

Community-based Intelligent Blood Glucose Management for Older Adults with Type 2 Diabetes Based on the Health Belief Model: A Randomized Controlled Trial

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Community-based Intelligent Blood Glucose Management for Older Adults with Type 2 Diabetes Based on the Health Belief Model: A Randomized Controlled Trial

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Abstract

Background: The number of older patients with type 2 diabetes has been on the rise, and effective self-management is key to controlling disease progression and its complications.

Objective: A home telemedicine intervention combining telemedicine and health education based on the Health Belief Model was designed, and the effectiveness on self-management in older patients with type 2 diabetes was evaluated.

Methods: A randomized controlled trial including 198 community-dwelling patients aged 65 years or older with type 2 diabetes was conducted. Patients were randomly assigned to a control group (conventional diabetes management program), or intervention group (home telemedicine intervention with a health education program based on the Health Belief Model). The intervention lasted for 6 months. The primary outcome was glycosylated hemoglobin; secondary outcomes were diabetes self-management capacity, self-efficacy, and health beliefs. Baseline, 3-month, and 6-month outcome metrics were collected. Generalized estimating equations were used to compare changes in outcomes. The study is registered with the China Clinical Trial Registry (ChiCTR2200057428).

Results: 96.5% (191/198) of patients completed the study. From baseline to 6 months, HbA1c decreased by -0.99 (95% CI, -1.60% to -0.60%) in the intervention group and -0.42 (95% CI, -0.90% to 0.90%) in the control group. The intervention group had a greater reduction, of 0.42, compared to the control group (95% CI, 0.12% to 0.73%). Compared to the control group, the intervention group showed significant improvements in diabetes self-management skills, self-efficacy, and health beliefs at 3 and 6 months.

Conclusions: Home telemedicine interventions with health education based on the Health Belief Model may result in greater benefits for community-dwelling older patients with type 2 diabetes, potentially offering new options for chronic disease prevention and management. However, future large-scale studies are needed to assess effectiveness and feasibility. Clinical Trial: China Clinical Trial Registry (ChiCTR2200057428); <https://www.chictr.org.cn/showproj.html?proj=152850>

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Original Manuscript

Community-based Intelligent Blood Glucose Management for Older Adults with Type 2 Diabetes
Based on the Health Belief Model: A Randomized Controlled Trial

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Abstract

Background: The number of older patients with type 2 diabetes is increasing, and effective self-management is crucial for controlling disease progression and its complications.

Objective: We designed a home telemedicine intervention that combines telemedicine with health education based on the Health Belief Model. This study evaluated its effectiveness on self-management in older patients with type 2 diabetes.

Methods: Between March and April 2022, we recruited 198 community-dwelling patients with type 2 diabetes aged 65 years and older. Patients were randomly assigned to either a control group, which received a conventional diabetes management program, or an intervention group, which received a home telemedicine intervention with a health education program based on the Health Belief Model. The intervention lasted six months. The primary outcome measured was glycosylated hemoglobin (HbA1c); secondary outcomes included diabetes self-management capacity, self-efficacy, and health beliefs. We collected outcome metrics at baseline, 3 months, and 6 months. Generalized estimating equations were used to compare changes in outcomes.

Results: A total of 96.5% (191/198) of patients completed the study. From baseline to 6 months, HbA1c decreased by -0.99% (95% CI, -1.60% to -0.60%) in the intervention group and -0.42% (95% CI, -0.90% to 0.90%) in the control group. The intervention group experienced a significantly greater reduction of 0.42% compared to the control group (95% CI, 0.12% to 0.73%). Furthermore, compared to the control group, the intervention group showed significant improvements in diabetes self-management skills (95% CI, 4.98 to 6.79), self-efficacy (95% CI, 8.15 to 10.66), and health beliefs (95% CI, 17.71 to 21.36) at both 3 and 6 months.

Conclusions: Home telemedicine interventions incorporating health education based on the Health Belief Model can provide significant benefits for community-dwelling older patients with type 2 diabetes, potentially offering new avenues for chronic disease prevention and management. However, future large-scale studies are required to further assess their effectiveness and feasibility.

Trial Registration: China Clinical Trial Registry (ChiCTR2200057428); <https://www.chictr.org.cn/showproj.html?proj=152850>

Keywords: older adults, type 2 diabetes, telemedicine, health belief model, glycosylated hemoglobin

Introduction

The global diabetes population has quadrupled in the last thirty years, making diabetes the ninth leading cause of death [1]. In China, the prevalence of diabetes has rapidly increased from less than 1% in 1980 to 11.9% in 2022 [2], ranking it the second highest in the world [3]. The incidence of diabetes mellitus in China is positively correlated with aging, with a prevalence of 11.5% among the middle-aged population (45-59 years old) and over 20% among the elderly (≥ 65 years old) [4]. Older adults with type 2 diabetes are at higher risk of comorbidities and complications. Approximately one-fifth of elderly patients with type 2 diabetes develop serious complications [5], such as cardiovascular disease, psychiatric disorders, and physical dysfunction [6]. This imposes a significant burden on both society and the individual [7]. Consequently, providing adequate healthcare services to enable effective diabetes management has become critical.

Emerging telemedicine practices may address these needs by facilitating the delivery of healthcare services and health education to patients across geographies via the Internet [8]. Particularly for chronic diseases like type 2 diabetes, which require repeated consultations with physicians, telemedicine offers a viable alternative for patients seeking medical guidance [9]. Telemedicine typically supports four functions: [1] health promotion and knowledge dissemination, [2] timely medical and nursing support, [3] remote disease monitoring, and [4] decision support systems [10]. Given the limitations of healthcare service systems and the utilization of 5G networks, remote medical interventions represent a new opportunity to improve chronic disease management for patients with type 2 diabetes [11]. Since the majority of patients with type 2 diabetes are treated in community hospitals, telemedicine can help patients benefit from long-term monitoring and regular self-management [12].

Telemedicine interventions guided by health theories may yield better results [13]. The Health Belief Model (HBM) is an important theoretical framework that uses social psychological approaches to explain and predict changes in health-related behaviors, and it is widely used in health

behavior research [14]. Studies show that applying the health belief model to diabetes management can enhance knowledge [15], improve self-care behaviors [16], promote healthy lifestyles [15], and encourage active participation in disease management [17]. HBM has been utilized as a theoretical foundation for developing mobile health or telemedicine interventions [18], and many of its constructs have been demonstrated to effectively predict a range of health behaviors in meta-analyses [19]. The model is designed to help patients understand the severity of their disease, provide strategies for management, increase self-efficacy, enhance health behaviors, and achieve better health outcomes [20]. Therefore, given the importance of behavior change in telemedicine interventions, HBM may be a particularly relevant theory to enhance the impact of such interventions on self-management behaviors in older adults with type 2 diabetes.

