

# Development of a self-efficacy questionnaire, 'Insulin Therapy Self-efficacy Scale (ITSS)', for insulin users in Japanese: The Self-Efficacy-Q study

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## Keywords

Insulin therapy, Insulin Therapy Self-efficacy Scale (ITSS), Self-efficacy

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## INTRODUCTION

Insulin therapy has long been used to treat diabetes mellitus and remains a critical component of treatment regimens. According to the American Diabetes Association and the European Association for the Study of Diabetes, insulin is the most effective option for glycemic control<sup>1</sup>, despite the associated risks of hypoglycemia and weight gain.

Insulin therapy regimens involve several steps, including the timing of injection, preparation for injection, titration of dosage,

injection process, and blood glucose monitoring and management. These steps are largely undertaken directly by patients. Therefore, each step must be carefully executed to achieve desirable outcomes<sup>2</sup>, and this careful execution is known to depend on many factors. These include diabetes education, cognitive function and physical function<sup>3–7</sup>. In addition, 'self-efficacy' has been identified as an important factor.

The concept of self-efficacy was initially proposed by Bandura<sup>7</sup>, and defined as a person's belief regarding his or her ability to execute a designated level of performance. Studies of diabetes therapy have since shown that self-efficacy enhances a patient's ability to execute self-management behaviors, such as diet, exercise, blood glucose, monitoring and medication<sup>8–13</sup>.

## ABSTRACT

**Aims/Introduction:** Although patient self-efficacy is known to affect adherence to therapy, no available tool measures self-efficacy of insulin therapy administration while addressing the entire therapeutic process and management. In light of this, we developed the 'Insulin Therapy Self-efficacy Scale (ITSS).'

**Materials and Methods:** Development of the ITSS involved three phases: (i) item generation and creation of a questionnaire draft; (ii) testing and correcting the items through interviews with patients; and (iii) a multicenter, single-arm study to validate the questionnaire.

**Results:** A factor analysis and Cronbach's  $\alpha$  both confirmed good internal consistency in the patients' confidence regarding the following four factors: the insulin injection procedure, insulin titration, glycemic control and ability to cope with hypoglycemia. Reproducibility was confirmed using weighted  $\kappa$  statistics and intraclass correlations. Good concurrent validity was confirmed with two other questionnaires. The ITSS score was also found to correlate with several patient characteristics and clinical parameters, as well as with a better adherence to injected insulin therapy 6 months later, suggesting the predictive validity of this scale.

**Conclusions:** The ITSS is a reliable and valid tool for assessing and quantifying patients' self-efficacy. The ITSS estimation of self-efficacy can predict a patient's glycemic control and future adherence to insulin therapy. These characteristics will ensure the usefulness of the ITSS in ensuring a successful therapeutic process for patients and physicians.

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These findings show that a patient's knowledge of self-efficacy is an important component of effective management of diabetes therapy.

Several questionnaires are currently used to measure self-efficacy in diabetes therapy, including Self-Efficacy for Diabetes<sup>14</sup>, Insulin Management Diabetes Self-Efficacy Scale<sup>15</sup>, Diabetes Management Self-Efficacy Scale<sup>16</sup>, Confidence in Diabetes Self-Care<sup>17</sup> and Diabetes Self-Efficacy Scale<sup>18</sup>. However, these tools were developed to address general aspects of diabetes therapy. In contrast, no available self-efficacy questionnaire specifically targets the entire process of insulin therapy and its management, despite the importance of insulin therapy. To address this gap, we aimed to develop a self-efficacy questionnaire specific for insulin therapy in the present study.

## METHODS

### Overview of questionnaire development

We developed the Insulin Therapy Self-efficacy Scale questionnaire (ITSS) using a three-phase process: (i) item generation and creation of the questionnaire draft; (ii) testing and correction of the items through interviews with patients; and (iii) validation of the questionnaire. The inclusion criteria for patients for all phases stipulated that participants were as follows: Japanese outpatients, taking insulin treatment for  $\geq 12$  weeks and were aged  $\geq 20$  years. Exclusion criteria were as follows: confirmed or possible dementia or cognitive dysfunction, an inability to provide written informed consent without a legally acceptable representative or a designation of unsuitability for the study by a physician. In phases 1 and 2, we obtained 12 segmentations using different combinations of three parameters for the patients being interviewed: sex (male/female), type of diabetes mellitus (type 1/type 2) and age ( $<30$ ,  $\geq 30$  to  $<65$  years and  $\geq 65$  years). During phase 1, we recruited one patient per segment (total 12 patients) to participate in detailed interviews, which were carried out one-to-one. We carefully listened to and recorded responses regarding therapeutic processes and insulin therapy management. These responses and existing self-efficacy questionnaires, plus opinions from specialists in the field, were used to generate provisional questions regarding the treatment process and to improve the wording of questions intended to measure patients' self-efficacy. During phase 2, we recruited two patients per segment (total 24 patients) to participate in interviews intended to evaluate the following aspects of the scale: comprehensibility, consistency, clarity and with/without discomfort. We subsequently revised questions according to the interview findings.

After completing phases 1 and 2, we carried out a phase 3 study at two institutions. For the phase 3 study, our target sample size was set at 200 patients including 50 with type 1 diabetes mellitus and 150 with type 2 diabetes mellitus. However, we did not exclude other types of insulin using patients. The target sample number was determined according to previous reports of self-efficacy scale development<sup>14–18</sup>.

