ORIGINAL RESEARCH

# Validity and Reliability of the Chinese Version of the Diabetes Treatment Burden Questionnaire (DTBQ) Among Patients with Type 2 Diabetes

Yujin Mei [1], Xue Yang[1], Yuqing Li [1], Xiaoyun Zhang [1], Jiaofeng Gui[1], Ying Wang[1], Wenyue Chen[1], Mingjia Chen[1], Changjun Liu[2], Lin Zhang [3]

[1]School of Nursing, Wannan Medical College, Wuhu City, Anhui Province, People's Republic of China; [2]School of Marxism, Jinzhou Medical University, Jinzhou City, Liaoning Province, People's Republic of China; [3]Department of Internal Medicine Nursing, Wannan Medical College, Wuhu City, Anhui Province, People's Republic of China

Correspondence: Lin Zhang, Email yaoran2008@163.com

**Background:** In China, diabetes has become a serious healthcare problem that plagues individuals and the government because of its high mortality rate and social burden, with type 2 diabetes mellitus (T2DM) accounting for the vast majority (about 90%) of cases. T2DM patients face a huge medication burden and it is imperative to find appropriate tools to assess the medication burden for patients. This study aimed to translate the original Diabetes Treatment Burden Questionnaire (DTBQ) into Chinese and assessed the reliability and validity of the DTBQ concerning the burden of medication treatment in patients with type 2 diabetes.

**Methods:** A total of 329 T2DM patients were recruited to participate in the survey. The original version scale was first translated into Chinese using the backward and forward translation procedures. The internal consistency reliability of the scale was measured by the Cronbach alpha coefficient, the test-retest reliability, and the item-total correlation. The validity of the scale was assessed by the content validity index, exploratory factor analysis and confirmatory factor analysis.

**Results:** The content validity index of the scale was 0.920. Cronbach alpha coefficient for the scale was 0.831. Exploratory factor analysis (EFA) supported a 15-item and 3-factor structure of the translated questionnaire. Confirmatory factor analysis (CFA) showed in the model fitness index, the chi-square degree of freedom was 3.575, the incremental fit index (IFI) was 0.917, the comparative fit index(CFI) was 0.916, the Tucker Lewis Index(TLI) was 0.900, all within acceptable limits. The retest reliability was 0.892, and the corrected item-total correlations for the items ranged from 0.293 to 0.729.

**Conclusion:** Verification results showed that the Chinese version of the 15-item DTBQ had reliable reliability and validity. Therefore, it can be considered as an appropriate tool to assess the burden of drug treatment for patients with type 2 diabetes in China.

**Keywords:** diabetes treatment burden questionnaire, T2DM, reliability, validity

## Introduction

The prevalence of diabetes is gradually increasing globally due to an increasingly aging population, increased urbanization, and changes in individual lifestyles.[1] Data from the International Diabetes Federation (IDF) showed that 463 million people worldwide have diabetes, and this number is expected to reach 700 million in 2045, representing approximately 11% of the total population.[2,3] In China, diabetes has become a serious problem plaguing both the government and individuals due to the high mortality rate and socio-economic burden.[4] From 1990 to 2013, the age-standardized mortality rate per 100,000 people with diabetes increased by 2.0%, with type 2 diabetes mellitus (T2DM) accounting for the majority of cases.[5]

T2DM is a chronic metabolic disease caused by inadequate secretion of the pancreatic islets or insensitivity of the target cells of the pancreas to insulin.[6,7] Since the introduction of insulin (the first injectable therapeutic drug for diabetes) and sulfonylureas (the first OHAs) in the 1920s, significant progress has been made in the pharmacological treatment of T2DM.[8] Although advances in pharmacotherapy have helped improve glycemic control in T2DM patients,

many patients still have poor glycemic control.[9] In a survey of US adults with T2DM, only 52.2% of subjects achieved the glycemic goal of HbA1c < 7.0% from 2007–2010.[10] Increasing the level of glycemic control in patients with T2DM is an important medical goal.

Multiple factors influence adherence to diabetes treatment.[11,12] Patient factors include complex demographic characteristics, psychological factors, physical factors, social well-being, and personal economic status.[13] On the other hand, specific medication factors exist in treatment efficacy, medication safety, cost, complexity, and convenience of taking medication.[14] In addition, patients with T2DM, especially the elderly, are often associated with hypertension and cardiovascular disease and are therefore at greater risk associated with combination drug therapy.[15]

One possible solution to reduce the medication burden in patients with diabetes is using a single fixed-dose combination of multiple OHAs.[16,17] Fixed-dose combinations require fewer tablets and reduce the complexity of treatment, thus reducing the burden of treatment by replacing multiple drugs with fixed-dose combinations.[18,19] Another solution is using long-acting preparations whose effect of lowering the patient's blood glucose lasts for one week.[20] However, in China, oral hypoglycemic agents or injectable insulin are still the main clinical treatment modality for diabetes.[21] Many patients often do not obey the medical staff's instructions to take their medication on time and in the right amount, or they take a wide range of medications. Patients have to endure the pain and other skin problems associated with long-term insulin injections, which not only fail to achieve the expected therapeutic effect but also increase the treatment burden of patients.[22–24] Also, some observational studies have reported that many diabetic patients report dangerous hypoglycemia as a result of taking diabetes medication.[24,25] Therefore, it is urgent to understand the burden of medication on patients. However, there is no established questionnaire available in China to measure the medication burden in T2DM patients.

Two scales have been used to measure the burden of treatment for people with diabetes, the PAID (Problem Areas in Diabetes Scale) and the DDS (Diabetes Distress Scale).[26–28] However, these scales focus on the general burden of diabetes rather than the treatment burden caused by medication. Although the LMQ (Living with Medicine Questionnaire) has more domains of the burden that may be experienced by people with long-term taking medicines (including diabetes), but it may not specifically for people with T2DM.[29] As such, they do not lend themselves to differentiation based on the characteristics of the medication, such as the patient's dosing regimen, which largely determines the complexity and difficulty of the patient's medication regimen.[30] Therefore, in order to measure the treatment burden of medication on patients with type 2 diabetes, we introduced a Chinese version of the DTBQ (Diabetes Treatment Burden Questionnaire), focusing on treatment results (ie, blood glucose control), medication safety (ie, hypoglycemia), medication regimen complexity (ie, frequency of administration) and ease of use (ie, whether there is difficulty taking or injecting the medication) and evaluating its reproducibility and effectiveness.

