496		
ATT3	0.952	0.078	12.135	<0.001	0.681	0.464		
Perceived risks (PR)							0.803	0.449
PR1	1.000				0.616	0.379		
PR2	1.350	0.110	12.289	<0.001	0.718	0.516		
PR3	1.115	0.093	11.929	<0.001	0.683	0.466		
PR4	1.253	0.103	12.118	<0.001	0.698	0.487		
PR5	1.115	0.098	11.322	<0.001	0.631	0.398		
Uniqueness neglect (UN)							0.893	0.747
UN1	1.000				0.546	0.298		
UN2	1.861	0.127	14.671	<0.001	0.990	0.980		
UN3	1.825	0.127	14.394	<0.001	0.981	0.962		
Intention to use (IU)							0.748	0.498
IU1	1.000				0.737	0.543		
IU2	0.914	0.067	13.711	<0.001	0.708	0.501		
IU3	0.890	0.070	12.729	<0.001	0.671	0.450		

premise of a positive attitude towards a specific product in general. According to the results, ATT had a significant positive influence on PU (beta = 0.378, P =.004). In this case, the results confirmed TAM theory as well as our assumption, and H5 was supported.

Previous studies have found that IU tends to be significantly affected by PU, PEOU, SN and PBC [46]. Therefore, we assume that whether SN has a significant impact on IU is influenced by local cultural customs. In our study, SN was one of the most important factors affecting

Table 3 Discriminant validity

	AVE	TR	UN	RB	PR	PBC	SN	ATT	PU	PEOU	IU
TR	0.488	0.699	—	—	—	—	—	—	—	—	—
UN	0.747	-0.068	0.864	—	—	—	—	—	—	—	—
RB	0.489	-0.250	0.312	0.699	—	—	—	—	—	—	—
PR	0.449	-0.197	0.498	0.590	0.670	—	—	—	—	—	—
PBC	0.663	0.204	0.009	-0.147	-0.056	0.814	—	—	—	—	—
SN	0.497	0.243	-0.035	-0.141	-0.146	0.352	0.705	—	—	—	—
ATT	0.484	0.430	-0.084	-0.499	-0.114	0.222	0.318	0.695	—	—	—
PU	0.416	0.193	-0.038	-0.224	-0.051	0.100	0.143	0.449	0.645	—	—
PEOU	0.726	0.051	-0.005	-0.031	-0.027	0.114	0.185	0.065	0.029	0.852	—
IU	0.498	0.549	-0.043	-0.409	-0.296	0.261	0.508	0.438	0.289	0.130	0.706

Table 4 Model fit of the research model

Model fit	Model fit of research model	Criteria
χ^2	1168.839	The smaller the better
df	662	The larger the better
Normed chi-square(χ^2/df)	1.766	$1<\chi^2/df<3$
RMSEA	0.038	<0.08
SRMR	0.062	<0.08
CFI	0.950	>0.9
GFI	0.897	>0.9
AGFI	0.879	>0.8

Table 6 Analysis of mediation and moderation effects

Mediation Effects	Estimates	SE	Lower	Upper	
ATT→PU→IU	0.070	0.026	0.030	0.132	
SN→PEOU→PU→IU	0.004	0.004	-0.001	0.015	
SN→PEOU→IU	0.025	0.012	0.005	0.052	
PBC→PEOU→PU→IU	0.004	0.004	0.000	0.013	
PBC→PEOU→IU	0.019	0.011	0.003	0.044	
PEOU→PU→IU	0.042	0.024	0.004	0.098	
PBC→PEOU→PU	0.015	0.011	0.000	0.043	
SN→PEOU→PU	0.018	0.015	-0.003	0.054	
Moderation Effects					
	Unstd.	**SE**	**CR**	**P**	**Std**
IU←PU	0.293	0.088	3.329	<0.001	0.222
IU←TR	0.470	0.070	6.673	<0.001	0.485
IU←PUTR	0.066	0.047	1.387	0.165	0.084

IU, and its direct effect on IU was even greater than the direct effect of PU on IU. In addition to the direct effect on IU, SN also had a significant indirect positive effect on IU through PEOU.