However, the effectiveness of such telemedicine interventions in community-dwelling older adults with type 2 diabetes has not yet been established. Studies have indicated that telemedicine users are generally younger, while older or less-educated individuals have lower usage rates, placing them at a relative disadvantage [21]. Moreover, mismatches between app design and user capabilities, along with the poor quality of diabetes apps, pose significant challenges to telemedicine implementation [22]. To date, there is a notable lack of directly applicable clinical trial data on telemedicine interventions for community-dwelling older adults with type 2 diabetes.

To provide clinical evidence to inform treatment recommendations for community-dwelling older adults, we conducted a randomized controlled trial (RCT) of a telemedicine intervention among this group with type 2 diabetes. We evaluated the effectiveness of a comprehensive, personalized education and behavioral intervention program, based on the Health Belief Model and telemedicine, in improving home self-management for these older adults.

Methods

Recruitment

From March 2022 to April 2022, we recruited participants with type 2 diabetes from a

community hospital in Yangzhou City.

Inclusion criteria: [1] age 65 years and above; [2] T2DM: Diabetes was diagnosed based on self-reports with verification (current treatment, medical records, confirmation from healthcare providers, fasting plasma glucose ≥ 126 mg/dL, or symptoms of hyperglycemia with plasma glucose ≥ 200 mg/dL); [3] informed consent and voluntary participation in the study; [4] capability for self-care, no communication barriers, and no cognitive impairment.

Exclusion criteria: [1] serious physical illnesses (e.g., malignant tumors, severe cardiac, hepatic, or renal insufficiency, cerebrovascular accidents); [2] serious diabetes mellitus-related comorbidities; [3] current participation in other clinical trials or plans to participate in other clinical trials.

Researchers screened eligible participants through electronic health records within the community hospital health system and contacted them by phone. Participants who agreed to participate in the study were invited to the community hospital, where researchers met them face-to-face to discuss the details of the intervention program again, following informed consent. Laboratory testing and questionnaire collection were completed for eligible participants. A total of 198 participants were recruited. At 3 and 6 months of intervention, nurses reminded all participants to visit the community hospital for laboratory examinations and to complete the corresponding questionnaire collection.

Randomization and masking

Using Excel to generate random numbers, eligible study participants were randomly divided into an intervention group and a control group, each comprising 99 individuals, thus maintaining a 1:1 ratio. Recruitment personnel, data collectors, and data analysts were kept unaware of the intervention allocation. Recruitment, data collection, and data analysis were conducted by respective research assistants, researchers, and statisticians. The physician conducting the lab tests was also unaware of the group assignments. Due to the nature of the intervention, the healthcare provider delivering the intervention was not blinded.

Intervention program

Control group

Routine community-based diabetes management was implemented, including a free health consultation yearly and random blood glucose testing every three months. Participants also received diabetes health management handbooks.

Intervention group

In addition to routine community diabetes management and receiving diabetes health management handbooks, participants in this group were managed by a team comprising eight doctors, two pharmacists, twenty nurses, and one information engineer. The interventions included: [1] telemedicine smart devices and their manuals for information collection and enhancing doctor-patient communication; [2] provision of a glucose meter for self-monitoring of blood glucose (SMBG); [3] telemedicine guidance from a multidisciplinary team; [4] personalized diet and exercise plans.

Home telemedicine interventions

The “Xiaodu Smart Screen X8” telemedicine smart device connects via Bluetooth to a glucometer. Health information collected from the smart device, including blood sugar levels, exercise, diet, weight, and blood pressure, is automatically transmitted over wireless networks to a centralized website. This setup allows a multidisciplinary team to easily access and analyze the data, motivating participants to maintain self-management through ongoing personal monitoring and intervention.

Participants self-measured their blood sugar at least twice a week during the study. They chose the timing of each measurement, either fasting or two hours post-meal. If a patient's blood glucose value deviates from the normal range, the system triggers an automatic alert on the physician's side. Within three minutes of receiving the alert, the physician contacts the patient by phone to assess whether medical attention is needed. The doctor also determines the cause of the abnormal values

and provides appropriate medical guidance. If a patient's blood glucose value has not been uploaded for more than a week, a nurse calls the patient to remind them.

Pharmacists provide guidance to participants on improving blood glucose levels and offer medication recommendations based on individual glucose control. Participants in the intervention group used a smart device to voice-record their daily medication intake, and pharmacists received these records along with blood glucose data for each patient via the physician. Based on data analysis, the healthcare team sent a monthly medication management program to participants in the intervention group.

Participants could also input health records, including exercise, diet, weight, and blood pressure, through voice or manual entry on their smart devices. The device then generated personalized diet and exercise regimens based on their conditions. The multidisciplinary team accessed the website every two weeks to review the participants' diet and exercise plans and sent nutritional education information through the smart devices.

Additionally, the smart devices featured a one-click medical alert and enabled bidirectional communication between participants and the healthcare team via a chat function.

Health guidance by the multidisciplinary team

Upon their initial inclusion in the study, all participants received a diabetes self-management handbook based on the Health Belief Model. The multidisciplinary team, consisting of physicians, nurses, and pharmacists, had undergone specialized training in diabetes management intervention based on the Health Belief Model, equipping them with expertise in diabetes management and health coaching. Each group of 25 intervention participants was assigned to a team that provided face-to-face group education sessions every two weeks for three consecutive months (40-50 minutes each). These sessions took place in the training room of the community hospital. The intervention group was divided into four groups, each comprising approximately 25 individuals. Each group attended educational sessions scheduled for the same week. The educational content was structured around the

dimensions of the Health Belief Model and covered topics such as the definition, symptoms, and risk factors of type 2 diabetes (perceived susceptibility); benefits of using smart devices for diabetes management (perceived benefits); impact of type 2 diabetes on quality of life and physical health (perceived severity); diabetes self-management through smart devices (cues to action); discussion of the patient's experience in self-management and use of smart devices, providing solutions to reduce and remove barriers (perceived barriers); mobilizing family support, showcasing role models, and increasing self-efficacy (self-efficacy). Each session featured a lecture and discussion on the week's topic, incorporating photos, videos, presentations, and other relevant materials.

Outcomes and Measures

Participants' baseline data were collected using a researcher-designed individual health information form, which included age, sex, living arrangements, educational level, marital status, medical insurance coverage, employment status, monthly household income, duration of diabetes, treatment methods, complications, comorbidities, and other demographic information.

Primary outcome

The primary outcome was the level of HbA1c, assessed at baseline, 3 months, and 6 months. A nurse collected a fasting venous blood sample through venipuncture. The samples were processed by the diagnostic testing laboratory at the community hospital and measured using high-performance liquid chromatography (HPLC) on a Tosoh Automatic Glycohemoglobin Analyzer HLC-723G8.

Secondary outcomes

The Summary of Diabetes Self-Care Activities Measure (SDSCA)

The SDSCA was used to measure the frequency of self-management practices in individuals with diabetes over the past 7 days. This scale, designed by Toobert et al. [23], includes 11 items divided into six dimensions: general diet, special diet, blood glucose monitoring, physical activity, foot care, and smoking. It employs a 7-point Likert scoring system, where the score for each dimension is the mean score of the items within that dimension. A higher total score indicates better

self-management behavior.