## Methods
### Design and Samples

A cross-sectional survey was conducted from June to December 2022 in Wuhu, Anhui Province, China. The participants were T2DM patients from the First Affiliated Hospital of Wannan Medical College. All participants completed the test voluntarily. The study was approved by the Medical Ethics Committee of Wan Nan Medical College (approval number 2021–3). The inclusion criteria were as follows: (i) all patients should meet the diagnostic criteria for T2DM established by the American Diabetes Association. (ii) patients are clearly conscious and have full mobility and cognitive ability. (iii) patients are willing to cooperate and complete the questionnaire. Exclusion criteria are as follows: (i) presence of severe mental impairment or intellectual problems; (ii) severe diabetic complications or inability to care for themselves; (iii) other serious illnesses such as severe cardiovascular disease, severe infectious diseases, cancer, visual and hearing impairment due to complications of T2DM; (iv) pregnancy or other specific diabetes. Based on the criteria proposed by Kendall (10 times the number of items and expanded by at least 10% to ensure an adequate sample size).[31] A sample size of at least 198 was calculated as the number of items for the DTBQ was 18. Finally, a total of 334 questionnaires were sent out.

## Instrument

The DTBQ is a three-factor scale consisting of 18 items, including Factor I (implementation burden, ten items), Factor II (flexibility burden, three items), and Factor III (BG control burden, five items).[32] Implementation burden represents whether patients with T2DM feel burdened with implementing their current medication regimen, and Flexibility burden represents whether patients feel burdened with the timing and schedule of their medication. Moreover, BG control burden represents whether patients feel burdened about controlling their blood glucose. The DTBQ uses a 7-point Likert scale with response options ranging from "strongly disagree" to "strongly agree". It should be noted that for questions 11–18, the relationship between scores and the level of treatment burden is reversed. In other words, in questions 1–10, higher scores imply a higher medication burden, but in questions 11–18, a lower medication burden.

## Translation Procedure

Permission was obtained from the authors of the DTBQ of Chinese it using the Brislin model.[33] (1) Direct translation: One Ph.D. in nursing and one MD in endocrinology independently translated the original scale, and the subject group discussed and resolved differences. Both translators were skilled in Chinese and English translation. (2) Back translation: Two medical English teachers who had not been exposed to or used the original scale translated the direct translation version of the DTBQ into English. Through repeated back-translation, the back-translated scale was consistent with the original scale in terms of content and semantics to form the first draft of the Chinese version of the DTBQ.

## Cultural Adaptation and Pre-Survey

A team of experts, including one senior internal medicine expert, two nursing experts, and three clinicians, were asked to comment on the relevance of the content, cultural background, language conventions, and linguistic clarity of each item in the first draft of the Chinese version of the DTBQ based on their clinical work experience and professional theoretical knowledge. The specific amendments are as follows: In Q11, "It requires short time and small effort to take the current medication" was changed to "easy", which is more conducive to the understanding and response of patients with T2DM; Q13 "With the current medication, I feel less burden to follow diet therapy" was revised to "follow diet therapy" to "follow the doctor's dietary advice", making it more suitable for measuring the expression habits of Chinese T2DM patients. In June 2022, 30 patients with T2DM who met the inclusion criteria were conveniently selected from the First Affiliated Hospital of Wannan Medical College for a pre-survey. Pre-survey interviews were conducted to find out if patients had difficulty understanding the entries and to record the time required to complete them. The final Chinese version of the DTBQ was formed after revision based on expert opinion and patient feedback. The Chinese and English versions of the DTBQ are shown in Supplementary Table 1.

## Data Collection

The questionnaires included the Chinese version of the DTBQ and the socio-demographic information questionnaire. Multi-stage sampling was used in this study. Firstly, the First Affiliated Hospital of Wannan Medical College was randomly selected from all tertiary hospitals in Wuhu, Anhui Province. Secondly, four departments were strategically selected from this hospital: endocrinology, geriatrics, traditional Chinese medicine, and dermatology. Thirdly, survey points were set up in each department, and T2DM patients were randomly selected for questionnaire surveys. A total of 344 questionnaires were sent out, and 329 valid questionnaires were returned, with a valid return rate of 95.6%. To reduce errors, uniform training was given to the five surveyors before the survey started, clarifying the communication skills with patients and the scale scoring criteria. After obtaining informed consent from the patients, the questionnaires were administered one-to-one and the questionnaire is completed by the patient on their own. All methods were implemented following the Declaration of Helsinki. The average time taken by patients to complete the questionnaire was approximately 3~5 mins.

## Statistical Analysis

SPSS 26.0 software was used for statistical analysis of the data, and AMOS 24.0 for validating factor analysis. Using (Mean ± SD) described quantitative information that obeyed normal distribution and, frequency and percentage to describe qualitative information. The critical ratio and correlation coefficient methods were used for item analysis; content and structural validity was used to evaluate the scale's validity; Cronbach's alpha coefficient and retest reliability was used to evaluate the scale reliability. The test level was α=0.05.

## Construct Validity

Exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) were used to examine the construct validity of the Chinese version of DTBQ. The sample of 329 cases was randomly divided into two groups, one group consisted of 164 individuals for EFA, and 165 individuals for CFA.

In the sample 1 (n = 164), a principal component analysis with Varimax rotation was used to assess the internal structure of the translated the Chinese version of DTBQ. The sample adequacy for the factorability was assessed by the Kaiser-Meyer-Olkin (KMO) metric and Bartlett test of sphericity, and sampling was considered adequate when the KMO value was greater than 0.600 and the Bartlett test of sphericity was significant ($P < 0.050$). The factors with eigenvalue $> 1$ were selected and items with loading values greater than or equal to 0.400 were considered for inclusion in a separate factor.

In the sample 2 (n = 165), CFA was conducted in order to verify the EFA result or test measurement model. CFA can facilitate further evaluation regarding the fitness of the model in line with the structure of the factors.

