

## ORIGINAL ARTICLE

# Validation and application of the Insulin Treatment Appraisal Scale in Cuban patients with type 2 diabetes mellitus



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## Abstract

**Introduction:** The purpose of this study was to validate the Insulin Treatment Appraisal Scale (ITAS) in the Cuban population with type 2 diabetes mellitus.

**Material and methods:** A cross-sectional, multicentre analytical study was performed in Cuba from February 2020 to April 2021; 199 patients were surveyed in a hospital institution and in primary healthcare. We used the Insulin Treatment Appraisal Scale, consisting of 20 items, with a minimum score of 20 points and a maximum of 100, where the higher the score, the worse the perception of insulin therapy. The validity of the instrument was determined by means of an exploratory factor analysis. The internal consistency and reliability of the scale were calculated by means of Cronbach's alpha coefficient. A K-means cluster analysis was performed to establish a cut-off point for poor perception of insulin therapy.

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**Results:** The exploratory factor analysis supported the validity of the instrument, with a Cronbach's alpha of 0.747. There were statistically significant differences between patients under insulin and non-insulin treatment in terms of the answers given in all items of the scale. The total mean score obtained was  $51.96 \pm 10.78$ , and it was lower in insulin users compared to those who used other drugs ( $49.79 \pm 10.07$  vs  $55.09 \pm 11.12$ ). A score  $\geq 65$  was proposed as a cut-off point for poor perception of insulin therapy. A positive relationship was found between the body mass index values and the total score of the scale. Being female and current treatment not involving insulin were factors associated with low perception of insulin therapy.

**Conclusions:** The instrument proved to be valid for the population in which it was applied. Insulin users turned out to be the ones with the best perception about its use. A cut-off point of  $\geq 65$  points for poor perception of insulin treatment was proposed for evaluation and comparison in future studies in other patient populations.

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## PALABRAS CLAVE

Diabetes mellitus;  
Diabetes mellitus tipo 2;  
Insulina;  
Análisis psicométrico;  
Resistencia psicológica a la insulina

## Validación y aplicación de la escala de percepción del tratamiento con insulina en pacientes cubanos con diabetes mellitus tipo 2

### Resumen

**Introducción:** El propósito de este estudio fue validar la escala de percepción del tratamiento con insulina en población cubana con diabetes mellitus tipo 2.

**Material y métodos:** Se realizó un estudio analítico transversal, multicéntrico, en Cuba, entre febrero de 2020 y abril de 2021. Se encuestaron 199 pacientes en una institución hospitalaria y en atención primaria de salud. A los participantes se les aplicó la Escala de Percepción del Tratamiento con Insulina, conformada por 20 ítems, con una calificación mínima de 20 puntos y máxima de 100, donde a mayor puntaje peor percepción de la terapia con insulina. Se determinó la validez del instrumento mediante un análisis factorial exploratorio. La consistencia interna y fiabilidad de la escala fue calculada con el coeficiente Alfa de Cronbach. Se realizó un análisis de conglomerados de K-medias para establecer un punto de corte de mala percepción de la terapia con insulina.

**Resultados:** El análisis factorial apoyó la validez del instrumento, con un alfa de Cronbach de 0,747. Existieron diferencias estadísticamente significativas entre los pacientes bajo tratamiento insulínico y no insulínico en cuanto a las respuestas otorgadas en todos los ítems de la escala. La media total de puntuación obtenida fue de  $51,96 \pm 10,78$ , y resultó menor en los usuarios de insulina comparado con los que usaban otros fármacos ( $49,79 \pm 10,07$  vs.  $55,09 \pm 11,12$ ). Se determinó la puntuación  $\geq 65$  como punto de corte para mala percepción de la terapia con insulina. Se encontró una relación positiva entre los valores de índice de masa corporal y la puntuación total de la escala. El sexo femenino y el tratamiento actual no insulínico fueron factores asociados a la baja percepción del tratamiento con insulina.

**Conclusiones:** El instrumento demostró ser válido para la población donde fue aplicado. Los usuarios de insulina resultaron ser los que mejor percepción tenían sobre el uso de la misma. Se propuso el punto de corte  $\geq 65$  puntos para mala percepción del tratamiento con insulina para su valoración y comparación en futuros estudios en otras poblaciones de pacientes.

