

Translation and validation of the Insulin Treatment Appraisal Scale in Hong Kong primary care patients

Kam Pui Lee*

Jockey Club School of Public Health and Primary Care, The Chinese University of Hong Kong, Shatin, Hong Kong

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*Correspondence

Kam Pui Lee

Tel.: +852-2252-8462

Fax: +852-2606-3500

E-mail address: lkp032@cuhk.edu.hk

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ABSTRACT

Aims/Introduction: Patients with type 2 diabetes mellitus often delay the initiation or titration of insulin treatment due to psychological factors. This phenomenon is referred to as psychological insulin resistance (PIR). The Insulin Treatment Appraisal Scale (ITAS) is a 20-item instrument for assessing PIR. A previous Chinese version of the ITAS (C-ITAS) was found to be subject to problems arising from its translation. The present study aimed to translate and validate this instrument, which will facilitate research and aid in counseling in a clinical setting.

Materials and Methods: The C-ITAS was modified to develop the Hong Kong version of the C-ITAS (C-ITAS-HK) according to published guidelines for the translation of transcultural research. A total of 328 diabetes mellitus patients who were followed-up in 10 different publically funded primary care outpatient clinics were recruited for self-administration of the C-ITAS-HK. Demographic data were recorded, and clinical data (e.g., presence of diabetes mellitus complications) were obtained from case records. The C-ITAS-HK results were subjected to psychometric analysis, including the assessment of Cronbach's alpha, factor analysis and test–retest reliability.

Results: Factor analysis supported a two-factor structure with good internal consistency (whole scale 0.846, negative subscale 0.882, positive subscale 0.619). The test–retest reliability correlation coefficients for all items were positive, at 0.871, 0.782, and 0.692 for the whole scale, negative subscale and positive subscale, respectively. The ITAS scores differed significantly between participants with PIR and those without in the expected direction, suggesting good discriminant validity.

Conclusions: The C-ITAS-HK is a valid tool for measuring and assessing PIR in the Hong Kong primary care diabetes mellitus population.

INTRODUCTION

Diabetes mellitus is an increasingly prevalent disease^{1,2}. Early glycemic control is important because strict control in the late stage of diabetes mellitus yields reduced protective results^{3–6}.

However, patients often delay insulin treatment⁷. The reluctance to initiate insulin^{8–10} and its subsequent titration¹¹ is termed psychological insulin resistance (PIR).

Despite the high prevalence of PIR, doctors, and especially those working in the primary care arena, often incorrectly estimate the reasons for PIR among patients (e.g., most nurses and

primary care doctors underestimate of the number of patients who blame themselves for needing to use insulin)¹⁰. In the large-scale Diabetes Attitudes, Wishes and Needs (DAWN) study, involving more than 5,000 diabetes mellitus patients and nearly 4,000 healthcare professionals, the comments included “less than half the health care professionals interviewed felt able to identify and evaluate patients’ psychological needs” and “...emotions are not always perceived or addressed adequately by health care providers”¹².

The Insulin Treatment Appraisal Scale (ITAS) was developed to identify the reasons for PIR among patients, to monitor changes in the appraisal of insulin treatment, and to aid in patient education and counseling¹³. The instrument, consisting

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of four positive and 16 negative statements (2-dimensional instrument with “appraisal of insulin therapy” as a single underlying construct), was developed and validated in the USA.

The ITAS has been used by researchers worldwide to understand PIR in different populations (e.g., in primary care in Amsterdam⁹, in Egypt¹⁴, in a German geriatric population¹⁵ and in Romania¹⁶), to study the relationship of PIR with depression^{9,17} and to investigate changes in PIR after the use of different types of insulin or insulin delivery methods^{18,19}, or after specific programs (e.g., team approaches involving diabetes nurses/endocrinologists)²⁰. The ITAS has been found to be sensitive to changes in PIR throughout the course of diabetes mellitus²¹.

The ITAS was translated and validated in Taiwan^{22,23} (C-ITAS). Subsequently, a Hong Kong (HK) study²⁴ that examined the relationship between psychosocial factors and PIR using the C-ITAS identified a possible translation issue with at least one ITAS statement. Because of language and cultural differences between Hong Kong and Taiwanese populations, validation of the ITAS in HK is warranted.