## Content Validity

Content validity index (CVI) was used to evaluate the content validity of the Chinese version of DTBQ. The CVI includes item-level content validity index (I-CVI) and scale-level content validity index (S-CVI). Each expert scored the relevance of each item to the corresponding dimension.

## Test-Retest Reliability

Two weeks after completing the first response, 30 adults who participated in the first test were recruited to evaluate the test-retest reliability. The correlation between the two tests was assessed using Spearman correlation.

# Results
## General Characteristics of the Study Subject

Table Supplementary Table 2 showed the general characteristics of the study population. Of the 329 T2DM patients, this included 198 (60.2%) males, and 131 (39.8%) females. The age of patients ranged from 32 ~ 96 years. The average age of T2DM patients was (62.02 ± 11.78) years. Most patients (72.9%) reported an educational level of junior secondary school or less. Only 8.5% of the respondents monitored their blood glucose regularly.

## Summary of DTBQ Item Scores

Descriptive statistics for the DTBQ item scores are shown in Supplementary Table 3. For the questions on the scale, more than half of the patients with type 2 diabetes reported item scores of 3 ~ 4, indicating a high level of medication burden. Thirteen of the 18 questions had mean item score of more than 3. Two questions with mean score above 4 were as following: "Q2. Use medication at busy time" and "Q10. To worry about the future".

## Construct Validity
### Exploratory Factor Analysis (EFA)

The EFA of the sample 1(n = 164) was first examined. KMO and Bartlett's sphericity test were performed before factor analysis. The results showed that the KMO value of the Chinese version of the DTBQ was 0.775 (> 0.600), and Bartlett's spherical test was significant ($\chi2=2867.674$; $P<0.001$), indicating that exploratory factor analysis

could be performed.[34] The Chinese version of DTBQ was subjected to principal component analysis and maximum variance rotation method to extract four common factors with eigen-value > 1. The cumulative variance contribution was 62.960%. The factor loadings for each entry ranged from 0.248 to 0.740, with no double loadings, as shown in Table 1. So, Q6 (To feel guilty when I miss a dose), Q8 (Concern about hypoglycemia), and Q10 (To worry about the future) were removed from the original scale because of their commonalities < 0.4. Although Q13 (To allow me to take a missed dose) had a commonality of 0.370, slightly lower than 0.4, its score had a significant positive correlation with the total score. At the same time, Q13 was almost essential as it was seldom asked by the investigators of people with type 2 diabetes. It was finally retained and further tested based on expert advice and feedback from the Chinese people with T2DM. Ultimately, 15 questions were included in the Chinese version of the DTBQ; factor one was 'Implementation burden' and included seven questions (Q1, Q2, Q3, Q4, Q5, Q7, and Q9); factor two included three questions (Q11, Q12, and Q13) identified as 'Flexibility burden'; and factor three included five questions (Q14, Q15, Q16, Q17, and Q18) identified as "blood glucose control burden", as shown in Table 2.

The KMO test for the Chinese version of the 15-item DTBQ was 0.765, with a significant Bartlett's sphericity test ($\chi2=2482.635$; $P<0.001$). The result was that each item had a loading value above 0.40 (except reserved Q13) on one of the common factors, and there was no double loading. These three factors explained 68.780% of the variance, respectively, and 26.802%, 22.013%, and 19.965%. This indicates that the revised scale outperforms the variance of the original scale.

## Confirmatory Factor Analysis(CFA)

The confirmatory factor analysis results in the 18-item DTBQ are shown in Figure 1, Table 3. In the original model fitness index, CMIN/DF = 7.066, IFI = 0.778, CFI = 0.776, TLI = 0.734, and PNFI = 0.631. The confirmatory factor analysis results in the 15-item DTBQ are shown in Figure 2. In the final model fitness index (original model fitness index), CMIN/DF = 3.575 (<5), IFI = 0.917 (>0.900), CFI = 0.916 (>0.900), TLI = 0.900 (>0.900), and PNFI = 0.711 (>0.500), all indicators meet the standard values.[35]

**Table 1** Factor Load and Communalities of Each Item in DTBQ of 18 Items (n=329)

| Item | F1 | F2 | F3 | Commonalities |
|------|------|------|------|------|
| Q9 | **0.750** | −0.141 | −0.089 | 0.590 |
| Q2 | **0.731** | 0.115 | 0.397 | 0.705 |
| Q5 | **0.720** | 0.242 | 0.016 | 0.577 |
| Q7 | **0.691** | −0.054 | −0.130 | 0.497 |
| Q1 | **0.680** | 0.106 | 0.367 | 0.608 |
| Q4 | **0.676** | 0.252 | 0.107 | 0.533 |
| Q3 | **0.637** | 0.173 | 0.411 | 0.605 |
| Q6 | **0.599** | 0.094 | −0.141 | 0.388 |
| Q10 | **0.557** | −0.128 | −0.177 | 0.358 |
| Q8 | **0.493** | 0.068 | 0.011 | 0.248 |
| Q17 | 0.029 | 0.032 | **0.853** | 0.729 |
| Q16 | −0.018 | 0.073 | **0.840** | 0.711 |
| Q15 | −0.087 | 0.081 | **0.804** | 0.661 |
| Q14 | 0.027 | 0.126 | **0.752** | 0.582 |
| Q18 | 0.032 | −0.064 | **0.735** | 0.545 |
| Q12 | 0.156 | **0.846** | 0.016 | 0.740 |
| Q11 | 0.188 | **0.814** | 0.034 | 0.700 |
| Q13 | −0.055 | **0.597** | 0.104 | 0.370 |

**Notes**: Statistically significant values are shown in bold.

**Table 2** Factor Load and Communalities of Each Item in DTBQ of 15 Items (n=329)

| Item | F1 | F2 | F3 | Commonalities |
|------|------|------|------|------|
| Q2 | **0.797** | 0.062 | 0.348 | 0.759 |
| Q1 | **0.733** | 0.054 | 0.325 | 0.645 |
| Q5 | **0.723** | 0.240 | −0.018 | 0.580 |
| Q9 | **0.712** | −0.107 | −0.120 | 0.533 |
| Q3 | **0.699** | 0.115 | 0.369 | 0.637 |
| Q4 | **0.689** | 0.236 | 0.072 | 0.536 |
| Q7 | **0.676** | −0.035 | −0.165 | 0.485 |
| Q17 | 0.074 | 0.014 | **0.850** | 0.727 |
| Q16 | 0.02 | 0.072 | **0.843** | 0.717 |
| Q15 | −0.075 | 0.108 | **0.817** | 0.684 |
| Q14 | 0.038 | 0.154 | **0.758** | 0.600 |
| Q18 | 0.057 | −0.057 | **0.735** | 0.547 |
| Q12 | 0.143 | **0.859** | 0.024 | 0.760 |
| Q11 | 0.178 | **0.838** | 0.041 | 0.735 |
| Q13 | −0.003 | **0.566** | 0.101 | 0.330 |