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## Introduction

Diabetes mellitus (DM) is a major public health problem with a high prevalence and financial burden. Type 2 diabetes mellitus (DM2) is the most common, accounting for approximately 90% of all cases, and it is associated with modifiable risk factors such as obesity and overweight, physical inactivity and high-calorie but low nutritional-value diets. Approximately 463 million people between the ages of

20 and 79 had DM in 2019, yielding a worldwide prevalence of 9.3%.<sup>1</sup> In Central and South America, the International Diabetes Federation (IDF) region that includes Cuba, there are 54.8 million people with DM (prevalence of 12.8%) and the number of deaths from this cause is estimated at 243,200.<sup>1</sup>

In Cuba, it is estimated that approximately 1,134,000 people between the ages of 20 and 79 live with DM, of whom 445,000 have not been diagnosed,<sup>1</sup> making a prevalence of 66.7 patients per 1,000 population.<sup>2</sup>

Diabetic Care Centres were created in Cuba in 1972, and the National Diabetes Mellitus Programme was implemented in 1975 when comprehensive care consultations for patients with diabetes were created in primary healthcare.<sup>3</sup> Nevertheless, using different measurement indicators, deficiencies have been identified in the quality of care received by these patients here in Cuba.<sup>4</sup>

The low level of knowledge of the use of insulins among primary care professionals and its direct relationship with blood glucose control in patients with diabetes has been reported previously.<sup>5–8</sup> Considering that treatment with insulin is necessary in 20% of patients with DM2,<sup>5</sup> the healthcare professionals involved in the integrated care of these patients should be trained in this regard and be conversant with insulin therapy regimens and how they are perceived by the users. However, these aspects are not always accomplished, and neither are all the tools required to achieve them available, and multiple barriers and negative attitudes towards insulin therapy are reported both by patients with DM2 and the healthcare professionals involved in their care.<sup>9,10</sup> This, in turn, affects therapy adherence, which has been reported as low by several authors.<sup>11,12</sup>

The Insulin Treatment Appraisal Scale (ITAS)<sup>13</sup> was published in 2007. This scale enables us to identify the positive and negative perceptions of insulin in patients with DM2 and act accordingly. With a Cronbach's alpha of 0.89 (0.90 for the negative subscale and 0.68 for the positive subscale) for its 20 items, the ITAS has been used and adapted by other authors in different settings.<sup>14–16</sup>

Therapeutic education including all the basic aspects the patient needs to know about DM should be provided in the early days after diagnosis of the disease. This education should be afforded continuity over time, with new elements provided at each consultation, including information about insulin therapy.

To date, there is no validated instrument available in Cuba for assessing patient perception of the use of insulin in the control of DM. As far as we were able to determine, the ITAS has not been validated for use in the DM2 patient population in Latin America and the Caribbean.

Most patients with diabetes in Cuba do not have access to "first-world" insulin delivery devices, which are relatively convenient and improve treatment adherence considerably. This all means that it is important to ascertain DM2 patients' perception of insulin therapy, how it affects their lifestyle and what thoughts of fear or rejection it may produce in them with regard to insulin injections. As a large proportion of people living with diabetes will require insulin treatment at some point in their lives, this research was carried out with a view to validating the ITAS in the Cuban DM2 population.

## Material and methods

### Type of study, place and period

A cross-sectional, multicentre, analytical study was carried out in five provinces in Cuba (Pinar del Río, Havana, Villa Clara, Ciego de Ávila and Santiago de Cuba), representing the country's three geographical regions. The study was carried out between February 2020 and April 2021, although it

was interrupted between April and September 2020 due to the emergency situation caused by COVID-19.

### Population and sample

We surveyed 199 patients who attended an Endocrinology outpatient clinic, at a hospital and in primary healthcare. The inclusion criteria were: 1) having DM2 according to the World Health Organization criteria; 2) being  $\geq 18$  years of age; 3) being treated in one of the health areas of the provinces where the study was carried out and where their medical records were located; and 4) being willing to participate in the research and answer the questionnaire after signing the informed consent form. Patients with severe mental illness or cognitive deficit (dementia, psychosis or mental retardation) or any other condition that compromised their ability to understand and complete the questionnaire were not included.

### Instrument and measurements

The population was characterised according to sociodemographic variables (gender, skin colour, education, whether they lived alone or with other relatives at home), disease-related variables (time since onset and family history of DM, initial and current treatment, if any change of treatment, comorbidities, complications of DM and therapeutic education on diabetes) and clinical variables (fasting blood glucose, weight, height and body mass index).

The ITAS<sup>7</sup> was applied to the patients. This instrument is comprised of 16 negative-perception and 4 positive-perception items.