These results indicate that individuals' perceptions and intentions are likely to be influenced by others when encountering new technologies in China. This phenomenon may be attributed to certain traditional Chinese cultures, including collectivist cultures (following the group's actions and prioritizing a group over the individual) [47] and authoritarianism (following the rule of team leaders) [48].

On the other hand, it was interesting to note that PEOU had no significant effect on either IU or PU, which did not support Hypotheses H2a and H2b. This finding means that the public IU of DR screening AI devices is not affected by perceptions of the ease of use of these devices. In this case, we assume that this may be caused

Table 5 Regression coefficient

	Unstd.	SE	t-value	*P*-value	Std	Supported	R^2	VIF	F^2
IU							0.348		
IU←PU (H1)	0.149	0.072	2.078	0.038	0.116	√		1.413	0.015
IU←PEOU (H2a)	0.060	0.076	0.793	0.428	0.033			1.078	0.014
IU←SN (H3a)	0.323	0.057	5.688	<0.001	0.352	√		1.216	0.061
IU←PBC (H4a)	0.010	0.072	0.144	0.885	0.007			1.126	0.019
IU←PR (H6)	– 0.098	0.082	-1.19	0.234	-0.089			1.572	0.008
IU←RB (H7)	– 0.215	0.070	-3.086	0.002	-0.220	√		1.340	0.021
IU←UN (H8)	0.124	0.057	2.174	0.030	0.113	√		1.358	0.026
PU							0.146		
PU←PEOU (H2b)	0.021	0.063	0.337	0.736	0.015			1.067	0.006
PU←ATT (H5)	0.378	0.052	2.853	0.004	0.449	√		1.074	0.068
PEOU							0.119		
PEOU←SN (H3b)	0.084	0.030	1.148	0.004	0.165	√		1.126	0.033
PEOU←PBC (H4b)	0.046	0.040	1.148	0.251	0.056			1.126	0.005

by the characteristics of AI devices. When talking about AI devices, they presume them as "smart and convenient' [49]. Therefore, the public may tag AI devices for DR screening as "easy to use" in the first place, and further cause the variable PEOU to be insignificant to IU.

PR does not have an effect on public IU, whereas RB reduces public IU and UN increases the public IU

PR was usually a negative impact factor from previous studies based on the dual-factor theory, yet it was not significant to public IU in this research. The average PR score was relatively low at 3.056 out of 5. We assume that this was caused by the public's lack of awareness of health risks and the protection of privacy. The lack of publicity for chronic diseases, especially for DR, has led to a lack of public knowledge about these diseases and further led people to not perceive the risk of blindness as an acute threat [50]. Regarding the protection of privacy, the general population of China does not strongly prioritize privacy [51], and they are accustomed to providing key personal information when registering on a smartphone app or receiving nuisance calls. Therefore, we assume that these are possible explanations for the insignificant PR in this research.

The other two variables from the DFT were RB and UN, and both were verified in terms of reliability and validity. Although both RB and UN were significant for IU, their impacts on IU went in very different directions.

The results show that RB has a negative impact on IU, confirming the Status Quo Bias theory. People may refuse to use AI devices for DR Screening because they are unfamiliar with new products, trying to avoid future regrets or bad experiences with new technological products in the past. This resistance reflects the public preference for familiar methods of health management.

Meanwhile, the result of the UN had a positive impact on IU, which is contrary to the research conducted in the U.S. We assume that this may be related to the insufficient and unbalanced medical resources in China. Owing to insufficient and unbalanced medical resources, many patients do not have access to good physicians. However, AI devices for DR screening and diagnosis are based on big data, and it would be easier for AI devices to find a similar case from big data than human physicians from primary health institutions.

PU and PEOU were significant when playing mediating role

During the mediation effect test, we found that PU and PEOU were effective mediators when the final dependent variable was IU. However, this was only significant when there was one mediator in the mediation chain. In our research, PU was a significant mediator between ATT and IU as well as between PEOU and IU, whereas PEOU was a significant mediator between SN and IU, as well as between PBC and IU. However, neither PU nor PEOU were significant when both were mediation variables, especially when they were between SN and IU, as well as between PBC and IU.