The Self-efficacy for Diabetes (SED)

The study utilized the Chinese version of the SED, originally developed by Lorig et al. and translated and revised by Wei Jie et al. [24]. This scale assesses participants' self-efficacy in managing their glycemia, diet, exercise, and disease monitoring. It includes nine items scored on a 5-point Likert scale, with higher scores indicating greater self-efficacy.

Health beliefs questionnaire

The study employed a health belief questionnaire designed by Chen Yamei, based on the Health Belief Model framework proposed by Rosenstock et al [25]. Tailored for individuals with diabetes, this questionnaire measures their health beliefs across 20 items, distributed among five dimensions: perceived benefits, perceived severity, perceived susceptibility, perceived barriers, and cues to action. Scoring used a 5-point Likert scale, where higher scores indicate stronger health beliefs.

Sample Size Calculation

This study used glycated hemoglobin (HbA1c) values as the primary outcome indicator. We set the reference values based on previous literature [26]. The mean HbA1c in the treatment group was 9%, with a standard deviation of 1.9%. In the control group, the mean HbA1c was 10%, with a standard deviation of 2.7%. We set a two-sided α of 0.05 with 80% power. Using G*Power 3.1 software, the sample size for the treatment group was calculated to be $N_1 = 87$ cases, and for the control group, $N_2 = 87$ cases. Accounting for a potential dropout and refusal rate of 10%, we determined that a minimum of 96 participants in each of the intervention and control groups was needed, totaling a minimum of 192 participants.

Statistical Analysis

Statistical analysis in this study was conducted using SPSS 27.0 (Chicago, IL, USA), R (version 4.0.3), and GraphPad Prism (9.4.1). A P -value <0.05 was considered statistically significant.

Descriptive statistics were employed to describe the demographic distribution and scores for the

SDSCA, SED, and HBM. Variables with normal distribution were expressed as mean $\pm$ standard deviation, categorical variables were expressed as frequencies (percentages), and non-normally distributed variables were expressed as medians (quartiles). Continuous values were compared to baseline data using the independent samples *t*-test or Mann-Whitney U test.

The study employed an intention-to-treat analysis (ITT) to analyze the data. With no pattern in the missing data, the 10% missing values were assumed to be missing at random. The predicted values of the missing data were estimated using Markov Chain Monte Carlo (MCMC) multiple imputation to obtain a complete dataset. For the primary outcome (6-month change in HbA1c), linear mixed-effects models were used with HbA1c as the dependent variable. This model included a random intercept with an unstructured covariance matrix, indicator variables for time and study group, and group-by-time interaction terms. The same approach was used for the secondary outcomes.

Ethical Considerations

The study protocol adhered to the Declaration of Helsinki and received approval from the Ethics Committee of the School of Nursing and Public Health at Yangzhou University (approval number YZUHL2022001). Written informed consent was obtained from all participants.

Results

Participant Characteristics

A total of 219 potential participants were assessed for eligibility in this study. Out of the 210 who were eligible, 12 were excluded due to scheduling conflicts and a lack of interest. Consequently, 198 individuals agreed to participate and were randomly assigned to either the intervention group ($n=99$) or the control group ($n=99$) after providing informed consent. A total of 191 (96.5%) participants completed the follow-up assessments (Fig. 1). The ages of the 198 participants ranged from 65 to 87 years. The duration of diabetes varied from 1 to 41 years, with a mean glycosylated hemoglobin level of 7.05% (range 6.20 to 8.25%). Additionally, 76.8% of the participants were

taking oral hypoglycemic drugs to control their blood glucose, 22.7% had complications, and 29.3% had two or more comorbidities. There were no significant differences in baseline characteristics between the two groups ($P>0.05$), as shown in Table 1.

Table 1 Demographic and clinical characteristics of the participants (n=198)

Variables	Intervention group (n=99)	Control group (n=99)	t/x^2	P value
Age(yesrs), M $\pm$ SD	72.82 $\pm$ 4.85	74.11 $\pm$ 5.49	-1.621	0.105
Disease duration (yesrs), M $\pm$ SD	12.67 $\pm$ 7.96	13.61 $\pm$ 9.83	-0.266	0.790
Sex, n (%)			-1.703	0.088
Male	53(53.54)	44(44.44)		
Female	46(46.46)	55(55.56)		
Living arrangements, n(%)			-0.097	0.923
Living alone	7(7.07)	8(8.08)		
Living with spouse	30(30.30)	31(31.31)		
Living with family	62(62.62)	60(60.61)		
Educational level, n(%)			-1.871	0.061
Elementary school or below	32(32.32)	47(47.47)		
Junior high school	38(38.38)	29(29.29)		
High school	24(24.24)	18(18.18)		
University and above	5(5.06)	5(5.06)		
Marital status, n(%)			-0.420	0.675
Married	85(85.85)	87(87.88)		
Divorced/widowed	14(14.15)	12(12.12)		
Medical insurance coverage, n(%)			-1.219	0.223
Employees health insurance	82(82.82)	76(76.77)		
Residential health insurance	10(10.10)	8(8.08)		
Commercial health insurance	7(7.08)	15(15.15)		
Employment status, n(%)			-1.790	0.073
Employed	1(1.06)	4(4.12)		
Unemployed	4(4.04)	8(8.08)		
Retired	94(94.95)	87(87.88)		
Monthly household income (RMB), n(%)			-0.064	0.949
Less than 3000	15(15.15)	21(21.21)		
3000 to 5000	33(33.33)	24(24.24)		
5000 to 10000	45(45.45)	46(46.46)		
Greater than 10000	6(6.07)	8(8.09)		
Treatment method, n(%)			-1.330	0.183

None	0	10(10.10)		
Oral medication	81(81.82)	71(71.72)		
Insulin	6(6.06)	5(5.05)		
Oral medication + insulin	12(12.12)	13(13.13)		
Comorbidities, n(%)			-1.583	0.113
No	11(11.11)	25(25.25)		
One	58(58.59)	46(46.47)		
Two	26(26.26)	25(25.25)		
Three	4(4.04)	3(3.03)		
Complications, n(%)			-1.867	0.062
No	71(71.72)	82(82.83)		
One	26(26.26)	16(16.16)		
Two	2(2.02)	1(1.01)		
HbA1c, M(95CI%)	7.3(6.30,8.50)	6.90(6.10,8.90)	-0.514	0.607
SDSCA, M±SD	16.86±5.02	17.18±4.83	-1.321	0.187
SED, M±SD	25.37±5.01	26.28±3.34	-1.197	0.231
HBM, M±SD	69.53±7.56	71.59±4.71	-1.110	0.267

Note: HbA1c: glycated hemoglobin; SDSCA: The Summary of Diabetes Self-Care Activities