The present study aimed to examine and modify the C-ITAS, and to validate the use of the modified version in HK primary care. A validated version could be applied clinically to identify and detect the reasons for PIR, and to facilitate the comparison of HK PIR data with those of other countries.

METHODS

The translation and validation process followed published guidelines²⁵. This research was approved by the ethics committee of the Kowloon West Cluster, HK Hospital Authority.

ITAS questionnaire

The ITAS, in its original version and in its Chinese translation, the C-ITAS, is a 20-item instrument that contains 16 negative and four positive statements that appraise insulin treatment. Each statement is ranked using a five-point Likert-type scale from 1 to 5. Positive scores are reversed to allow for summation. The total possible score ranges from 0 to 80. A higher score signifies a more negative appraisal of insulin. The total scores of the positive and negative subscales can be calculated by summing the scores of the four positive and 16 negative statements, respectively.

The original Taiwan Chinese version of the C-ITAS questionnaire was back-translated into English by two bilingual primary care doctors and one layman, who was an architect. The primary care doctors and the architect were local Chinese who obtained bachelor degrees using English as the primary language. They were blind to the English version of the ITAS. The C-ITAS was used as the first step to allow comparison of C-ITAS data with data from other Asian regions (e.g., Taiwan).

The ITAS questionnaires back-translated by the doctors (BT1) and the layman (BT2) were compared by a committee composed of nine family medicine (FM) doctors, the translators and the principle investigator. These individuals were bilingual,

and all of the doctors had experience in prescribing insulin. They rated the comparability of the language and the similarity of the interpretation of BT1/BT2 with the original English version. All of the non-equivalent items were modified by the committee to enhance their translational equivalence to the original English version (in terms of sentence structure, meaning and wording) until equivalence was achieved, resulting in the modified questionnaire (ITAS-1).

The ITAS-1 was pilot tested by interviewing 10 diabetes mellitus patients, who were randomly selected at an outpatient clinic (East Kowloon General Outpatient Clinic) during their diabetes mellitus follow-up visits. Any wording or statement that the patients did not understand was clarified, and potential improvements were reported. The instructions, response format and items of the instruments that were found to be unclear by at least 20% of the sample population were re-evaluated²⁵. Any questions that could not be clarified by the committee were sent to the developer for clarification, resulting in a second modified questionnaire (ITAS-2)²⁵.

The ITAS-2 was further evaluated by an expert panel composed of two endocrinologists, two specialized diabetes nurses, one FM professor, two FM specialists and two FM doctors. The questionnaire was evaluated for its conceptual equivalence (clarity), and each member who rated the instructions, response format or any item of the instruments as unclear was asked to provide suggestions for rewriting the statements and clarifying the language. Any instructions, response formatting or items of the instruments that were found to be unclear by at least 20% of the members were revised and re-evaluated²⁵.

The expert panel was then asked to evaluate each item for contact equivalence (relevancy) using the following scale: 1, not relevant; 2, unable to assess relevance; 3, relevant but needs minor alteration; and 4, very relevant and succinct. The content equivalence index values at the item level (I-CVI) and scale level (S-CVI) were calculated through averaging. The minimum accepted I-CVI value was 0.78, whereas the minimum accepted S-CVI value was 0.9²⁵. Any item that did not fulfill the index criterion was revised and re-evaluated²⁵. Interrater reliability was calculated by the Kappa coefficient of agreement²⁵.

The finalized version (C-ITAS-HK) was then subjected to psychometric testing in a sample of patients²⁵.

Patients

The study was carried out in 10 government-funded general outpatient clinics in the Kowloon West Cluster in Hong Kong from July to September 2015. We aimed to recruit a representative sample of diabetes mellitus patients who regularly followed up in Hong Kong government-funded clinics, where most patients (>87%) with chronic diseases have their regular follow ups. A recruitment period of 3 months was selected, because most diabetes mellitus patients receive follow up at 3-month intervals²⁶.