The response options for each of the items are presented on Likert-type scales with the following values: negative opinions (1, 2, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, 15, 16, 18, 20), where 1 = strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, 5 = strongly agree; and positive opinions (3, 8, 17, 19), where 5 = strongly disagree, 4 = disagree, 3 = neither agree nor disagree, 2 = agree, 1 = strongly agree. The survey is scored from 20 to 100 points, and the higher the score the more negative the opinion.

### Statistical analysis

Pearson's Chi-square, Student's t and Mann-Whitney U tests were used, as appropriate, to detect any statistical differences between patients on insulin or non-insulin treatment for all the variables analysed. The instrument's validity was determined by means of an exploratory factor analysis. The Kaiser-Meyer-Olkin measure of sampling adequacy and Bartlett's test of sphericity were used to identify whether the items clustered a latent factor. The internal consistency and reliability of the scale were calculated using Cronbach's alpha coefficient. A K-means cluster analysis was performed and the total ITAS score was taken as the dependent variable to establish the centre of the cluster with the highest negative-perception values determined by the scale as the cut-off point. The distributions of the quantitative variables and the total score obtained in the questionnaire were compared using the one-way ANOVA test, which made it possible

to analyse their variance values according to the cluster they belonged to. Lastly, we determined the relationship between variables of clinical interest and the perception of insulin therapy according to the established cut-off point, through which we identified the variables related to a poorer perception of insulin therapy in the sample studied. For this analysis, Pearson's Chi-square and Student's t tests for independent samples were used (after checking for normality of distribution according to the Kolmogorov-Smirnov test). The entire study was carried out with a 95% confidence interval.

### Ethical considerations

The research was carried out in accordance with the Declaration of Helsinki. Each one of the participants was provided with information on the objectives, methods, benefits and risks of the research. Informed consent was obtained and anonymity was guaranteed. There was no potential harm to the participants.

## Results

### Participants' sociodemographic and clinical characteristics

199 patients with DM2 from the Cuban provinces of Pinar del Río (20; 10.1%), Havana (90; 45.2%), Villa Clara (21; 10.6%), Ciego de Ávila (13; 7%) and Santiago de Cuba (54; 27.1%) were surveyed. Table 1 shows the sociodemographic and clinical characteristics of the patients who were part of the study sample according to whether they were insulin users or non-insulin users at the time of the study.

The mean age was  $57.50 \pm 18.49$  years and the patients were predominantly female, with a pre-university education, living with another family member and no family history of diabetes. 48.5% of the sample had changed treatment at some point. When they were first diagnosed, most patients were taking oral medications (49%), whereas at the time of responding to the survey the percentage of patients who were using insulin only was higher (44.9%).

Most of the patients had no comorbidities or complications from their diabetes and 81.8% of those surveyed had received therapeutic education about the disease. The mean time since the onset of diabetes was slightly higher in insulin users compared to non-insulin users ( $13.14 \pm 11.04$  vs  $10.23 \pm 9.41$  years). The sample comprised predominantly overweight patients, with a body mass index of  $27.07 \pm 4.91$  kg/m<sup>2</sup>.

### Application of the scale

Table 2 shows that there were statistically significant differences between insulin users and non-insulin users in terms of the responses given in the ITAS in all the items assessed in the scale, determined by means of the Monte Carlo two-sided asymptotic significance test. The total mean score obtained in the questionnaire was  $51.96 \pm 10.78$ , with values ranging from 20 to 76 points. In patients treated with insulin, the scores were significantly lower than those of

patients treated with non-insulin regimens ( $49.79 \pm 10.07$  vs  $55.09 \pm 11.12$ ;  $p < 0.001$ ).

### Internal consistency and reliability of the ITAS

The validity of the measurement instrument was demonstrated by means of an exploratory factor analysis, which made it possible to determine that the sample was adequate for the instrument, as there was an association between the items. This analysis found that all the extracted commonalities were greater than 0.4, with a Kaiser-Meyer-Olkin measure of sampling adequacy greater than 0.5 and a statistical significance of the Bartlett test of sphericity of less than 0.05. These results allow the scale to be legitimately applied and assessed in order to say that it is valid in the sample analysed.

Table 3 shows the reliability analysis by applying Cronbach's alpha coefficient, which enables the internal consistency of the instrument in question to be assessed. The internal consistency of the ITAS proved to be good (Cronbach's alpha = 0.747), which supports the psychometric properties of the scale and demonstrates the high degree of correlation between the items of the instrument. The results of the descriptive reliability analysis for Cronbach's alpha if the element is deleted showed little variation in the results if some of the items are deleted to increase the scale's reliability and is only slightly higher in items 3, 7, 8, 17, 18 and 19, thus confirming the validity and precision of the ITAS instrument.