**Notes**: Statistically significant values are shown in bold.

## Content Validity

The content validity of the Chinese version of the 15-item DTBQ was evaluated by expert evaluation. The content validity analysis result shows that the I-CVI of the Chinese version of the 15-item DTBQ is 0.900~1.000, and the S-CVI is 0.920, which has good content validity.
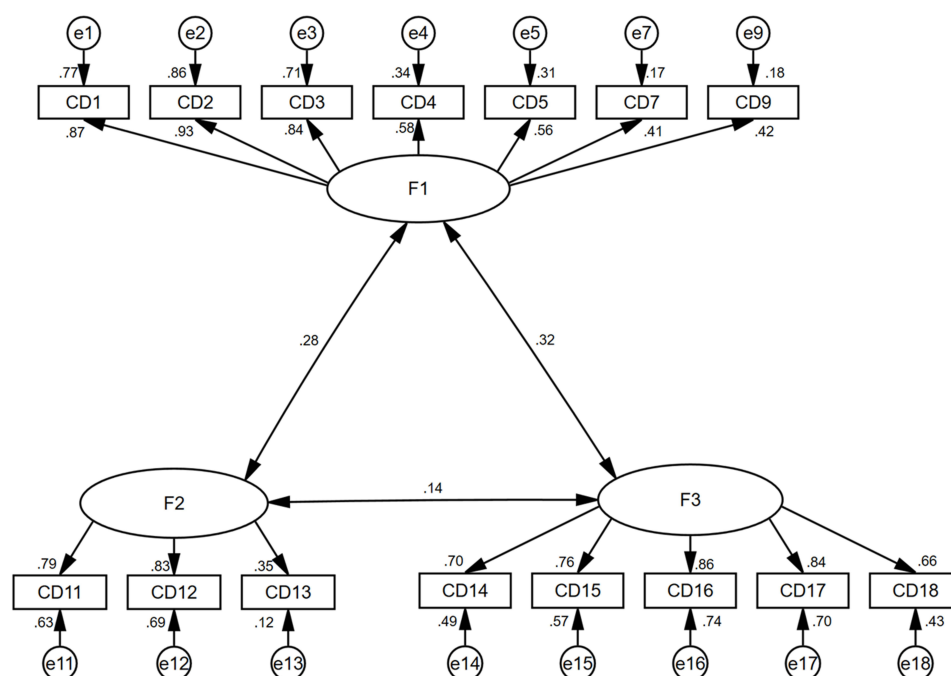


**Figure 1** Standardized three-factors structural model of the Chinese version of the 18-item DTBQ (n=329); F1(Implementation burden, 7 items), F2(Flexibility burden, 3 items), and F3(BG control burden, 5 items).

**Table 3** Evaluation Fitness of DTBQ Model

| Model | CMIN/DF | NFI | RFI | IFI | TLI | CFI | PNFI | PCFI |
|---|---|---|---|---|---|---|---|---|
| Initial model | 7.066 | 0.750 | 0.703 | 0.778 | 0.734 | 0.776 | 0.631 | 0.653 |
| Modified model | 3.575 | 0.888 | 0.860 | 0.917 | 0.900 | 0.916 | 0.711 | 0.733 |
| Standard value | <5.000 | >0.900 | >0.900 | >0.900 | >0.900 | >0.900 | >0.500 | >0.500 |

**Abbreviations**: CMIN/DF, Chi-Square Degree of Freedom; NFI, Normed Fit Index; RFI, Relative Fit Index; IFI, Incremental Fit Index; TLI, Tucker Lewis Index; CFI, Comparative Fit Index; PNFI, Parsimonious Normed-of-Fit Index; PCFI, Parsimonious Comparative-of-Fit Index.

## Test-Retest Reliability

Two weeks later, a random sample of 30 adults who participated in the first survey completed the questionnaire again and the Spearman correlation coefficient was 0.920, which was greater than 0.700, and the Chinese version of the DTBQ had good test-retest reliability.

## Discriminant Validity

The critical ratio method was used to demonstrate that the questionnaire items were well discriminated. The Chinese version of the DTBQ scores of the 329 survey respondents were ranked in order of high and low, and those with scores in the top 27% were grouped into high score group and those with scores in the bottom 27% were grouped into low score group. Independent samples $t$-test showed that was a significant difference between the items in the two groups ($P < 0.001$) and the critical ratio (CR) of each item ranged from 1.279 to 96.178. The specific statistical results are shown in Table 4.
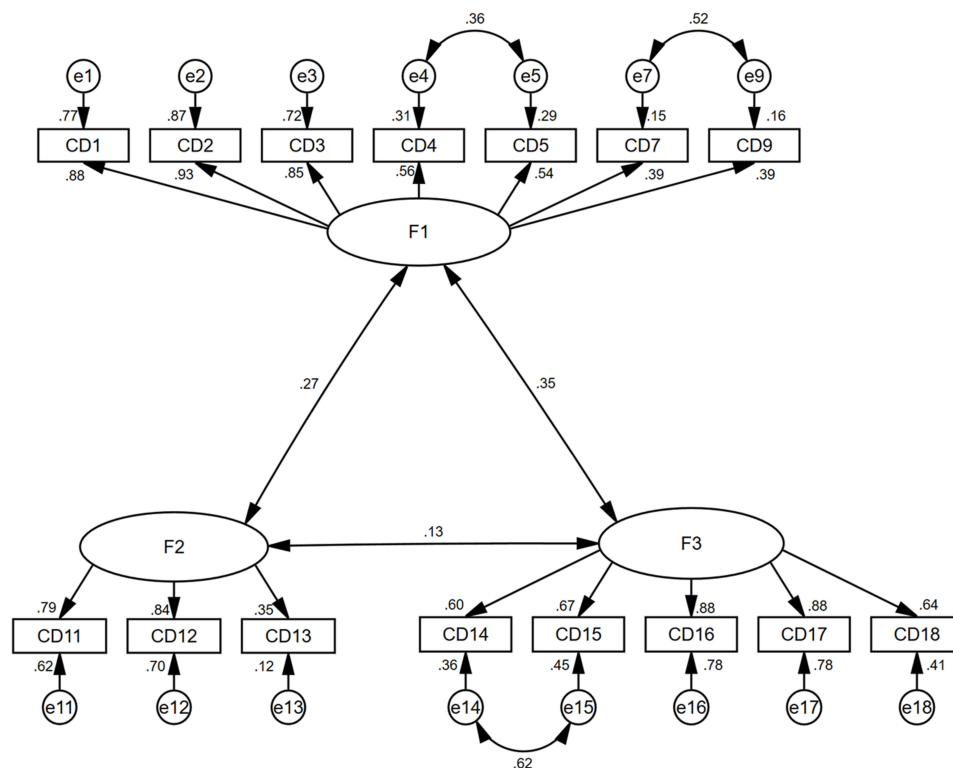