Using a criterion of 10 participants per question, a sample size of 200 was required. Considering a dropout rate of 40%, 333 participants were recruited. Patients who were diagnosed with type 2 diabetes according to the World Health Organization criteria²⁷, aged >18 years and Chinese were recruited consecutively by diabetes mellitus nurses when they came in for counseling, annual checks or blood tests. As the questionnaires can be self-administered, only patients who could read and write in Chinese were recruited. The exclusion criteria were a current pregnancy, illiteracy, or severe mental or physical illness that prevented completion of the questionnaire.

Measurements

Sociodemographic data were input by the patient. The patients were asked if their doctors had suggested insulin to them previously, if their relatives were using insulin, and if they lived with family members. Clinical data, including glycosylated hemoglobin (HbA1c) levels, low-density lipoprotein levels, the duration of diabetes mellitus, the presence of impaired foot vibration sense, the presence of retinopathy requiring referral to a specialist, the presence of an impaired estimated glomerular filtration rate (<60) and the presence of microalbuminuria, were retrieved from medical records.

All of the patients were asked if they were willing to begin insulin treatment (or to titrate insulin if already on insulin treatment) if suggested by their case doctors. Their answers were recorded on a Likert-scale of “very unwilling,” to “unwilling,” to “willing,” to “very willing.” Participants who chose “very unwilling” or “unwilling” were defined as “subjects with PIR.”

A total of 22 participants were contacted by telephone to repeat the ITAS questionnaire approximately 4 weeks after the initial interview to assess test–retest reliability.

Statistical analysis

IBM SPSS Statistics for Windows version 22 (IBM, Armonk, NY, USA) was used for statistical analysis. The frequency, mean, median and standard deviation were calculated with descriptive statistics for all measures. Comparisons among various demographic categories, and between participants with and without PIR and ITAS scores were made using χ^2 -tests for categorical data and *t*-tests for continuous data.

Exploratory factor analysis with oblimin rotation was carried out on the 20 ITAS items. Oblimin rotation was used in the original validation study¹³ for statements that the authors believed were related. The Kaiser criterion (eigenvalue >1) and the scree plot of eigenvalues were used to determine the optimal number of factors

Internal consistency was examined by calculating Cronbach's alpha, item total correlations and inter-item correlations. An internal consistency of 0.7–0.8 was defined as satisfactory, and the item total correlation was defined as desirable if the value was >0.20. An inter-item correlation >0.80 indicated redundancy.

RESULTS

Development of the C-ITAS-HK

Before and during pilot testing with patients, any identified discrepancy was resolved by the committee. However, participants had difficulty in understanding the meaning of “flexible” (ITAS statement 5), which the committee could not resolve. Clarification by the original developer was sought by e-mail exchange, and the statement was later translated to “life being more restricted.”

The finalized C-ITAS-HK was agreed on by the expert panel, with the I-CVI ranging from 0.83 to 1.00 and an S-CVI of 0.97. The interrater reliability was high, with a coefficient of 0.894 (95% confidence interval 0.760–0.972).

Participants

A total of 333 patients from 10 different clinics were recruited; 18 individuals refused to participate. One questionnaire was invalidated, as all of the answers were “neutral.” The response rate was 94.3%.

The respondents' demographic data can be found in Table 1. The non-respondents were not significantly different from the respondents in terms of sex, the presence of complications, treatment modality, education level, HbA1c level, low-density lipoprotein level or age (Table 1). However, the non-respondents showed a relatively shorter duration of diabetes mellitus (3.17 years vs 8.31 years; $P < 0.001$)

The prevalence of PIR among participants who had never used insulin before (insulin-naive participants) was 63.1%, whereas that among insulin users was 29.4%.

Factor analysis

Exploratory factor analyses revealed four factors with an eigenvalue >1. The first four eigenvalues were 6.04, 2.12, 1.35 and 1.15, which explained 30.2%, 40.79%, 47.55% and 53.3% of the variance, respectively. The “knick” in the scree plot suggested a two- or three-factor structure. The one-, two-, three- and four-factor solutions were generated by principle axis factoring with oblimin oblique rotation (Table 2).