### Cut-off point for poor perception of insulin therapy

Table 4 shows the clusters obtained from the K-means analysis, through which three homogeneous groups were created, albeit at the same time significantly different from each other ( $p < 0.001$ ) according to the ITAS score. The final cluster centres represent the average values of each cluster, so it is interpreted as the mean score obtained by the subjects belonging to each group.

Cluster 1 was comprised of the 58 individuals with the highest scores on the ITAS scale (29.15%), hence its centre is proposed as a reference to establish the cut-off point  $\geq 65$  for poor perception of taking insulin in DM2 patients in the sample studied.

### Relationship between variables of clinical interest and the ITAS score

Table 5 shows the analysis of variance of the quantitative variables according to the cluster they belong to, from which we found a significant difference in the distribution of the medians of the body mass index and time since the onset of DM variables among the three clusters created according to the ITAS scores. This suggests that there is a relationship between these variables and the perception of taking insulin among diabetic patients.

Table 6 shows the relationship between variables of clinical interest and perception of insulin therapy according to the established cut-off point on the ITAS scale ( $\geq 65$ ), where being female and currently being a non-insulin user were

**Table 1** Clinical and epidemiological characteristics reported by diabetic patients according to insulin treatment.

Variables	Treatment		Total	p
	Insulin users n (%)	Non-insulin users n (%)		
<i>Age (years)<sup>a</sup></i>	55.27 ± 19.77	60.49 ± 16.10	57.50 ± 18.49	0.133
<i>Gender</i>				
Male	50 (42.7)	17 (21)	67 (33.8)	0.001 <sup>b</sup>
Female	67 (57.3)	64 (79)	131 (66.2)	
<i>Skin colour</i>				
White (Caucasian)	67 (57.3)	42 (51.9)	109 (55.1)	0.329
Black	22 (18.8)	12 (14.8)	34 (17.2)	
Mixed race	28 (23.9)	27 (33.3)	55 (27.8)	
<i>Education</i>				
No schooling	2 (1.7)	2 (2.5)	4 (2)	0.295
Primary	14 (12.0)	4 (4.9)	18 (9.1)	
Secondary/High school	17 (14.5)	8 (9.9)	25 (12.6)	
Pre-university	48 (41.0)	34 (42)	82 (41.4)	
University	36 (30.8)	33 (40.7)	69 (34.8)	
<i>Cohabitation</i>				
Lives alone	29 (24.8)	16 (19.8)	45 (22.7)	0.406
Lives with another relative	88 (75.2)	65 (80.2)	153 (77.3)	
<i>Family history of DM</i>				
Yes	44 (37.6)	39 (48.1)	83 (41.9)	0.139
No	73 (62.4)	42 (51.9)	115 (58.1)	
<i>Initial treatment</i>				
Diet and exercise	21 (17.9)	25 (30.9)	46 (23.2)	<0.001 <sup>b</sup>
Oral hypoglycaemic drugs and medications	49 (41.9)	48 (59.3)	97 (49)	
Insulin	42 (35.9)	3 (3.7)	45 (22.7)	
Insulin and oral hypoglycaemic drugs	5 (4.3)	5 (6.2)	10 (5.1)	
<i>Current treatment</i>				
Diet and exercise	0 (0)	16 (19.8)	16 (8.1)	<0.001 <sup>b</sup>
Oral hypoglycaemic drugs and medications	0 (0)	65 (80.2)	65 (32.8)	
Insulin	89 (76.1)	0 (0)	89 (44.9)	
Insulin and oral hypoglycaemic drugs	28 (23.9)	0 (0)	28 (14.1)	
<i>Change of treatment</i>				
Yes	79 (67.5)	17 (21.0)	96 (48.5)	<0.001 <sup>b</sup>
No	38 (32.5)	64 (79.0)	102 (51.5)	
<i>Comorbidities</i>				
Yes	75 (64.1)	66 (81.5)	141 (71.2)	0.008 <sup>b</sup>
No	42 (35.9)	15 (18.5)	57 (28.8)	
<i>Complications</i>				
Yes	67 (57.3)	17 (21)	84 (42.4)	<0.001 <sup>b</sup>
No	50 (42.7)	64 (79)	114 (57.6)	
<i>Type of complications</i>				
None	59 (56.2)	58 (80.6)	117 (66.1)	<0.001 <sup>b</sup>
Nephropathy	5 (4.8)	2 (2.8)	7 (4)	
Retinopathy	9 (8.6)	2 (2.8)	11 (6.2)	
Neuropathy	4 (3.8)	8 (11.1)	12 (6.8)	
Diabetic foot	21 (20)	2 (2.8)	23 (13)	
Retinopathy, neuropathy and diabetic foot	4 (3.8)	0 (0)	4 (2.3)	
Neuropathy and diabetic foot	1 (1)	0 (0)	1 (0.6)	
Nephropathy, neuropathy and diabetic foot	1 (1)	0 (0)	1 (0.6)	
Nephropathy and retinopathy	1 (1)	0 (0)	1 (0.6)	