Overall, mediation effects exist among certain variables in this study. The beta value of each mediation was relatively small, and caused a weak mediation effect. The strongest mediation effect was observed when PU was the mediator between ATT and IU. This suggests that good attitudes or the subjective usefulness of new technology have more impact on public IU than on the convenience of learning. In addition, the results show that the number of mediators should be limited; otherwise, the mediation effect would have disappeared.

The moderation effect of TR was not significant on PU to IU

In this study, TR was assumed to moderates the path on PU to IU (H9), but results showed that its moderation effect was not significant (P=.165). However, non-standard factor loading (beta = 0.066) suggested that TR might have a weak positive effect on the pathway PU to IU. We further explore the following possible causes and alternative explanations:

Positive beta values make sense from a psychological point of view. Participants with a high level of trust in AI usually come with high expectations of how AI will perform in healthcare, which means they may not need a greater PU to be willing to experiment with relevant AI devices. Alternatively, participants with low trust in AI may need a greater PU to try these devices because expectations are inherently low. Although the direct regulating effect of TR was not significant, SEM analysis showed that TR had a significant direct positive effect on IU (beta = 0.485, P<.001). This may indicate that TR indirectly affects IU through other pathways, such as enhancing SN or ATT, rather than by moderating the path on PU to IU. Follow-up studies could explore the role of TR as an antecedent or mediating variable.

In addition, although the moderating effect of TR in the overall sample is not significant, there may be heterogeneity in trust in AI devices among different populations (e.g., age, education level, access to healthcare resources). For example, younger patients or those with a high level of education may rely more on PU than SN, in which case the regulatory role of TR may be more significant. Due to the age distribution of the samples, this study has not carried out subgroup analysis for the time being, and a targeted stratified study can be designed in the future.

Finally, in theory, TR may play an indirect role by mitigating the negative effects of PR on IU. Although PR did not significantly affect IU in this study, the interaction effect between TR and PR is noteworthy. For example, high TR may reduce resistance to AI devices among high-risk perceivers. We may introduce subsequent studies to investigate the moderation effect on the pathway PR to IU.

Practical advices

For health administration departments, we propose a "Three-Period Experiential Promotion" for aim at the significant negative effect of Status Quo Bias (RB). The beginning period is Education Period, to disseminate AI diagnostic accuracy rates (95% CI) and manual verification mechanisms via short-video platforms such as Douyin (TikTok). Next becomes the Pilot Period, which is free AI screening trials at community health centers; Lastly becomes the Institutionalization Period, which integrate AI screening into diabetes chronic disease management under medical insurance reimbursement.

In addition, we propose establishing an "Authority Endorsement-Community Diffusion" dual mechanism aim at the SN's high explanatory power. Require deputy physicians from tertiary hospitals to sign AI diagnostic endorsement statements, and cultivate "AI Experience Ambassadors" in patient communities.

As for patient education, we recommend case comparisons to demonstrate AI's big-data advantages in rare disease screening (e.g., "AI matches similar cases from 100,000-patient databases"), and invite beneficiary patients to share experiences.

Strengths, limitations and future studies

In this study, an integrated model was adopted to combine the TAM and TPB. Compared with the single model, more variables, such as ATT, SN, PBC, PU, and PEOU, were included in this study. In addition, the main variables in the integrated TAM and TPB are enabling factors. To make the model more comprehensive, we introduced DFT theory into the model to investigate the public's acceptance of AI medical equipment from both inhibiting and enabling sides. Under the DFT theory, new inhibitory variables such as PR, RB, and UN were introduced. All the variables showed good convergence and discriminant validity. The proposed integrated model reveals the asymmetric game-theoretic mechanisms between facilitating factors (e.g., SN, PU) and inhibiting factors (e.g., RB, PR). For instance, the direct effect intensity of SN→IU (beta = 0.323) far exceeds that of PU→IU (beta = 0.149), demonstrating that in the Chinese context, group pressure exerts significantly stronger driving forces on technology adoption than perceived utility itself.

While this study provides insights into the acceptance of AI medical devices, the following limitations remain.