**Figure 2** Standardized three-factors structural model of the Chinese version of the 15-item DTBQ (n=329); F1(Implementation burden, 7 items), F2(Flexibility burden, 3 items), and F3(BG control burden, 5 items).

**Table 4** Discriminant Validity Analysis of the Chinese version of the 15-item DTBQ (n = 329)

| Item | Low-Score Group | High-Score Group | CR(t) | P |
|------|-----------------|------------------|-------|---|
|      | Mean ± SD       | Mean ± SD        |       |   |
| Q1   | 2.06±0.96       | 5.16±0.37        | 29.597 | <0.001 |
| Q2   | 2.58±1.30       | 5.51±0.50        | 57.265 | <0.001 |
| Q3   | 2.10±1.05       | 5.13±0.40        | 49.116 | <0.001 |
| Q4   | 1.55±1.10       | 4.57±0.64        | 38.893 | <0.001 |
| Q5   | 2.24±1.01       | 5.09±0.36        | 71.698 | <0.001 |
| Q7   | 2.43±0.99       | 5.09±0.29        | 84.555 | <0.001 |
| Q9   | 1.89±0.99       | 4.46±0.57        | 9.734  | <0.001 |
| Q11  | 1.75±0.83       | 4.34±0.62        | 2.935  | <0.001 |
| Q12  | 1.64±0.64       | 4.02±0.74        | 1.279  | <0.001 |
| Q13  | 1.62±0.67       | 4.28±0.58        | 3.662  | <0.001 |
| Q14  | 1.81±0.50       | 4.21±0.85        | 16.225 | <0.001 |
| Q15  | 1.83±0.46       | 4.34±0.81        | 29.970 | <0.001 |
| Q16  | 1.82±0.56       | 4.34±0.80        | 20.038 | <0.001 |
| Q17  | 1.81±0.52       | 4.64±0.83        | 55.421 | <0.001 |
| Q18  | 1.76±0.54       | 4.90±0.94        | 96.178 | <0.001 |

**Note**: *P*: significance coefficient.
**Abbreviations**: SD: Standard Deviation; *CR*: Critical Ratio.

## Correlation Between Items and Total Score

The correlation coefficient method was used to examine the representativeness of each item, and entries with correlation coefficients <0.400 were considered for deletion. The correlation coefficients between scores on each of the 18-items scale and the total score ranged from 0.238 to 0.768 ($P < 0.001$), indicating that the items were well represented. As shown in Table 5, after removing items with correlation coefficients < 0.4 (Q6, Q8, and Q10, retaining Q13). The

**Table 5** Item-Total Score Pearson Correlation Analysis Results in the Chinese version of the 18-item DTBQ (n=329)

| Item | Questions Abbreviated | r | P |
|------|-----------------------|---|---|
| Q1  | Medication on time | 0.700 | <0.001 |
| Q2  | Medication during busy hours | 0.768 | <0.001 |
| Q3  | Time ensure for medication | 0.715 | <0.001 |
| Q4  | Pain associated with medication | 0.652 | <0.001 |
| Q5  | To feel that I should not miss a dose | 0.637 | <0.001 |
| Q6  | To feel guilty when I miss a dose | 0.350 | <0.001 |
| Q7  | Medication away from home | 0.470 | <0.001 |
| Q8  | Concern about hypoglycemia | 0.343 | <0.001 |
| Q9  | Not to flexibly adjust the time for medication | 0.529 | <0.001 |
| Q10 | To worry about future | 0.367 | <0.001 |
| Q11 | Short time and small effort for medication | 0.442 | <0.001 |
| Q12 | Medication without time pressure | 0.414 | <0.001 |
| Q13 | To allow me to take a missed dose | 0.238 | <0.001 |
| Q14 | To feel that my diabetes is getting better | 0.484 | <0.001 |
| Q15 | To allow me to control BG with small effort | 0.405 | <0.001 |
| Q16 | To feel less burden to follow diet therapy | 0.458 | <0.001 |
| Q17 | To feel less burden to continue diabetes treatment | 0.477 | <0.001 |
| Q18 | Satisfied with my current BG control | 0.424 | <0.001 |

**Notes**: *r*: correlation coefficient; *P*: significance coefficient.

**Table 6** Item-Total Score Pearson Correlation Analysis Results in the Chinese version of the 15-item DTBQ (*n*=329)

| Item | Questions Abbreviated | r | P |
|------|----------------------|------|--------|
| Q1 | Medication on time | 0.703 | <0.001 |
| Q2 | Medication during busy hours | 0.782 | <0.001 |
| Q3 | Time ensure for medication | 0.729 | <0.001 |
| Q4 | Pain associated with medication | 0.633 | <0.001 |
| Q5 | To feel that I should not miss a dose | 0.606 | <0.001 |
| Q7 | Medication away from home | 0.427 | <0.001 |
| Q9 | Not to flexibly adjust the time for medication | 0.465 | <0.001 |
| Q11 | Short time and small effort for medication | 0.448 | <0.001 |
| Q12 | Medication without time pressure | 0.416 | <0.001 |
| Q13 | To allow me to take a missed dose | 0.293 | <0.001 |
| Q14 | To feel that my diabetes is getting better | 0.526 | <0.001 |
| Q15 | To allow me to control BG with small effort | 0.453 | <0.001 |
| Q16 | To feel less burden to follow diet therapy | 0.516 | <0.001 |
| Q17 | To feel less burden to continue diabetes treatment | 0.533 | <0.001 |
| Q18 | Satisfied with my current BG control | 0.466 | <0.001 |

**Notes**: *r*: correlation coefficient; *P*: significance coefficient.

correlation coefficients between scores on each of the 15-items scale and the total score ranged from 0.293 to 0.729 (*P*<0.001), indicating that the entries were highly representative, as shown in Table 6.