Measure; SED: The Self-efficacy for Diabetes; HBM: health belief model

Fig. 1 Flow chart of the study

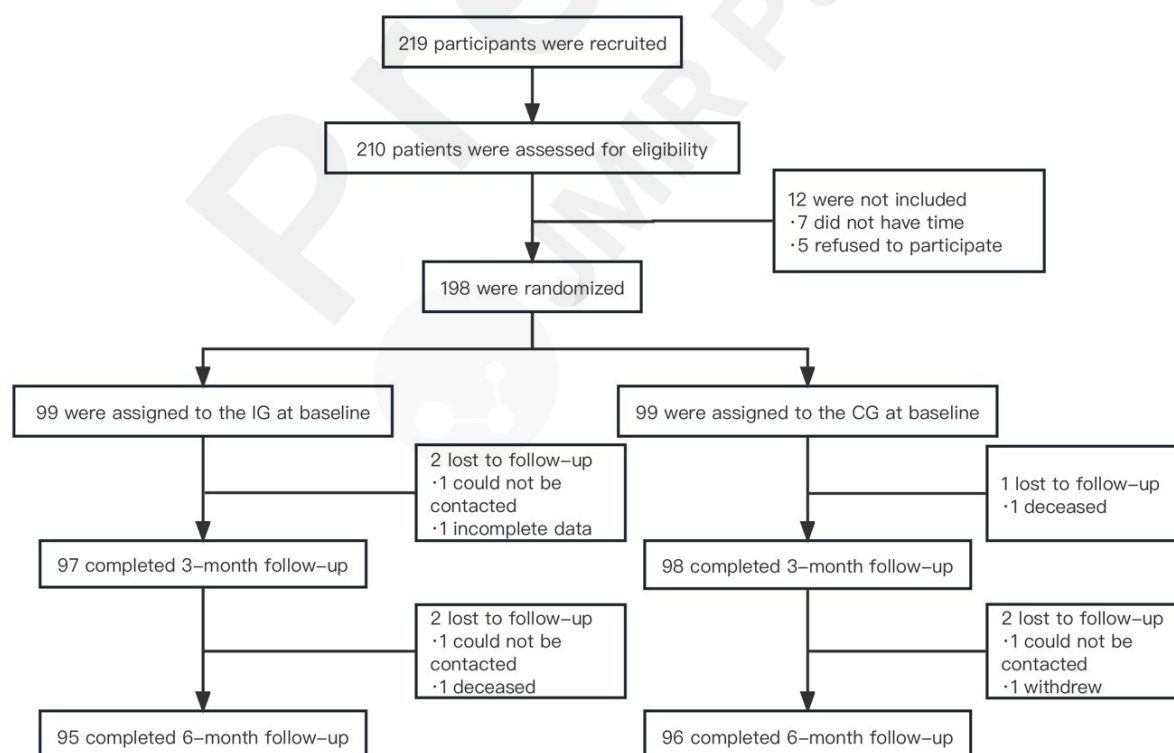


Fig. 1 Flow chart of the study

Note: IG: Intervention group; CG: Control group

Primary outcome

Participants' HbA1c levels decreased after 3 months of intervention ($P=0.021$), with a more significant improvement noted at 6 months ($P<.001$). In the intervention group, participants' HbA1c levels showed better control during follow-up ($P<.001$). The decrease in HbA1c levels at 6 months in the control group was not statistically significant ($P=0.061$). The interaction between group and time was not statistically significant ($P=0.51$), as shown in Table 2. In the intervention group, HbA1c levels decreased from a baseline of 7.87% to 7.28% at 3 months and further to 6.88% at 6 months. In the control group, HbA1c levels decreased from a baseline of 7.72% to 7.30% at 6 months. These changes are illustrated in Fig. S1.

Table 2 The Impact of home telemedicine interventions based on the Health Belief Model on HbA1c levels in older adults with type 2 diabetes

Outcome Measurement	β	SE	95% CI		P value
HbA1c (%)					
Group effect	8.02	0.404	7.228	8.812	<0.001
Time 2	-1.04	0.451	-1.924	-0.156	0.021
Time 3	-1.56	0.451	-2.444	-0.676	<0.001
Group*time2	0.45	0.285	-0.109	1.009	0.113
Group*time3	0.57	0.285	0.011	1.129	0.046

Note: β : regression coefficient; SE: standard error; CI: confidence interval; group effect: difference between groups at baseline; time 2, time 3: time effects at 3 and 6 months compared to baseline; group*time effect: difference in change at 3 and 6 months post-intervention compared to baseline.

Secondary outcomes

At 3 months of intervention, mean SDSCA scores increased from baseline levels in both the intervention (17.13 [SD24.50] vs. 19.59 [SD21.54]) and control groups (16.97 [SD22.52] vs. 18.43

[SD17.58]). At 6 months, mean SDSCA scores were higher than baseline levels in the intervention group (17.13 [SD24.50] vs 22.93 [SD14.59]) ($P<.001$), whereas mean SDSCA scores were lower than baseline levels in the control group (16.97 [SD22.52] vs. 16.93 [SD22.49]). The difference in scores between the two groups was statistically significant ($P<.001$).

Mean SED scores also improved from baseline in both groups at 3 months: the intervention (25.38 [SD25.38] vs. 29.51 [SD28.25]) and control groups (26.18 [SD11.16] vs. 26.44 [SD7.55]). At 6 months, mean SED scores were higher than baseline levels in the intervention group (25.38 [SD25.38] vs 34.99 [SD17.95]) ($P<.001$), while mean SED scores were slightly higher than baseline levels in the control group (26.18 [SD11.16] vs 26.24 [SD8.75]). There was a statistically significant difference between the two groups ($P<.001$) at both 3 and 6 months.

At 3 months, HBM scores were higher than baseline in both the intervention group (69.91 [SD56.44] vs. 77.89 [SD29.95]) and the control group (1.55 [SD22.12] vs. 73.35 [SD19.73]). At 6 months, HBM scores were significantly higher than baseline levels in both the intervention group (89.65 [SD18.44]) and the control group (77.04 [SD23.05]), and the intervention group showed a greater improvement in HBM scores. There was a statistically significant difference between the two groups ($P<.001$) at both 3 and 6 months, as detailed in Table 3 and Fig. S2.