In the one-factor solution, all of the positive statements and the question 1 item “failed on pre-insulin therapy” failed to load sufficiently. In the three-factor solution, the only difference from the two-factor solution was found for question 2 “diabetes has gotten worse,” which loaded on all three factors and was the sole statement in factor three. In the four-factor solution, only question 4 “perceived by others as sicker” and question 9 “causes weight gain” were loaded on the third and fourth factors, respectively.

Given the minimal additional variance explained by the three- or four-factor solutions and the fact that grouping was not improved in the three- to four-factor solutions, a two-factor solution was concluded to provide the best representation of the latent structure of the ITAS.

Within the two-factor solution, using a loading of >0.4 as a criterion (which was used in the original study in which the

Table 1 | Respondent and non-respondent characteristics

	Respondents	Non-respondents	P-value
Mean age (years)			
Age	63.29	64.23	0.743
Age distribution (%)			
≤50	11.2	7.7	0.929
51–60	25.6	30.8	
61–70	41.5	46.2	
71–80	17.3	7.7	
>80	4.5	7.7	
Sex (%)			
Male	45.3	58.3	0.375
Female	54.7	41.7	
Marriage status (%)			
Married	76.1		
Single	10.5		
Divorced	5.9		
Widowed	7.5		
Employment status (%)			
Working	35.9	42.9	0.497
Unemployed	5.8	0	
Retired	58.3	57.1	
Education (%)			
No education	7.3	8.3	0.826
Primary level	39.8	50	
Secondary level	43	3.6	
University level	8.6	0	
Master's or above	1.3	0	
Relative on insulin (%)			
Yes	27.6		
Lived with family (%)			
Yes	88.3		
Monthly family income (%)			
<\$5,000	31.2		
\$5,001–10,000	20		
\$10,001–20,000	26.8		
\$20,001–30,000	15.6		
>\$30,000	6.4		
DM complications (%)			
MDRD <60	14.8	25	0.336
Microalbuminuria	17.4	25	0.5
Retinopathy	9.8	8.3	0.869
Impaired foot vibration sense	1.0	8.3	0.143
Tx modality (%)			
Insulin	5.8	0	1.0
Oral drugs	84.2	91.7	0.7
Diet alone	15.4	8.3	1.0
HbA1c (%)			
Mean value	7.26	7.25	0.967
HbA1c ≤7%	49.7	66.7	0.378
LDL			
Mean value	2.51	2.76	0.256
≤2.67 (%)	62.5	50	0.383
Years of Dx of DM			
≤10 years (%)	70.7	100	0.023*
Mean value	8.31	3.17	<0.001*

Missing data from non-respondents were due to a lack of information from the medical records system. DM, diabetes mellitus; Dx, duration; HbA1c, glycosylated hemoglobin; LDL, low-density lipoprotein; MDRD, estimated glomerular filtration rates by Modification of Diet in Renal Disease formula; Tx, treatment.

* $P < 0.05$.

instrument was developed¹³), question 1 “failed on pre-insulin therapy” and Q2 “diabetes has gotten worse” loaded on both factors, whereas question 9 “causes weight gain” and question 19 “helps to improve energy levels” did not load on either factor.

As the negative statement question 1 “failed on pre-insulin therapy” was the only statement that was loaded with other positive statements, it was removed, and the two-factor solution was re-generated. All of the positive statements were then loaded on factor two, and all of the negatively worded statements were loaded on factor one (Table 2).

Internal consistency

Cronbach's alpha was 0.846 for the 20-item scale; 0.882 for the 16-item, negatively worded item scale; and 0.619 for the 4-item, positively worded ITAS scale.

For the 20-item scale, Cronbach's alpha was improved when the few positively worded statements were removed: questions 3, 8, 17, and 19 showed low item total scores of 0.116, 0.064, 0.073 and -0.160 , respectively, and their removal yielded higher alpha values of 0.851, 0.852, 0.851 and 0.859, respectively. The item total scores of the other questions ranged from 0.315 to 0.659.

For the 16-item scale, Cronbach's alpha was only minimally improved from 0.882 to 0.885 when question 1 was removed. The item total score for question 1 was 0.286.

For the four-item positive scale, removal of any item resulted in a lower Cronbach's alpha.