## Reliability Analysis

As shown in Table 7, the Cronbach's alpha coefficient of the Chinese version of the 15-item DTBQ was 0.831, which was lower than the value of the original scale (0.885) but slightly higher than the value of the Chinese version of 18-item DTBQ (0.829). In the Chinese version of the 15-item DTBQ, Cronbach's alpha coefficient of BG control burden was 0.873, higher than the original version (0.862). However, Cronbach's alpha coefficient of implementation burden (0.863) and flexibility burden (0.665) was lower than the original version. In the Chinese version of the 18-item DTBQ, the implementation burden dimension (0.855) has a lower Cronbach's alpha coefficient than the Chinese version of 15-item DTBQ (0.863), and the other two dimensions have the same value.

**Table 7** Comparison of Cronbach's Alpha of DTBQ

| | Factors | Cronbach's Alpha |
|---|---------|------------------|
| Original 18-item scale | Implementation burden | 0.887 |
| | Flexibility burden | 0.775 |
| | BG control burden | 0.862 |
| | Overall | 0.885 |
| Chinese 18-item scale | Implementation burden | 0.855 |
| | Flexibility burden | 0.665 |
| | BG control burden | 0.873 |
| | Overall | 0.829 |
| Chinese 15-item scale | Implementation burden | 0.863 |
| | Flexibility burden | 0.665 |
| | BG control burden | 0.873 |
| | Overall | 0.831 |

## Discussion

In this study, the content validity and structural validity of the scale were evaluated. Content validity refers to the extent to which each item of the scale reflects the content being measured. The I-CVI of the Chinese version of the 15-item DTBQ was ≥0.780, and the S-CVI was ≥0.900, indicating that the content validity of the scale is good and can better quantify the current situation of drug treatment burden in patients with T2DM in China. Construct validity can be used to propose framework ideas and is suitable for testing the extent to which the assessment tool is consistent with the theoretical framework. The Chinese version of the 15-item DTBQ was subjected to exploratory factor analysis to extract three common factors, which together explained 68.780% of the variance (>50%), and the factor loadings of each item met the retention criteria. The Chinese version of the 15-item DTBQ differs slightly from the original scale, and it removed three items (Q6, Q8, and Q10) from the "implementation burden score" dimension of the original scale. It may be related to the differences between cultures and the characteristics of the treatment modalities. In addition, the results of CFA showed that all fit indices met the standards, indicating that the Chinese version of the 15-item DTBQ has a reasonable and clear factor structure and is a suitable structure for Chinese patients with T2DM.

The recommended value for Cronbach's alpha coefficient is no less than 0.600. In the Chinese version of the 15-item DTBQ, the overall Cronbach's alpha coefficient was 0.831, which was a little lower than the original scale value, indicating acceptable homogeneity. In the dimension of BG control burden, Cronbach's alpha coefficient was 0.873, which was a little higher than the original version. However, on the other two dimensions, implementation burden (0.863) and flexibility burden (0.665), Cronbach's alpha coefficient was a little lower than the original version, possibly due to different cultural differences and economic conditions. However, it still indicated good internal correlation, and homogeneity between the entries of the scale. The overall scale split-half reliability was 0.836, and the dimensions fold-half reliability 0.728~0.842, further indicating that the scale has good internal consistency, and suggesting that the scale has good stability. The Chinese version of the 15-item DTBQ has good reliability.

Many domestic research on the burden of treatment for diabetic patients has focused on financial, family, and psychological aspects.[36,37] Excessive attention unpleasant emotional experiences or difficulties in follow-up treatment due to various reasons while neglecting the burden of the patient's inability to tolerate their current medication in the context of the need for long-term or lifelong medication. Meanwhile, during the survey, we found that only 8.5% of respondents regularly monitored their blood sugar, which was much lower than that in Western countries, indicating that Chinese T2DM patients should pay more attention to this aspect.[38] Therefore, the Chinese version of the DTBQ was introduced in this study, and it was completed strictly with the BRISILIN translation model. The Chinese version of the DTBQ was revised according to the comments of the original authors and experts, the subjects' feedback, and the research team's discussion, considering Chinese linguistic and cultural environment to ensure scientific and cultural sensitivity. The Chinese version of the 15-item DTBQ was developed. The scale has been validated among the T2DM patients in China. It has good reliability and validity, indicating that the scale can provide a scientific and objective way to measure medication burden for the T2DM patients in China.

Medication is currently the primary tool that enables diabetic patients to control their blood glucose levels, and accurately measuring and improving patients' medication burden is one of the essential factors in ensuring that patients receive the best possible form of medication.[39,40] The items of the Chinese version of the 15-item DTBQ in this study are a high-level overview of the burden of medication in patients with T2DM. The time required to complete the test is 3–5 mins, and the recall rate is 98.5%, which has good operability and feasibility. At the same time, the scale has good reliability and validity and can be used in endocrine clinics and healthcare facilities. The clinical application of the Chinese version of the 15-item DTBQ not only provides a scientific, objective, and a quantitative way for healthcare professionals to assess the drug treatment burden of T2DM patients but also allows healthcare professionals to provide targeted and reasonable intervention plans for patients based on the reporting of the scale, which has a particular promotion effect on reducing the drug treatment burden of T2DM patients in China.