1. Sample selection bias. The data mainly came from inpatients with diabetes in two Class A tertiary hospitals in Chengdu, and the proportion of people over 50 years old was too high, so the results may not reflect the differences in acceptance among outpatients, young people, or rural areas.
2. Surface validity risk of measurement tools. Although the questionnaire passed expert validation and statistical Test, no Pilot Test was conducted.
3. Uniformity of practice scenarios. The research focuses on individual patient decision-making and does not include the perspectives of key stakeholders such as physicians and administrators, making it difficult to fully reveal systemic obstacles to clinical integration of AI devices.

In future studies, the research team intends to address the above limitations in the following ways.

1. Sample diversity and method optimization. First, multi-center sampling could be conducted to expand the sampling frame to urban and rural medical institutions in eastern, central and western provinces of China, and the sample size was determined by age (≤ 50 years vs. > 50 years), disease duration (newly diagnosed vs. Long-term patients) to improve sample representativeness. The second is the tracking design, which can analyze the dynamic changes in patient acceptance of AI devices and the long-term cumulative effect of TR through 3–5 years of follow-up data.
2. The refinement and verification of measurement tools can be carried out by recruiting 30–50 target people of Pilot Test, and combining cognitive interview feedback to optimize item expression.
3. Multi-stakeholder collaborative research: Firstly, a doctor-patient dual-perspective survey can be carried out, to identify systemic obstacles to clinical integration by simultaneously collecting doctors' operating experience of AI equipment (e.g., diagnostic efficiency and system usability) and administrators' willingness on investing (e.g., training costs and data security measures). At the same time, discrete selection experiments could also be used to quantify the marginal effects of different promotion strategies (e.g., medical insurance coverage and community publicity) on patient acceptance, providing evidence-based evidence for policy formulation.

Conclusion

In this study, the SEM method was used to explore the complex relationship between factors that influence public acceptance and the IU of AI devices for DR screening based on the actual situation in China. Enablers such as ATT have a significant impact on the public's use of AI devices for DR screening, in addition to SN and PU. On the inhibitor side, PR does not significantly affect the public's IU, as they are not aware of the protection of personal privacy and health information. The new integrated inhibitor RB fits the way of thinking as well as the language customs of the Chinese people, and showed both good convergence and discriminant validity. Additionally, the newly introduced UN had a positive effect on IU, which may have been caused by insufficient and unbalanced medical resources in China. In this study, we found that both PU and PEOU have a mediation effect; however, the number of mediators should be limited to one, or the mediation effect would be insignificant. In terms of the moderating effect, we have not yet found that TR has a moderating effect on the pathway from PU to IU, and it is recommended to strengthen the publicity and education of AI medical equipment to the public.

Abbreviations

AI	Artificial intelligence
AGFI	Adjusted goodness-of-fit index
ATT	Attitude
AVE	Average variance extracted
CFI	Comparative fit index
CR	Composite reliability
df	Degrees of freedom
DFT	Dual factor theory
DR	Diabetic retinopathy
GFI	Goodness-of-fit index
IU	Intention to use
PBC	Perceived behavioral control
PEOU	Perceived ease of use
PR	Perceived risks
PU	Perceived usefulness
RB	Resistance bias
RMSEA	Root mean squared error of approximation
SEM	Structural equation modeling
SMC	Square multiple correlations
SN	Subjective norms
SRMR	Standardized root mean square residual
STD	Standardized factor loadings
TAM	Technology acceptance model
TPB	Theory of planned behavior
TR	Trust
UN	Uniqueness neglect
Unstd	Unstandardized factor loadings
UTAUT	Unified theory of acceptance and use of technology
χ^2	Chi-square

Supplementary Information

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Supplementary Material 1

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Author contributions

L. J. analyzed the data and drafted the paper. Y.T. contributed to data curation and investigation., and manuscript revision. Y.L. contributed to data acquisition. G.L. and L.L. provided administrative, technical, and material support for the research. Z.C. contributed to the manuscript revision. S.P. contributed to funding obtaining and study design.

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Data availability

The data that supports the findings of this study, including any relevant details needed to reproduce the published results, are available from the corresponding author upon reasonable request.

Declarations

Ethical approval

The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki, and it was approved by the Bio-medicine Ethics Committee of Chengdu Medical College (2023No.114). The participants signed consent forms prior to data collection. This study did not involve clinical trials, and it was conducted only in the form of questionnaires. Therefore, registration of clinical trials was not necessary in this study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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