Table 3 Changes in secondary outcomes during the home telemedicine intervention compared to baseline

Variables and time	Intervention group, mean (95% CI)	Control group, mean (95% CI)	Difference between groups, mean (95% CI)
SDSCA-compared to Baseline			
Change in 3 months	2.58(1.27,3.88)	1.34(0.17,2.51) ^b	-0.97(-2.19,0.26)
Change in 6 months	5.88(4.98,6.79) ^a	-0.11(-1.34,1.14)	-5.72(-6.89, -4.55) ^a
SED-compared to baseline			
Change in 3 months	3.98(2.72,5.24) ^a	0.18(-0.23,0.60)	-3.15(-4.22, -2.07) ^a
Change in 6 months	9.40(8.15,10.66) ^a	0.05(-0.49,0.59)	-8.70(-9.68, -7.66) ^a
HBM-compared to Baseline			
Change in 3 months	8.42(6.54,10.30) ^a	1.71(1.02,2.39) ^a	-4.89(-6.21, -3.57) ^a

Change in 6 months	19.54(17.71,21.36) ^a	5.52(4.43,6.60) ^a	-12.19(-13.57, -10.81) ^a
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Note: SDSCA: The Summary of Diabetes Self-Care Activities Measure; SED: The Self-efficacy for

Diabetes; HBM: Health belief model; ^a: $P < .001$; ^b: $P < 0.05$

Adverse events

No serious adverse clinical events were reported from enrollment to the 6-month follow-up. However, some operational issues with the devices, such as Bluetooth pairing problems between blood glucose meters and smart devices, were reported as inconvenient by participants. Indeed, it has been demonstrated that such issues can lead to lower satisfaction and reduced use of remote technology [27]. Prior to the start of the study, all participants were informed about the potential for these problems and the availability of telephone assistance.

Discussion

Principal Findings

In this study, we tested a home telemedicine intervention and health education program based on the Health Belief Model among community-recruited elderly patients with type 2 diabetes. Screening, recruitment, and participation outcomes indicated that, although the number of participants was small, the vast majority were willing to participate and complete the program. While adherence was high in both groups, adherence to self-management varied significantly. Overall, this program has shown potential in helping elderly patients with type 2 diabetes achieve safe and effective home diabetes self-management under the supervision and guidance of healthcare providers.

Longitudinal analyses demonstrated significant improvements in HbA1c levels at 3 and 6

months, as well as significant enhancements in diabetes self-management, self-efficacy, and health belief scores in the intervention group. In contrast, in the control group, only health beliefs showed significant improvement at 6 months. HbA1c levels were significantly lower following the intelligent blood glucose management in the intervention group compared to the control group. This study underscores the effectiveness of intelligent blood glucose management as a means of delivering behavioral health interventions to older adults with type 2 diabetes [28]. At 3 months, HbA1c levels in the intervention group decreased significantly by 0.59% from baseline, compared to 0.13% in the control group; however, this difference was not statistically significant. At 6 months, HbA1c levels in the intervention group further decreased by 0.40% compared to 0.29% in the control group, indicating sustained improvement. This finding is consistent with research by Chenglin Sun et al. [29], suggesting that older adults may require time to familiarize themselves with telemedicine systems. Furthermore, after training and remote guidance from the healthcare team, participants were better able to use smart devices independently [30]. In this study, glycemic management improved in both groups, which may be attributed to several factors. Firstly, the Hawthorne effect [31] could explain improvements, as control participants also had frequent contact with researchers and received additional attention, including regular tests of their glycosylated hemoglobin every three months. Secondly, all subjects received a diabetes self-management handbook and specialized care from healthcare professionals, potentially allowing for more intensive glucose management than usual [32]. However, sustained and effective long-term effects are challenging without ongoing telemedicine oversight and support [33]. Therefore, long-term follow-up of older adults with type 2 diabetes is crucial.

The significant and long-lasting improvement in self-management in the intervention group, compared to the control group, suggests that our intervention may promote improved self-management behaviors, aligning with findings from previous studies [34]. However, one study indicated that the difference between groups using intelligent blood glucose management alone was

not significant, possibly due to older adults' lack of experience with and incomplete knowledge of smart devices [35]. After incorporating group health education based on the Health Belief Model, participants in the intervention group significantly improved their self-management skills. This underscores the vital role that face-to-face diabetes health education plays in helping older adults overcome the challenges of using smart devices and enhancing their self-management. A systematic evaluation noted that an essential component of diabetes self-management is the active participation of the patient in their care [9]. One effective method is through health education, which facilitates the learning process of self-management. Farhan Ahmad et al. [36] found that older adults with type 2 diabetes may require regular face-to-face counseling to address the challenges they encounter during telemedicine interventions. Providing support and education through a dedicated community-based diabetes healthcare team can help participants achieve optimal self-management [32]. Therefore, combining telemedicine with face-to-face health education appears to be a promising approach for enhancing diabetes self-management.

In this study, the health belief scores of participants in the intervention group were higher than those in the control group. The longer the intervention period, the more pronounced the differences in health belief scores became. This suggests that telemedicine-based health education is more effective in improving the health beliefs of elderly participants with type 2 diabetes compared to traditional health education [37]. Health education makes participants aware of the complications, severity, and harms associated with their condition, as well as the benefits of adopting a healthy lifestyle. This encourages them to take the initiative in managing their health and deepens their understanding of diabetes. Additionally, the feedback and reminders provided by telemedicine play a positive role in enhancing participants' health beliefs [38], which strengthens their health motivation and helps them establish a correct and comprehensive set of health beliefs. The results of this study show that health education based on the HBM within the context of telemedicine has a positive impact, increasing patient self-efficacy, reducing perceived barriers in the intervention group, and

facilitating an increase in patient health behaviors.

We also found that the intervention improved self-efficacy in older adults with type 2 diabetes, similar to the results of other studies [39]. Given that increased health beliefs are associated with higher diabetes self-efficacy [21], participants in the intervention group experienced higher self-efficacy as their level of health beliefs increased. Elevated levels of self-efficacy are often linked with decreased barriers to engaging in health behaviors, which in turn leads to increased motivation to engage in desired activities [40].

Limitations

First, while studies have shown the short-term impact of telemedicine on glycemic management in older adults with type 2 diabetes, the long-term validity of these effects remains unassessed. Second, the participants who chose to join this study likely demonstrated some level of readiness for digital health literacy change. Therefore, strategies have yet to be developed for those uninterested individuals who did not participate in the study. Finally, the study relied on structured questionnaires for participants to self-assess their self-efficacy, health beliefs, and diabetes self-management skills, which may have introduced recall bias into the results.

Conclusions

The findings of this study suggest that health education and telemedicine interventions based on the Health Belief Model can improve HbA1c levels and other related outcomes in older adults with type 2 diabetes. The telemedicine system provided timely access to the health status of elderly participants with type 2 diabetes, facilitated communication and feedback between doctors and participants, and enabled the inclusion of healthcare provider counseling to enhance patient motivation. This, in turn, improved the effectiveness of medical care, leading to better glycemic management in the intervention group. Future research should further evaluate the long-term effects of this approach compared to routine community diabetes care. Additionally, it should focus on

providing better support for lifestyle changes through enhanced interventions and counseling to improve patient motivation and confidence, ultimately offering more comprehensive diabetes management for participants.

Authors' Contributions: AZ, XW, and JW conceived and designed the study, and AZ, YM, SB, SZ, SY, XJ, and ZZ collected data. AZ and JW for statistical analysis. AZ, XW, and JW drafted the manuscript. All authors contributed to the article and approved the submitted version.

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Conflicts of Interest: None declared.

Availability of data and materials: The data sets generated during and/or analyzed in the current study are available from the corresponding author upon reasonable request.