Discriminant validity

The ITAS scores were compared between participants with and without PIR, and between participants who were using insulin and those who were insulin-naive. Patients receiving insulin treatment are known to show a lower PIR^{13,21}. The ITAS scores between these groups were all significantly different in the expected direction, suggesting good discriminant validity (Table 3).

Test-retest reliability

The Pearson correlation for individual statements ranged from 0.008 to 0.869. The correlation for the total ITAS score, negative-scale score and positive-scale score ranged from moderate to strong, at 0.871, 0.782 and 0.692, respectively (Table 4).

Other results

Individual ITAS statements were examined for ceiling or flooring effects (i.e., >20% of participants answering strongly agree or strongly disagree to a statement). Only ITAS question 6 showed a mild ceiling effect (21.9%).

Patients with an HbA1c >8% were more likely to be counseled by doctors about insulin treatment ($P \leq 0.001$). However, the majority of these patients (67.3%) did not recall having a discussion about insulin treatment with their case doctor in the previous 6 months.

Table 2 | Exploratory factor analyses of the 20 items of the Insulin Treatment Appraisal Scale: forced one- to four-factor solutions after oblimin rotation and a two-factor solution excluding question 1

Item content	One-factor solution		Two-factor solution			Three-factor solution			
	h2	F1/1	h2	F1/2	F2/2	h2	F1/3	F2/3	F3/3
1. Failed on pre-insulin therapy	0.72		0.209		0.365	0.324		0.397	
2. Diabetes has gotten worse	0.112	0.334	0.234	0.342	0.342	0.456	0.356	0.397	-0.413
3. Prevent complications	0		0.248		0.498	0.281		0.493	
4. Perceived by others as more sick	0.205	0.453	0.213	0.453		0.309	0.461		
5. Life less flexible	0.411	0.641	0.42	0.641		0.417	0.64		
6. Fear of injecting with needle	0.229	0.479	0.238	0.479		0.276	0.481		
7. Risk of hypoglycemia	0.165	0.406	0.206	0.409		0.204	0.408		
8. Improves health	0.001		0.262		0.51	0.359		0.528	
9. Causes weight gain	0.113	0.336	0.114	0.336		0.114	0.335		
10. Takes time and energy	0.431	0.656	0.438	0.656		0.449	0.656		
11. Give up activities I enjoy	0.544	0.737	0.543	0.736		0.541	0.734		
12. My health will deteriorate	0.402	0.634	0.405	0.633		0.435	0.636		
13. Injecting is embarrassing	0.507	0.712	0.508	0.711		0.506	0.709		
14. Injecting is painful	0.371	0.609	0.371	0.608		0.402	0.61		
15. Difficult to always inject correctly	0.481	0.693	0.521	0.697		0.568	0.701		
16. Difficult to fulfill responsibilities	0.608	0.78	0.646	0.784		0.667	0.785		
17. Helps to control blood glucose	0.003		0.414		0.641	0.39		0.619	
18. Family/friends more concerned	0.532	0.729	0.533	0.728		0.531	0.726		
19. Helps to improve energy levels	0.057		0.142			0.222			
20. More dependent on doctor	0.214	0.462	0.227	0.462		0.237	0.462		
Explained variance (%)		30.2		40.79			47.55		

Item content	Four-factor solution					Two-factor solution (without Q1)		
	h2	F1/4	F2/4	F3/4	F4/4	h2	F1/2	F2/2
1. Failed on pre-insulin therapy	0.318		0.392					
2. Diabetes has gotten worse	0.435					0.229	0.317	
3. Prevent complications	0.279		0.493			0.292		0.541
4. Perceived by others as more sick	0.361	0.464		-0.323		0.201	0.446	
5. Life less flexible	0.415	0.638				0.415	0.637	
6. Fear of injecting with needle	0.338	0.485				0.246	0.479	
7. Risk of hypoglycemia	0.297	0.414				0.2	0.403	
8. Improves health	0.37		0.532			0.298		0.544
9. Causes weight gain	0.235	0.342			0.341	0.113	0.335	
10. Takes time and energy	0.482	0.658				0.437	0.659	
11. Give up activities I enjoy	0.559	0.735				0.548	0.74	
12. My health will deteriorate	0.472	0.639				0.404	0.632	
13. Injecting is embarrassing	0.506	0.708				0.508	0.712	
14. Injecting is painful	0.47	0.616				0.388	0.61	
15. Difficult to always inject correctly	0.569					0.515	0.702	
16. Difficult to fulfill responsibilities	0.674	0.784				0.642	0.789	
17. Helps to control blood glucose	0.404		0.623			0.401		0.629
18. Family/friends more concerned	0.544	0.726				0.535	0.731	
19. Helps to improve energy levels	0.217					0.172		0.334
20. More dependent on doctor	0.255	0.463				0.237	0.463	
Explained variance (%)		53.3					41.86	