Table 1 (Continued)

Variables	Treatment		Total	p
	Insulin users n (%)	Non-insulin users n (%)		
<i>Previous education about treatment</i>				
Yes	105 (89.7)	57 (70.4)	162 (81.8)	0.001 <sup>b</sup>
No	12 (10.3)	24 (29.6)	36 (18.2)	
<i>Time since onset of DM (years)<sup>a</sup></i>	15.11 ± 11.70	10.23 ± 9.41	13.14 ± 11.04	0.001 <sup>b</sup>
<i>Fasting blood glucose levels (mmol/l)<sup>a</sup></i>	7.94 ± 3.84	6.79 ± 1.98	7.47 ± 3.25	0.139
<i>Weight (kg)<sup>a</sup></i>	72.37 ± 11.28	75.25 ± 12.89	73.42 ± 11.93	0.136
<i>Height (m)<sup>a</sup></i>	166.90 ± 11.23	163.23 ± 8.20	165.57 ± 10.36	0.028 <sup>b</sup>
<i>BMI (kg/m<sup>2</sup>)<sup>a</sup></i>	26.09 ± 4.21	28.79 ± 5.58	27.07 ± 4.91	0.001 <sup>b</sup>

DM: diabetes mellitus; BMI: body mass index.

<sup>a</sup> Result expressed as mean ± standard deviation.

<sup>b</sup> Statistically significant.

seen to be related to a poorer perception of insulin therapy in the sample studied. These results are based on the fact that there was a high degree of statistical significance according to Pearson's Chi-square test between the clinical variables and the highest scores obtained on the ITAS, and the analysis also included the quantitative variables which had a significantly different distribution among the three clusters created, although they did not present statistical significance as they were related to the cut-off point  $\geq 65$ .

## Discussion

This is the first study to validate a Spanish version of the ITAS and the first one to apply it to the Cuban population or to that of Latin America and the Caribbean.

In our study, when the ITAS was applied, the average score was above 50 and it was lower in insulin users compared to subjects whose treatment regimens did not include insulin. Another study also concluded that the perception of insulin therapy is more negative in subjects who take oral antidiabetics or other treatments compared to those who take insulin.<sup>16</sup> DM patients' negative perception of their disease has been demonstrated by other authors.<sup>17-19</sup>

That the majority of patients who were taking insulin had a better perception of the positive-perception items of insulin therapy was an expected outcome, and the majority agreed that insulin "helps to prevent diabetes complications", "helps to improve my health", "helps to maintain good blood glucose control" and "helps to improve my energy levels". For these same items, patients who had not used insulin were found to have a poor perception.

Chen et al.<sup>20</sup> recently validated a Chinese version of the ITAS, in which the estimated Cronbach's alpha for the internal consistency of the whole scale was 0.72; in our case, this value was slightly higher (0.747). However, the Cronbach's alpha obtained by Lee<sup>21</sup> applied to primary care patients in Hong Kong was higher than ours (0.78).

The ITAS can be used as a tool to assess treatment adherence and determine the psychosocial causes of poor metabolic control, as well as to predict which patients will have better treatment adherence if they require insulin therapy.

Ku et al.<sup>22</sup> found a relationship between the score obtained on the ITAS and blood glucose control according to the glycated haemoglobin (HbA<sub>1c</sub>) criterion. Patients with high HbA<sub>1c</sub> at diagnosis, in whom insulin therapy is initially necessary, are more likely to be referred to Endocrinology.<sup>23</sup> In our case, this measurement of choice for assessing blood glucose control was not available in primary care, where the study was conducted.