References

1. Ali MK, Pearson-Stuttard J, Selvin E, Gregg EW. Interpreting global trends in type 2 diabetes complications and mortality. *Diabetologia*. 2022;1//;65(1):3-13. doi: 10.1007/s00125-021-05585-2.
2. Society CD, Care NOofPD. National guidelines for the prevention and control of diabetes in primary care (2022). *Chinese Journal of Internal Medicine*. 2022;61(3):249-62. doi: 10.3760/cma.j.cn112138-20220120-000063.
3. Sun H, Saeedi P, Karuranga S, et al. IDF Diabetes Atlas: Global, regional and country-level diabetes prevalence estimates for 2021 and projections for 2045. *Diabetes Res Clin Pract*. 2022 Jan;183:109119. PMID: 34879977. doi: 10.1016/j.diabres.2021.109119.
4. Overbeek JA, Nijpels G, Swart KMA, Blom M, Elders PJM, Herings RMC. Type 2 Diabetes, the Epidemic: Trends in Prevalence and Incidence, 2004-2020. *Diabetes Metab Syndr Obes*. 2024;17:1503-9. PMID: WOS:001192379000001. doi: 10.2147/dmso.S445288.

5. Guldemon N. What is meant by 'integrated personalized diabetes management': A view into the future and what success should look like. *Diabetes Obes Metab*. 2024 Feb;16. PMID: WOS:001157665800001. doi: 10.1111/dom.15476.
6. Ali MK, Pearson-Stuttard J, Selvin E, Gregg EW. Interpreting global trends in type 2 diabetes complications and mortality. *Diabetologia*. 2022 Jan;65(1):3-13. PMID: 34837505. doi: 10.1007/s00125-021-05585-2.
7. Nauck MA, Wefers J, Meier JJ. Treatment of type 2 diabetes: challenges, hopes, and anticipated successes. *Lancet Diabetes Endocrinol*. 2021 Aug;9(8):525-44. PMID: 34181914. doi: 10.1016/s2213-8587(21)00113-3.
8. Sood S, Mbarika V, Jugoo S, Dookhy R, Doarn CR, Prakash N, et al. What is telemedicine? A collection of 104 peer-reviewed perspectives and theoretical underpinnings. *Telemed J E Health*. 2007 Oct;13(5):573-90. PMID: 17999619. doi: 10.1089/tmj.2006.0073.
9. Altabtabaei R, Alhuwail D. Challenges and Opportunities of the Use and Adoption of Telemedicine for Diabetes Care and Management During the COVID-19 Pandemic and Beyond. *iproc*. 2023 2023/2/15;9:e41285. doi: 10.2196/41285.
10. Fleming GA, Petrie JR, Bergenstal RM, Holl RW, Peters AL, Heinemann L. Diabetes Digital App Technology: Benefits, Challenges, and Recommendations. A Consensus Report by the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) Diabetes Technology Working Group. *Diabetes Care*. 2019;43(1):250-60. doi: 10.2337/dci19-0062.
11. Hood K, Bergenstal RM, Cushman T, Gal RL, Raghinaru D, Kruger D, et al. Patient-Reported Outcomes Improve with a Virtual Diabetes Care Model that Includes Continuous Glucose Monitoring. *Telemedicine and E-Health*. 2024 Aug;10. PMID: WOS:001295028200001. doi: 10.1089/tmj.2024.0093.
12. Lozano Hernández CM, Medina-García R, de Hoyos-Alonso MC, Garrido-Barral A, Minué Lorenzo C, Sanz-Cuesta T, et al. Improvement in Quality of Life With the Use of a Technological

System Among Patients With Chronic Disease Followed Up in Primary Care (TeNDER Project): Protocol for a Randomized Controlled Trial. *JMIR Res Protoc.* 2023 2023/7/3;12:e47331. doi: 10.2196/47331.

13. Del-Valle-Soto C, López-Pimentel JC, Vázquez-Castillo J, Nolasco-Flores JA, Velázquez R, Varela-Aldás J, et al. A Comprehensive Review of Behavior Change Techniques in Wearables and IoT: Implications for Health and Well-Being. *Sensors.* 2024 Apr;24(8):36. PMID: WOS:001210597300001. doi: 10.3390/s24082429.

14. Du QH, Zhang ZC, Yang Y, Luo XX, Liu L, Jia HH. How health seeking behavior develops in patients with type 2 diabetes: a qualitative study based on health belief model in China. *Front Public Health.* 2024 Jul;12:11. PMID: WOS:001274026900001. doi: 10.3389/fpubh.2024.1414903.

15. Owolabi EO, Boakye MDS, Omololu SO, Smalls BL, Shaibi GQ. Technology-Based Interventions to Promote Diabetes Self-Management Behaviors for Persons Newly Diagnosed with Type 2 Diabetes: A Scoping Review. *Curr Diabetes Rep.* 2024 2024 Oct:16. PMID: WOS:001324165100001. doi: 10.1007/s11892-024-01553-3.

16. Melkamu L, Berhe R, Handebo S. Does Patients' Perception Affect Self-Care Practices? The Perspective of Health Belief Model. *Diabetes Metab Syndr Obes.* 2021;14:2145-54. PMID: 34012280. doi: 10.2147/dmso.S306752.

17. Hashim SA, Mohd Yusof BN, Abu Saad H, Ismail S, Hamdy O, Mansour AA. Effectiveness of simplified diabetes nutrition education on glycemic control and other diabetes-related outcomes in patients with type 2 diabetes mellitus. *Clin Nutr ESPEN.* 2021 Oct;45:141-9. PMID: 34620310. doi: 10.1016/j.clnesp.2021.07.024.

18. Sharifat R, Borazjani F, Araban M, Pakpour AH, Angali KA, Aiiashi S. Nutritional education on health beliefs, metabolic profiles, and quality of life among high-risk pregnant women for gestational diabetes mellitus: a randomized controlled trial. *Sci Rep.* 2024 Nov 12;14(1):27712. PMID: 39532953. doi: 10.1038/s41598-024-78447-7.