Only factors with a loading >0.3 are shown. F, factor; h2, communality; Q1 question 1.

Table 3 | Insulin Treatment Appraisal Scale scores

	Insulin users	Non-insulin users	P-value
Scores of patients treated with insulin and non-insulin users			
Total ITAS score	26.28	37.36	<0.001
16-item negative scale score	41.94	51.17	<0.001
4-item positive scale score	15.67	13.74	<0.001
	PIR -ve	PIR +ve	P-value
Scores of patients with and without PIR			
Total ITAS score	32.56	40.33	<0.001
16-item negative scale score	47.09	53.78	<0.001
4-item positive scale score	14.49	13.29	<0.001

-ve, negative; +ve, positive; ITAS, Insulin Treatment Appraisal Scale; PIR, psychological insulin resistance.

When all of the participants were included, the mean total ITAS score was 36.6 (standard deviation 9.5, range 12–59), the mean negative-scale score was 50.6 (standard deviation 9.2, range 27–73) and the mean positive-scale score was 13.9 (standard deviation 2.1, range 7–19).

The ITAS identified different perceptions towards insulin use among different social and treatment groups. It has previously been established that psychosocial factors are important determinant factors in PIR in Asian patients²⁴ (Table 4).

DISCUSSION

The translated C-ITAS-HK yielded very similar results to those of the original development study¹³ and the only published study to re-evaluate the psychometric performance of the ITAS²⁸. Excluding ITAS statement 1, the current study showed a clear two-factor structure, as in the original study. It echoed the re-evaluation study²⁸ in showing that the ITAS cannot be better explained by a one-factor structure, because all of the positively worded statements could not be loaded onto a single factor.

The reason that question 1 “failed on pre-insulin therapy” could not be loaded into the two-factor solution was not fully understood. This issue is known to be a major reason for PIR^{10,29}. In a Taiwanese study²², question 1 “failed on pre-insulin therapy” was scored significantly differently between insulin users and insulin-naive patients (mean score 3.3–3.6; $P < 0.01$). Ad hoc analysis of the results of the current study showed that the results for question 1 were not significantly different between the different treatment or characteristic groups; that is, patients with and without PIR, patients with or without complications, and patients of different social groups. This finding was unexpected, because the current C-ITAS-HK was modified from that used in the previous Taiwanese study^{22,23}. The wording in the C-ITAS-HK was minimally changed from that in the C-ITAS. This change was made after a pilot study in which patients expressed that they did not comprehend “signify” in Chinese. Nevertheless, retaining question 1 in the ITAS is recommended for the following reasons: first, it has been found to

be a major reason for PIR in many other studies¹⁰; second, the removal of question 1 did not significantly improve internal consistency (Cronbach’s alpha) in the total scale (0.846 to 0.844 if deleted); third, the re-evaluation study²⁸ suggested that the results of factor analysis can differ between insulin-naive patients and insulin users, and considering that the present study included mostly insulin-naive diabetes mellitus patients, question 1 could still be an important factor in insulin users; finally, retaining this item allows comparison with other studies^{9,13,16–18}.