Additionally, our study proposes a cut-off point  $\geq 65$  as reference for a poor perception of insulin use in DM2 patients. Applying this cut-off point would differentiate patients with scores higher than the root mean square belonging to the cluster with higher scores on the ITAS and consequently those with a poorer perception of insulin use.

Continual therapeutic education is needed for patients with DM2 to have a positive perception about using insulin to control their blood glucose.<sup>22</sup> More than a third of DM patients who discontinue drug therapy have an inappropriate perception of their disease,<sup>24</sup> with the resulting detrimental effects on metabolic control. Inadequate representation of DM is known to affect emotional state and treatment adherence in patients with this disease.<sup>25</sup> This is why it is important to know, *a priori*, how patients perceive the possible therapeutic options and the effect they may have on their quality of life.

DM2 patients are often overweight or obese, which has a directly proportional relationship with blood glucose control and the time since disease onset. It is therefore normal that the higher the body mass index the poorer a patient's perception of taking insulin will be, as they probably associate this with advanced stages of the disease, weight gain and the failure of oral antidiabetic therapy. However, this relationship was not statistically significant in the sample studied.

## Limitations, strengths and conclusions

The limitations of our study include those inherent to cross-sectional studies when statistical rather than causality associations are established. Other limitations include the sampling procedures (non-probabilistic) and the period during which the study was partially halted. The results

**Table 2** Distribution of the score in the Insulin Treatment Appraisal Scale in patients with type 2 diabetes according to insulin treatment.

Items	Strongly disagree		Disagree		Neither agree nor disagree		Agree		Strongly agree		p <sup>a</sup>
	Insulin users	Non-insulin users	Insulin users	Non-insulin users	Insulin users	Non-insulin users	Insulin users	Non-insulin users	Insulin users	Non-insulin users	
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
1. Taking insulin means I have failed to manage my diabetes with diet and tablets	49 (41.9)	9 (11.1)	7 (6)	21 (25.9)	7 (6)	15 (18.5)	14 (12)	30 (37)	40 (34.2)	6 (7.4)	<0.001
2. Taking insulin means my diabetes has gotten much worse	51 (43.6)	11 (13.6)	12 (10.3)	19 (23.5)	4 (3.4)	12 (14.8)	20 (17.1)	24 (29.6)	30 (25.6)	15 (18.5)	<0.001
3. Taking insulin helps to prevent the complications of diabetes	15 (12.8)	6 (7.4)	3 (2.6)	6 (7.4)	8 (6.8)	18 (22.2)	15 (12.8)	39 (48.1)	76 (65)	12 (14.8)	<0.001
4. Taking insulin means other people see me as a sick person	70 (59.8)	16 (19.8)	12 (10.3)	29 (35.8)	9 (7.7)	6 (7.4)	12 (10.3)	24 (29.6)	14 (12)	6 (7.4)	<0.001
5. Taking insulin makes life less flexible	80 (68.4)	18 (22.2)	19 (16.2)	29 (35.8)	19 (16.2)	9 (11.1)	11 (9.4)	22 (27.2)	7 (6)	3 (3.7)	<0.001
6. I am afraid of injecting myself with a needle	90 (76.9)	22 (27.2)	9 (7.7)	16 (19.8)	2 (1.7)	6 (7.4)	8 (6.8)	19 (23.5)	8 (6.8)	18 (22.2)	<0.001
7. Taking insulin increases the risk of low blood glucose levels (hypoglycaemia)	35 (29.9)	4 (4.9)	15 (12.8)	22 (27.2)	7 (6)	26 (32.1)	16 (13.7)	23 (28.4)	44 (37.6)	6 (7.4)	<0.001
8. Taking insulin helps to improve my health	20 (17.1)	3 (3.7)	5 (4.3)	10 (12.3)	3 (2.6)	18 (22.2)	20 (17.1)	34 (42)	69 (59.0)	16 (19.8)	<0.001
9. Insulin causes weight gain	64 (54.7)	12 (14.8)	19 (16.2)	24 (29.6)	17 (14.5)	32 (39.5)	5 (4.3)	11 (13.6)	12 (10.3)	2 (2.5)	<0.001
10. Managing insulin injections takes a lot of time and energy	86 (73.5)	17 (21)	25 (21.4)	51 (63)	0 (0)	7 (8.6)	1 (0.9)	5 (6.2)	5 (4.3)	1 (1.2)	<0.001
11. Taking insulin means I have to give up activities I enjoy	92 (78.6)	24 (29.6)	10 (8.5)	36 (44.4)	4 (3.4)	7 (8.6)	4 (3.4)	12 (14.8)	7 (6)	2 (2.5)	<0.001
12. Taking insulin means my health will deteriorate	79 (67.5)	20 (24.7)	21 (17.9)	29 (35.8)	3 (2.6)	6 (7.4)	7 (6)	23 (28.4)	7 (6)	3 (3.7)	<0.001
13. Injecting insulin is embarrassing	102 (87.2)	31 (38.3)	10 (8.5)	38 (46.9)	2 (1.7)	6 (7.4)	1 (0.9)	6 (7.4)	2 (1.7)	0 (0)	<0.001
14. Injecting insulin is painful	90 (76.9)	22 (27.2)	15 (12.8)	35 (43.2)	3 (2.6)	14 (17.3)	4 (3.4)	6 (7.4)	5 (4.3)	4 (4.9)	<0.001
15. It is difficult to inject the right amount of insulin correctly at the right time every day	94 (80.3)	19 (23.5)	12 (10.3)	34 (42)	5 (4.3)	15 (18.5)	4 (3.4)	7 (8.6)	2 (1.7)	6 (7.4)	<0.001
16. Taking insulin makes it more difficult to fulfil my responsibilities	92 (78.6)	23 (28.4)	16 (13.7)	40 (49.4)	1 (0.9)	10 (12.3)	3 (2.6)	7 (8.6)	5 (4.3)	1 (1.2)	<0.001
17. Taking insulin helps to maintain good blood glucose control	13 (11.1)	2 (2.4)	3 (2.6)	7 (8.6)	1 (0.9)	15 (18.5)	22 (18.8)	34 (42)	78 (66.7)	23 (28.4)	<0.001
18. Being on insulin causes family and friends to be more concerned about me	15 (12.8)	6 (7.4)	8 (6.8)	23 (28.4)	9 (7.7)	23 (28.4)	13 (11.1)	17 (21)	72 (61.5)	12 (14.8)	<0.001
19. Taking insulin helps to improve my energy levels	12 (10.3)	4 (4.9)	5 (4.3)	17 (21)	6 (5.1)	30 (37)	24 (20.5)	19 (23.5)	70 (59.8)	11 (13.6)	<0.001
20. Taking insulin makes me more dependent on my doctor	34 (29.1)	16 (19.8)	16 (13.7)	23 (28.4)	9 (7.7)	12 (14.8)	13 (11.1)	16 (19.8)	45 (38.5)	14 (17.3)	<0.001