19. Skovlund SE, Troelsen LH, Noergaard LM, Pietraszek A, Jakobsen PE, Ejlskjær N. Feasibility and Acceptability of a Digital Patient-Reported Outcome Tool in Routine Outpatient Diabetes Care: Mixed Methods Formative Pilot Study. *JMIR Form Res*. 2021 2021/11/3;5(11):e28329. doi: 10.2196/28329.
20. Liu YW, Tang CC. Health Beliefs, Protective Behaviors, and Information-Seeking. *Nurs Res*. 2024 Mar-Apr;73(2):158-65. PMID: WOS:001176309100002. doi: 10.1097/nnr.0000000000000712.
21. Guo SH, Lin JL, Hsing HC, Lee CC, Chuang SM. The Effect of Mobile eHealth Education to Improve Knowledge, Skills, Self-Care, and Mobile eHealth Literacies Among Patients With Diabetes: Development and Evaluation Study. *J Med Internet Res*. 2023 Dec 6;25:e42497. PMID: 38055321. doi: 10.2196/42497.
22. Toschi E, Adam A, Atakov-Castillo A, Slyne C, Laffel L, Munshi M. Use of Telemedicine in Adults with Type 1 Diabetes: Do Age and Use of Diabetes-Related Technology Matter? *Telemed J E Health*. 2023 Sep;29(9):1374-82. PMID: 36695656. doi: 10.1089/tmj.2022.0397.
23. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure - Results from 7 studies and a revised scale. *Diabetes Care*. 2000 Jul;23(7):943-50. PMID: WOS:000087890200013. doi: 10.2337/diacare.23.7.943.
24. Wei J. A study on the correlation between knowledge, self-efficacy and self-management behavior of elderly diabetic patients in rural areas [master]: Hangzhou Normal University; 2013.
25. Chen Y. A survey of compliance and its influencing factors in readmitted diabetic patients [master]: Central South University; 2007.
26. Egede LE, Dawson AZ, Walker RJ, Garraci E, Knapp RG. Randomized controlled trial of technology-assisted case management in low-income adults with type 2 diabetes: Effect on quality of life and blood pressure. *J Telemed Telecare*. 2021 Jul 12;1357633x211028491. PMID: 34251865. doi: 10.1177/1357633x211028491.
27. Bradway M, Pfuhl G, Joakimsen R, Ribu L, Grøttland A, Årsand E. Analysing mHealth usage

logs in RCTs: Explaining participants' interactions with type 2 diabetes self-management tools. *PLoS One*. 2018;13(8):e0203202. PMID: 30161248. doi: 10.1371/journal.pone.0203202.

28. Chong CJ, Makmor-Bakry M, Hatah E, Tahir NAM, Mustafa N, Capule FR, et al. Factors influencing type 2 diabetes mellitus patients' readiness, acceptance and barriers towards mobile apps adoption for medication adherence. *Int Diabetes Dev Ctries*. 2024 Oct;11. PMID: WOS:001335124100001. doi: 10.1007/s13410-024-01413-6.

29. Sun C, Sun L, Xi S, Zhang H, Wang H, Feng Y, et al. Mobile Phone-Based Telemedicine Practice in Older Chinese Patients with Type 2 Diabetes Mellitus: Randomized Controlled Trial. *JMIR Mhealth Uhealth*. 2019 Jan 4;7(1):e10664. PMID: 30609983. doi: 10.2196/10664.

30. Altabtabaei R, Alhuwail D. Exploring the Challenges and Opportunities of Adopting and Using Telemedicine for Diabetes Care and Management: Qualitative Semistructured Interview Study Among Health Care Providers and Patients With Diabetes. *JMIR Hum Factors*. 2023 2023/9/7;10:e46324. doi: 10.2196/46324.

31. McCarney R, Warner J, Iliffe S, van Haselen R, Griffin M, Fisher P. The Hawthorne Effect: a randomised, controlled trial. *BMC Med Res Methodol*. 2007 Jul 3;7:30. PMID: 17608932. doi: 10.1186/1471-2288-7-30.

32. Sankoda A, Nagae Y, Waki K, Sze WT, Oba K, Mieno M, et al. Glycemic Control, Renal Progression, and Use of Telemedicine Phone Consultations Among Japanese Patients With Type 2 Diabetes Mellitus During the COVID-19 Pandemic: Retrospective Cohort Study. *JMIR Diabetes*. 2023 2023/11/21;8:e42607. doi: 10.2196/42607.

33. Lewinski AA, Walsh C, Rushton S, Soliman D, Carlson SM, Luedke MW, et al. Telehealth for the Longitudinal Management of Chronic Conditions: Systematic Review. *J Med Internet Res*. 2022 Aug 26;24(8):e37100. PMID: 36018711. doi: 10.2196/37100.

34. Barnard-Kelly K. Utilizing eHealth and Telemedicine Technologies to Enhance Access and Quality of Consultations: It's Not What You Say, It's the Way You Say It. *Diabetes Technol Ther*.

2019 Jun;21(S2):S241-s7. PMID: 31169431. doi: 10.1089/dia.2019.0015.

35. ten Klooster I, Kip H, van Gemert-Pijnen L, Crutzen R, Kelders S. A systematic review on eHealth technology personalization approaches. *iScience*. 2024 Sep;27(9):34. PMID: WOS:001309754200001. doi: 10.1016/j.isci.2024.110771.

36. Ahmad F, Wysocki RW, Fernandez JJ, Cohen MS, Simcock XC. Patient Perspectives on Telemedicine During the COVID-19 Pandemic. *Hand (N Y)*. 2021 Sep 13;15589447211030692. PMID: 34515550. doi: 10.1177/15589447211030692.

37. Webb TL, Joseph J, Yardley L, Michie S. Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy. *J Med Internet Res*. 2010 Feb 17;12(1):e4. PMID: 20164043. doi: 10.2196/jmir.1376.

38. Shariful IM. Theories applied to m-health interventions for behavior change in low-and middle-income countries: a systematic review. *Telemedicine and e-Health*. 2018.

39. Guo J, Wang H, Ge L, Valimaki M, Wiley J, Whittemore R. Effectiveness of a nurse-led mindfulness stress-reduction intervention on diabetes distress, diabetes self-management, and HbA1c levels among people with type 2 diabetes: A pilot randomized controlled trial. *Res Nurs Health*. 2022 Feb;45(1):46-58. PMID: 34741544. doi: 10.1002/nur.22195.

40. Izquierdo M, Merchant RA, Morley JE, Anker SD, Aprahamian I, Arai H, et al. International Exercise Recommendations in Older Adults (ICFSR): Expert Consensus Guidelines. *J Nutr Health Aging*. 2021;25(7):824-53. PMID: 34409961. doi: 10.1007/s12603-021-1665-8.

Online-Only Supplemental Material

Figure S1 Mean and confidence intervals of glycated hemoglobin levels in both groups

Figure S2 Mean and confidence intervals of SDSCA, SED and HBM scores for the two groups in the study