## Strength and Limitations

Standard translation by a committee of experts, including patients with T2DM, through a rigorous adaptation process, produced the 15-item DTBQ with good cross-cultural validity. Construction and discriminant validation was done with multiple validated and well-known results. But there are limitations in this study, as the sample data were only collected from one region in Anhui Province, and the sample was not widely representative, which may affect the study results. It is necessary to expand the sample size and enrich the sample sources to examine further the applicability of the Chinese version of the 15-item DTBQ in T2DM patients in China.

## Conclusion

The Chinese version of the DTBQ consists of three factors and fifteen items, with good reliability and validity. It is suitable for investigating the current medication burden and influencing factors of Chinese T2DM patients and provides a basis for developing and implementing personalized medication burden intervention plans.

## Abbreviations

IDF, International Diabetes Federation; OHAs, Oral Hypoglycemic Agents; T2DM, Type 2 Diabetes Mellitus; HbA1c, Glycated Hemoglobin/Hemoglobin A1c; DTBQ, Diabetes Treatment Burden Questionnaire; CMIN/DF, Chi-Square Degree of Freedom; NFI, Normed Fit Index; RFI, Relative Fit Index; IFI, Incremental Fit Index; CFI, Comparative Fit Index; TLI, Tucker Lewis Index; PNFI, Parsimonious Normed-of-Fit Index; PCFI, Parsimonious Comparative-of-Fit Index; CR, Critical Ratio; BG, Blood Glucose; I-CVI, Item-level Content Validity Index; S-CVI, scale-level Content Validity Index; KMO, Kaiser-Meyer-Olkin.

## Data Sharing Statement

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

## Ethics Approval and Consent to Participate

Approval for this study was given by the medical ethics committee of Wannan Medical College (approval number 2021–3) and written informed consent was obtained from the participants. All methods were performed following the Declarations of Helsinki.

## Acknowledgments

We thank all participants for their contributions and study members for their cooperation.

## Author Contributions

Conceived and designed the research: L Z. Wrote the paper: Y-j M. Analyzed the data: Y-j M and L Z. Revised the paper: Y-j M, L Z. All authors contributed to data analysis, drafting or revising the article, have agreed on the journal to which the article will be submitted, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

## Funding

## Disclosure

The authors declare that they have no competing interests.

# References

1. Hu S, Wang S, Qi C, et al. Cost-utility analysis of once-weekly semaglutide, dulaglutide, and exenatide for type 2 diabetes patients receiving metformin-based background therapy in China. *Front Pharmacol*. 2022;13:831364. doi:10.3389/fphar.2022.831364

2. Saeedi P, Petersohn I, Salpea P, et al. IDF Diabetes Atlas Committee. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: results from the international diabetes federation diabetes atlas. *Diabetes Res Clin Pract*. 2019;157:107843. doi:10.1016/j.diabres.2019.107843

3. Sinclair A, Saeedi P, Kaundal A, Karuranga S, Malanda B, Williams R. Diabetes and global ageing among 65-99-year-old adults: findings from the international diabetes federation diabetes atlas. *Diabetes Res Clin Pract*. 2020;162:108078. doi:10.1016/j.diabres.2020.108078

4. Zhou M, Wang H, Zhu J, et al. Cause-specific mortality for 240 causes in China during 1990-2013: a systematic subnational analysis for the global burden of disease study 2013. *Lancet*. 2016;387(10015):251–272. doi:10.1016/S0140-6736(15)00551-6

5. Chen L, Magliano DJ, Zimmet PZ. The worldwide epidemiology of type 2 diabetes mellitus--present and future perspectives. *Nat Rev Endocrinol*. 2011;(4):228–236. doi:10.1038/nrendo.2011.183

6. American Diabetes Association. Classification and diagnosis of diabetes: standards of medical care in diabetes-2020. *Diabetes Care*. 2020;43(Suppl1):S14–S31. doi:10.2337/dc20-S002

7. Ganasegeran K, Hor CP, Jamil MFA, et al. A systematic review of the economic burden of type 2 diabetes in Malaysia. *Int J Environ Res Public Health*. 2020;17(16):5723. doi:10.3390/ijerph17165723

8. Thrasher J. Pharmacologic management of type 2 diabetes mellitus: available therapies. *Am J Cardiol*. 2017;120(1S):S4–S16. doi:10.1016/j.amjcard.2017.05.009

9. Migdal AL, Fortin-Leung C, Pasquel F, Wang H, Peng L, Umpierrez GE. Inpatient glycemic control with sliding scale insulin in noncritical patients with type 2 diabetes: who can slide? *J Hosp Med*. 2021;16(8):462–468. doi:10.12788/jhm.3654

10. Ali MK, Bullard KM, Saaddine JB, Cowie CC, Imperatore G, Gregg EW. Achievement of goals in U.S. diabetes care, 1999–2010. *N Engl J Med*. 2013;368(17):1613–1624. doi:10.1056/NEJMsa1213829

11. Bailey CJ, Kodack M. Patient adherence to medication requirements for therapy of type 2 diabetes. *Int J Clin Pract*. 2011;65(3):314–322. doi:10.1111/j.1742-1241.2010.02544.x

12. García-Pérez LE, Alvarez M, Dilla T, Gil-Guillén V, Orozco-Beltrán D. Adherence to therapies in patients with type 2 diabetes. *Diabetes Ther*. 2013;4(2):175–194. doi:10.1007/s13300-013-0034-y

13. Islam SM, Biswas T, Bhuiyan FA, Mustafa K, Islam A. Patients' perspective of disease and medication adherence for type 2 diabetes in an urban area in Bangladesh: a qualitative study. *BMC Res Notes*. 2017;10(1):131. doi:10.1186/s13104-017-2454-7

14. Ayele AA, Tegegn HG, Ayele TA, Ayalew MB. Medication regimen complexity and its impact on medication adherence and glycemic control among patients with type 2 diabetes mellitus in an Ethiopian general hospital. *BMJ Open Diabetes Res Care*. 2019;7(1):e000685. doi:10.1136/bmjdrc-2019-000685

15. Peron EP, Ogbonna KC, Donohoe KL. Antidiabetic medications and polypharmacy. *Clin Geriatr Med*. 2015;31(1):17–27, vii. doi:10.1016/j.cger.2014.08.017