In the current study and the two previous studies^{13,28}, Cronbach’s alpha for the whole scale was high, suggesting good internal consistency and that the removal of any statement could only minimally improve the Cronbach’s alpha value. However, Cronbach’s alpha for the 20-item total scale was lower than for the 16-item negative ITAS scale, and the positive items showed low item total correlations in the 20-item scale. Given these results, the authors of the re-evaluation study²⁸ suggested that “the subscale should not be combined to create a total score.” Based on the results of this study, which suggest that the ITAS has a two-factor structure, it might be more useful to calculate the positive and negative subscale scores separately than to calculate the total score. Nevertheless, in contrast to the re-evaluation study²⁸, the current study showed that positive statements and their subscale scores were significantly different between the treatment groups, between patients with or without PIR, and between some social groups (Tables 3 and 4), suggesting that these items show strong discriminatory power in the study population.

PIR changes over the course of treatment, and insulin users show much lower PIR than their counterparts^{13,21}. The ITAS showed good discriminatory power, with patients who were insulin naive and patients with PIR showing significantly higher total ITAS scores, 16-item negative scale scores and lower four-item positive scale scores than their counterparts (Table 3).

The test–retest reliability for all 20 statements showed a positive value. However, the correlation of some statements was weak, which might have been due to the different methods of

Table 4 | Test–retest reliability, Insulin Treatment Appraisal Scale statements and different social/treatment groups

Item content	Test–retest reliability		On insulin? (%)			PIR +ve? (%)			Lives with family? (%)		
	Pearson's correlation	<i>P</i> -value	Yes	No	<i>P</i> -value	Yes	No	<i>P</i> -value	Yes	No	<i>P</i> -value
Agree to the following statements:											
1. Failed on pre-insulin therapy	0.313	0.198									
2. Diabetes has gotten worse	0.512	0.054									
3. Prevent complications	0.656	0.011	94.4	62.5	0.003	75.3	55.2	0.001			
4. Perceived by others as sicker	0.293	0.217									
5. Life less flexible	0.566	0.035	16.7	61	<0.001	52.6	66	0.033			
6. Fear of injecting with needle	0.4	0.125	38.9	70.4	0.005	58.8	77.9	0.001	66.1	88.6	0.004
7. Risk of hypoglycemia	0.499	0.06									
8. Improves health	0.591	0.023	59.2	88.9	0.008	72.6	51.8	0.001			
9. Causes weight gain	0.428	0.105				5.2	17.7	0.004	11.9	30.6	0.002
10. Takes time and energy	0.723	0.002	16.7	45.9	0.012	27.8	55.8	<0.001			
11. Give up activities I enjoy	0.562	0.036				18.9	41.6	<0.001			
12. My health will deteriorate	0.779	0.001				31.3	49.4	0.004			
13. Injecting is embarrassing	0.643	0.011				18.6	50.6	<0.001			
14. Injecting is painful	0.523	0.053				28.1	57.1	<0.001			
15. Difficult to always inject correctly	0.869	<0.001	11.1	53.8	<0.001	38.9	63.8	<0.001			
16. Difficult to fulfill responsibilities	0.817	<0.001	16.7	41.6	0.028	24.5	53.7	<0.001			
17. Helps to control blood glucose	0.008	0.493	94.4	70.4	0.018	86.5	61.4	<0.001			
18. Family/friends more concerned	0.699	0.004	16.7	51	0.004	40.6	59.6	0.003			
19. Helps to improve energy levels	0.369	0.15	50	23.5	0.012	37.9	16.3	<0.001			
20. More dependent on doctor	0.51	0.055	22.2	47.4	0.031						
Scoring											
Total item score mean	0.817	<0.001	26.28	37.36	<0.001	32.56	40.33	<0.001	36.32	39.32	0.04
Negative 16-item score mean	0.782	0.001	41.94	51.17	<0.001	47.09	53.78	<0.001	50.22	53.56	0.02
Positive 4-item score mean	0.692	<0.001	15.67	13.73	<0.001	14.49	13.29	<0.001			