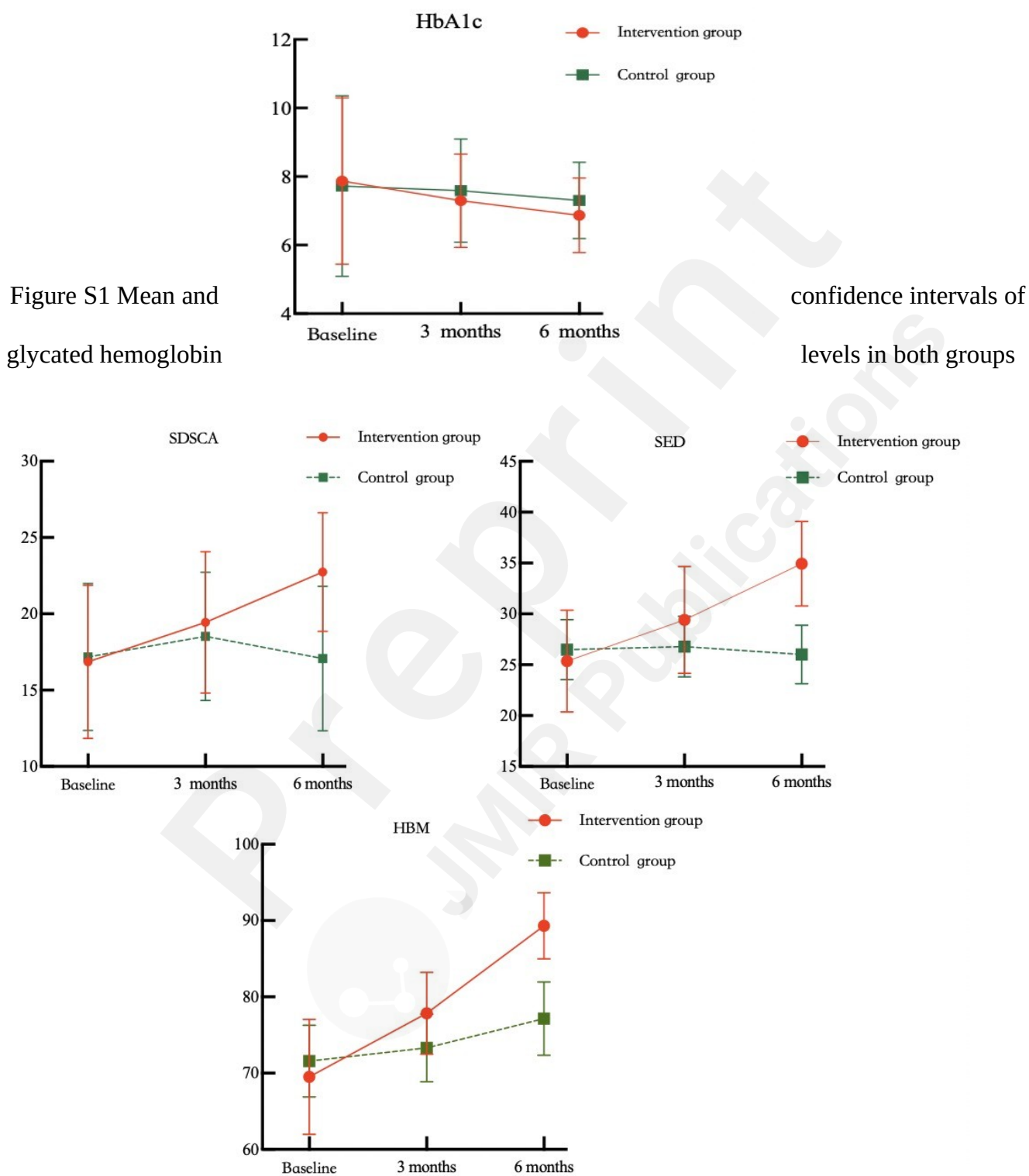
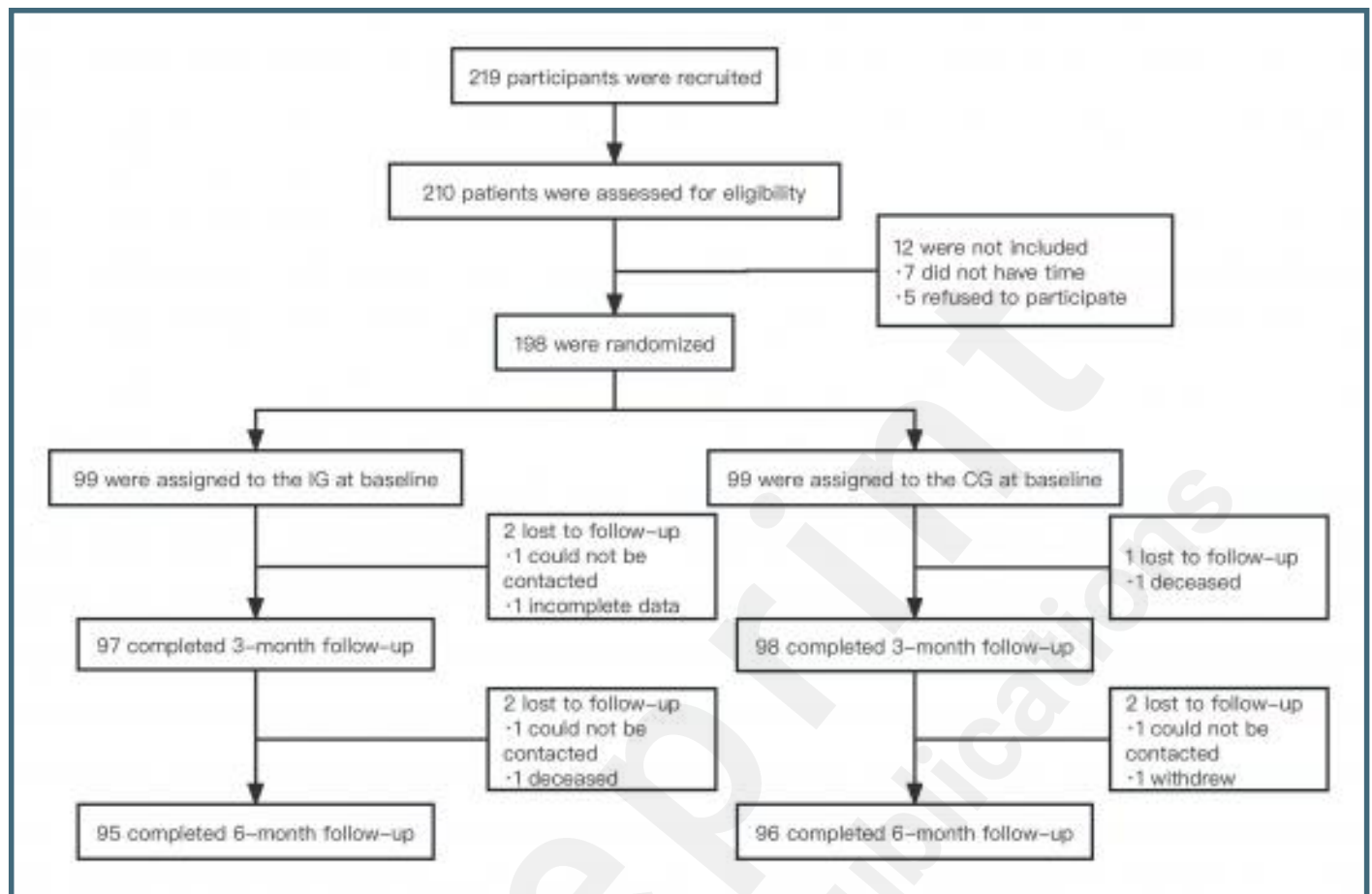


Figure S2 Mean and confidence intervals of SDSCA, SED and HBM scores for the two groups in the study



Supplementary Files

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CONSORT (or other) checklists

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