<sup>a</sup> Monte Carlo two-sided asymptotic significance test.

**Table 3** Analysis of reliability of the *Insulin Treatment Appraisal Scale* in patients with diabetes according to insulin treatment.

Items	Mean of the scale if the element is deleted	Variance of the scale if the element is deleted	Corrected item-total correlation	Cronbach's alpha if the element is deleted
1. Taking insulin means I have failed to manage my diabetes with diet and tablets	49.12	100.935	0.423	0.727
2. Taking insulin means my diabetes has gotten much worse	49.19	100.516	0.430	0.726
3. Taking insulin helps to prevent the complications of diabetes	48.18	112.129	0.106	0.752
4. Taking insulin means other people see me as a sick person	49.78	100.244	0.504	0.720
5. Taking insulin makes life less flexible	50.05	100.098	0.582	0.716
6. I am afraid of injecting myself with a needle	49.94	100.941	0.442	0.725
7. Taking insulin increases the risk of low blood glucose levels (hypoglycaemia)	48.97	112.009	0.083	0.757
8. Taking insulin helps to improve my health	48.26	115.234	-0.011	0.762
9. Insulin causes weight gain	49.84	104.964	0.402	0.730
10. Managing insulin injections takes a lot of time and energy	50.42	108.598	0.384	0.734
11. Taking insulin means I have to give up activities I enjoy	50.32	105.127	0.438	0.728
12. Taking insulin means my health will deteriorate	50.09	99.614	0.615	0.713
13. Injecting insulin is embarrassing	50.61	110.895	0.303	0.739
14. Injecting insulin is painful	50.33	103.607	0.534	0.722
15. It is difficult to inject the right amount of insulin correctly at the right time every day	50.33	105.979	0.424	0.730
16. Taking insulin makes it more difficult to fulfil my responsibilities	50.42	105.254	0.512	0.726
17. Taking insulin helps to maintain good blood glucose control	47.95	113.316	0.077	0.753
18. Being on insulin causes family and friends to be more concerned about me	48.46	115.098	-0.012	0.763
19. Taking insulin helps to improve my energy levels	48.32	113.835	0.044	0.757
20. Taking insulin makes me more dependent on my doctor	49.05	107.286	0.210	0.747

Cronbach's Alpha = 0.747.