Item content	Married? (%)			Relative(s) on insulin? (%)			Sex (%)		
	Yes	No	<i>P</i> -value	Yes	No	<i>P</i> -value	Male	Female	<i>P</i> -value
Agree to the following statements:									
1. Failed on pre-insulin therapy									
2. Diabetes has gotten worse									
3. Prevent complications									
4. Perceived by others as sicker									
5. Life less flexible									
6. Fear of injecting with needle	65.1	80.6	0.013				58.9	76.8	0.001
7. Risk of hypoglycemia									
8. Improves health									
9. Causes weight gain	10.4	24.7	0.002						
10. Takes time and energy									
11. Give up activities I enjoy									
12. My health will deteriorate									
13. Injecting is embarrassing									
14. Injecting is painful							34.1	54.8	<0.001
15. Difficult to always inject correctly				40.7	57.1	0.012			
16. Difficult to fulfill responsibilities									
17. Helps to control blood glucose									
18. Family/friends more concerned									
19. Helps to improve energy levels	28.4	16.4	0.041						
20. More dependent on doctor									
Scoring									
Total item score mean	36.02	38.78	0.017						
Negative 16-item score mean	49.98	52.77	0.014						
item score mean									

Table 4 (Continued)

Item content:	Counseled by doctor in last 6 months? (%)			Retinopathy? (%)			MDRD <60? (%)		
	Yes	No	P-value	Yes	No	P-value	Yes	No	P-value
Agree to the following statements:									
1. Failed on pre-insulin therapy									
2. Diabetes has gotten worse									
3. Prevent complications									
4. Perceived by others as sicker							37	54.4	0.029
5. Life less flexible									
6. Fear of injecting with needle									
7. Risk of hypoglycemia									
8. Improves health									
9. Causes weight gain				33.3	12.8	0.003			
10. Takes time and energy									
11. Give up activities I enjoy	17.1	34.7	0.037						
12. My health will deteriorate									
13. Injecting is embarrassing				56.7	35.3	0.021			
14. Injecting is painful									
15. Difficult to always inject correctly									
16. Difficult to fulfill responsibilities				60	37.8	0.018			
17. Helps to control blood glucose							58.7	74	0.033
18. Family/friends more concerned				63.3	44	0.044			
19. Helps to improve energy levels	44.1	23.4	0.009						
20. More dependent on doctor									
Scoring									
Total item score mean	32.97	37.23	0.008						
Negative 16-item score mean	47.48	51.11	0.017	53.31	50.2	0.042			
Positive 4-item score mean	14.71	13.74	0.005						

Only results with statistical significance at $P \leq 0.05$ are shown. MDRD, estimated glomerular filtration rates by Modification of Diet in Renal Disease formula.

administration: the original test was self-administered, whereas the retest was carried out by telephone interview by a trained research assistant. However, it is also possible that the C-ITAS-HK presented weak-to-moderate test-retest reliability, suggesting that patients underwent a change of attitude after administration of the questionnaire. Further research might clarify this matter. Nevertheless, the total score and the subscale scores showed good-to-excellent test-retest reliability (ranging from 0.692 to 0.871).

It was observed that in addition to patient PIR, physicians likely play an important role in delaying insulin treatment, as just 37% of patients showing HbA1c >8% were counseled about insulin treatment. This phenomenon is well described^{12,13,30,31}.

The current study used a well-established method for the translation and validation of a transcultural questionnaire following established international guidelines. After translation, the C-ITAS-HK had psychometric properties similar to those described in previous studies^{13,21}. The response rate was high, and the participants included patients from different areas of HK. In addition to examining assessment, as carried out in previous studies^{13,21}, the present study examined the instrument's test-retest reliability.

The study population represented our primary care population, in which most patients were insulin naive. However, as

noted in a previous study²¹ in which the two-factor analysis results for insulin-naive patients and insulin users were significantly different, the extent to which the results of the current study can be generalized to patients undergoing secondary or tertiary care, where a large proportion of patients might be using insulin, is unknown.

As expected, most of the participants had a lower income level (31.2% had a family monthly income <\$5,000), and it is not known whether the results can be applied to patients of higher socioeconomic status. However, there were no statistically significant differences in the responses to the scale among people from different social classes in the current study.

The question "will you start insulin or titrate insulin if suggested by your case doctor?" is hypothetical – the patient might develop a different point of view when his or her illness worsens or when complications arise.

The C-ITAS-HK showed good psychometric properties, demonstrating its potential for primary care diabetes mellitus patients. Analyses based on the subscales might be more accurate or meaningful than those using only the total scale score.

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DISCLOSURE

The author declares no conflict of interest.

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