16. Böhm AK, Schneider U, Aberle J, Stargardt T. Regimen simplification and medication adherence: fixed-dose versus loose-dose combination therapy for type 2 diabetes. *PLoS One*. 2021;16(5):e0250993. doi:10.1371/journal.pone.0250993

17. Jannuzzi FF, Cornélio ME, São-João TM, Gallani MC, Godin G, Rodrigues RCM. Psychosocial determinants of adherence to oral antidiabetic medication among people with type 2 diabetes. *J Clin Nurs*. 2020;29(5–6):909–921. doi:10.1111/jocn.15149

18. Blonde L, San Juan ZT, Bolton P. Fixed-dose combination therapy in type 2 diabetes mellitus. *Endocr Pract*. 2014;20(12):1322–1332. doi:10.4158/EP14259.RA

19. Kalra S, Das AK, Priya G, et al. Fixed-dose combination in management of type 2 diabetes mellitus: expert opinion from an international panel. *J Family Med Prim Care*. 2020;9(11):5450–5457. doi:10.4103/jfmpc.jfmpc_843_20

20. Khdour MR, Awadallah HB, Al-Hamed DH. Treatment satisfaction and quality of life among type 2 diabetes patients: a cross-sectional study in west bank, Palestine. *J Diabetes Res*. 2020;2020:1834534. doi:10.1155/2020/1834534

21. Jia W, Weng J, Zhu D, et al. Standards of medical care for type 2 diabetes in China 2019. *Diabetes Metab Res Rev*. 2019;35(6):e3158. doi:10.1002/dmrr.3158

22. Ceriello A, deValk HW, Guerci B, et al. The burden of type 2 diabetes in Europe: current and future aspects of insulin treatment from patient and healthcare spending perspectives. *Diabetes Res Clin Pract*. 2020;161:108053. doi:10.1016/j.diabres.2020.108053

23. Dugani SB, Mielke MM, Vella A. Burden and management of type 2 diabetes in rural United States. *Diabetes Metab Res Rev*. 2021;37(5):e3410. doi:10.1002/dmrr.3410

24. Bellary S, Kyrou I, Brown JE, Bailey CJ. Type 2 diabetes mellitus in older adults: clinical considerations and management. *Nat Rev Endocrinol*. 2021;17(9):534–548. doi:10.1038/s41574-021-00512-2

25. Amiel SA, Aschner P, Childs B, et al. International Hypoglycaemia Study Group. Hypoglycaemia, cardiovascular disease, and mortality in diabetes: epidemiology, pathogenesis, and management. *Lancet Diabetes Endocrinol*. 2019;7(5):385–396. doi:10.1016/S2213-8587(18)30315-2

26. Dennick K, Sturt J, Speight J. What is diabetes distress and how can we measure it? A narrative review and conceptual model. *J Diabetes Complications*. 2017;31(5):898–911. doi:10.1016/j.jdiacomp.2016.12.018

27. Polonsky WH, Anderson BJ, Lohrer PA, et al. Assessment of diabetes-related distress. *Diabetes Care*. 1995;18(6):754–760. doi:10.2337/diacare.18.6.754

28. Polonsky WH, Fisher L, Earles J, et al. Assessing psychosocial distress in diabetes: development of the diabetes distress scale. *Diabetes Care*. 2005;28(3):626–631. doi:10.2337/diacare.28.3.626

29. Katusiime B, Corlett SA, Krska J. Development and validation of a revised instrument to measure burden of long-term medicines use: the living with medicines questionnaire version 3. *Patient Relat Outcome Meas*. 2018;9:155–168. doi:10.2147/PROM.S151143

30. Andreasen CR, Andersen A, Knop FK, Vilsbøll T. Understanding the place for GLP-1RA therapy: translating guidelines for treatment of type 2 diabetes into everyday clinical practice and patient selection. *Diabetes Obes Metab*. 2021;23(Suppl3):40–52. doi:10.1111/dom.14500

31. Kendall JM. Designing a research project: randomised controlled trials and their principles. *Emerg Med J*. 2003;20(2):164–168. doi:10.1136/emj.20.2.164

32. Ishii H, Shin K, Tosaki T, et al. Reproducibility and Validity of a Questionnaire Measuring Treatment Burden on Patients with Type 2 Diabetes: diabetic Treatment Burden Questionnaire (DTBQ). *Diabetes Therapy*. 2018;9(3):1001–1019. doi:10.1007/s13300-018-0414-4

33. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine*. 2000;25 (24):3186–3191. doi:10.1097/00007632-200012150-00014

34. Wu ML. *Questionnaire Statistical Analysis Practices: SPSS Operation and Application*. Chongqing: Chongqing University Press; 2010.

35. Wu ML. *Structural Equation Modeling-AMOS Operation and Application*. Chongqing: Chongqing University Press; 2009.

36. Sun XJ, Zhang GH, Guo CM, et al. Associations between psycho-behavioral risk factors and diabetic retinopathy: NHANES (2005–2018). *Front Public Health*. 2022;10:966714. doi:10.3389/fpubh.2022.966714

37. Chen C, Song J, Xu X, Zhou L, Wang Y, Chen H. Analysis of influencing factors of economic burden and medical service utilization of diabetic patients in China. *PLoS One*. 2020;15(10):e0239844. doi:10.1371/journal.pone.0239844

38. Lecomte P, Romon I, Fosse S, Simon D, Fagot-Campagna A. Self-monitoring of blood glucose in people with type 1 and type 2 diabetes living in France: the Entred study 2001. *Diabetes Metab*. 2008;34(3):219–226. doi:10.1016/j.diabet.2007.11.005

39. Nauck MA, Wefers J, Meier JJ. Treatment of type 2 diabetes: challenges, hopes, and anticipated successes. *Lancet Diabetes Endocrinol*. 2021;9 (8):525–544. doi:10.1016/S2213-8587(21)00113-3

40. Bhat S, Chowta M, Chowta N, Shastry R, Kamath P. The proportion of type 2 diabetic patients achieving treatment goals and the survey of patients' attitude towards insulin in tiation ini patient s with inadequate glycaemic control with oral anti-diabetic drugs. *Curr Diabetes Rev*. 2021;17(5): e110620182719. doi:10.2174/1573399816666200611134121