**Table 4** K-means cluster analysis according to score on the *Insulin Treatment Appraisal Scale*.

Score on the ITAS scale	Final cluster centres			Number of cases in each cluster			Root mean square	df	ANOVA	
	1	2	3	1	2	3			F	p
	65	37	50	58	36	105	23.513	196	390.990	0.000 <sup>a</sup>

df: degrees of freedom; ITAS: Insulin Treatment Appraisal Scale.

<sup>a</sup> Statistically significant.



**Table 5** Analysis of variance of the quantitative variables according to the cluster they belong to

ANOVA		Sum of squares	df	Root mean square	F	p
Body mass index	Intergroup	249.352	2	124.676	5.449	0.005 <sup>a</sup>
	Intragroup	3,706.975	162	22.883		
	Total	3,956.327	164			
Time since onset (years)	Intergroup	810.143	2	405.072	3.404	0.035 <sup>a</sup>
	Intragroup	23,323.917	196	119.000		
	Total	24,134.060	198			
Height	Intergroup	660.894	2	330.447	3.162	0.055
	Intragroup	16,931.554	162	104.516		
	Total	17,592.448	164			
Weight	Intergroup	143.805	2	71.903	0.502	0.606
	Intragroup	23,201.506	162	143.219		
	Total	23,345.312	164			

ANOVA: analysis of variance; df: degrees of freedom.

<sup>a</sup> Statistically significant.**Table 6** Relationship between variables of clinical interest and perception of insulin therapy according to the cut-off point established.

Variables of clinical interest	ITAS scale score		Total	p
	<65	≥65		
Being female	107 (62.6)	24 (85.7)	131 (65.8)	0.018 <sup>a</sup>
Skin colour white	92 (53.8)	18 (64.3)	110 (55.3)	0.513
High educational level	133 (77.8)	19 (67.9)	152 (76.4)	0.336
Lives alone	39 (22.8)	6 (21.4)	45 (22.6)	1.000
Family history of DM	75 (43.9)	8 (28.6)	83 (41.7)	0.151
Has comorbidities	119 (69.6)	23 (82.1)	142 (71.4)	0.259
Complications of diabetes	76 (44.4)	9 (32.1)	85 (42.7)	0.303
Previous diabetes education	139 (81.3)	24 (85.7)	163 (81.9)	0.792
Initial treatment non-insulin	122 (71.3)	22 (78.6)	144 (72.4)	0.501
Current treatment non-insulin	62 (36.5)	19 (67.9)	81 (40.9)	0.003 <sup>a</sup>
Body mass index <sup>b</sup>	26.87 ± 4.75	29.46 ± 6.217	27.07 ± 4.91	0.067
Time since onset (years) <sup>b</sup>	13.67 ± 11.14	9.89 ± 9.96	13.14 ± 11.04	0.093

DM: diabetes mellitus; ITAS: *Insulin Treatment Appraisal Scale*.<sup>a</sup> Statistically significant.<sup>b</sup> Result expressed as mean ± standard deviation.

may have also been influenced by the fact that the survey was applied during an epidemic in which many patients did not have access to follow-up consultations. Additionally, the HbA<sub>1c</sub> for each patient could not be determined, as the availability of this analysis is limited in primary healthcare in Cuba. Future studies may expand upon the relationship between HbA<sub>1c</sub> and the ITAS score. Despite these limitations, the validity and internal consistency of the ITAS were demonstrated.

One of the strong points of our research is that it is the first study in Cuba and Latin America to validate a Spanish-language version of the ITAS. Another strength is provided by the representation of patients from different provinces in Cuba. The main contributions are the validation of the ITAS for Cuban DM2 patients and the proposal of the cut-off point ≥65 for poor perception of insulin therapy, in addition to the identification of being female and currently being on

non-insulin therapy as variables related to a poorer perception of insulin treatment. Determining which patients have a poorer perception of insulin therapy will allow us to come up with strategies to increase patient education in diabetes and therapy to guarantee better treatment adherence among these patients.

## Authorship

Frank Hernández-García: conceptualisation, data curation, formal analysis, fundraising, research, methodology, project manager, resources, supervision, validation, visualisation, writing-original draft, writing-revision and editing.

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All the authors approved the final version of the article.

## Conflicts of interest

The authors declare that they have no conflicts of interest.

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