The study protocol was registered with the University Hospital Medical Information Network (UMIN-CTR: UMIN000020062)

before the commencement of the study. We adhered to the 'Ethical Guidelines for Medical and Health Research Involving Human Subjects' issued by the Japanese government after receiving permission from the ethics committees at each of the participating medical facilities. This study was carried out in accordance with the ethical standards set forth in the Declaration of Helsinki and its later amendments. All participants provided written informed consent after explanation of the study. All personal information was anonymized.

### Phase 3 study

The provisional version of the ITSS questionnaire developed during phases 1 and 2 was used in the phase 3 study concurrently with two other questionnaires: the Diabetes Treatment Satisfaction Questionnaire (DTSQ)<sup>19</sup> and Problem Areas in Diabetes Questionnaire (PAID)<sup>20</sup>. To evaluate reproducibility, we requested  $>50$  patients to complete the provisional version of ITSS twice at an interval of between 1 and 7 days. The patients also answered several questions soliciting information about hypoglycemic episodes during the preceding month, a subjective evaluation of glycemic control and quality of their communications with physicians about insulin treatment. The latter two questions were scored using a 5-point Likert scale ranging from 'very good' (5 points) to 'very bad' (1 point) and from 'could communicate all of my thoughts and feelings' (5 points) to 'did not communicate any of my thoughts and feelings' (1 point), respectively. The patients completed the questionnaires by themselves and in private to avoid any influences from physicians and healthcare providers. Additionally, patients' characteristics, including sex, age, glycosylated hemoglobin (HbA1c) level, type of diabetes mellitus, duration of diabetes, duration of insulin treatment, number of insulin injections/day, total insulin dosage/day, presence or absence of allowance/instruction for insulin self-titration and complications, were recorded by physicians on a case report form.

### Scoring of the questionnaires

The provisional version of the ITSS comprised of 21 questions, which were scored using a 7-point Likert scale ranging from 'absolutely confident' (7 points) to 'not confident at all' (1 point). After the simple summation of the item scores, the total and domain scores were converted to a 100-point range (worst 0 to best 100). If any answer was missing from an item in a domain, the score of that domain was not calculated nor was it considered for the total score.

The DTSQ and PAID were scored according to previously described procedures<sup>19,20</sup>.

### Implementation status after 6 months

Six months after completion of the ITSS questionnaire in the phase 3 study, we asked patients at Nara Medical University a single question to determine their insulin injection status: 'How many times did you forget your insulin injection in the past month?' The answers were selected from the following five

choices: (i) four or more times per week; (ii) two to three times per week; (iii) one time per week; (iv) one to three times per month; or (v) never. These choices were recorded as implementation scores of 1–5, respectively, with a higher implementation score indicating better adherence to insulin injection therapy. All patients who were enrolled at Nara Medical University and continued to attend the institute during the study were investigated. We used data collected from patients who did not change their number of injection times per day within a 6-month period.

### Statistical analysis in the phase 3 study

Patients were excluded from the analysis set if a provisional version of the ITSS questionnaire was not collected. The descriptive statistics of patients' characteristics were calculated, and all statistical tests were two-sided with a significance level of 5%.

### Construct validity and internal consistency

We carried out a factor analysis of the 21 items of the provisional version of the ITSS to determine the domains; data from patients without missing entries for any of the questionnaire's 21 items were used. We applied a four-factor model with promax rotation – we expected to generate four domains from the contents of the questions. After the factor analysis, Cronbach's  $\alpha$  was calculated for the total score and each domain score to evaluate internal consistency.

### Reproducibility analysis

The test–retest method was used to carry out a reproducibility analysis on a subpopulation of patients who completed the provisional version of the ITSS twice. The weighted  $\kappa$  statistics were calculated for each question, and the intraclass correlation coefficients were calculated for the total score and each domain score.

### Criterion-based validity

We analyzed the correlations of the ITSS scores with the DTSQ and PAID scores to determine concurrent validity. Additionally, we analyzed the correlations between ITSS scores and patients' characteristics and experiences to determine discriminant validity. These analyses utilized Spearman's rank correlation coefficients. We also carried out a subgroup analysis to examine associations between ITSS scores and patients' characteristics and experiences. Here, we applied the unpaired *t*-test for comparisons of two subgroups, and the Jonckheere–Terpstra trend test for comparisons of three or more subgroups.

### Predictive validity

A Spearman's rank correlation analysis of the ITSS scores with the implementation scores collected 6 months after ITSS questionnaire completion was carried out to evaluate predictive validity.

## RESULTS

### Participants

A total of 222 patients were enrolled in the phase 3 study from May 2015 to June 2016. After excluding seven patients from

the analysis, due to the lack of collected ITSS questionnaires, 215 patients were included in the analysis set (Figure S1). Table 1 lists the characteristics of patients in the analysis set (data are presented as numbers and percentages or means  $\pm$  standard deviations). The analysis set included 110 men (51.2%) and 105 women (48.8%), with a mean age of  $62.7 \pm 12.8$  years and HbA1c of  $7.8 \pm 1.0\%$  ( $62 \pm 11$  mmol/mol). Regarding diabetes mellitus type, 61 patients (28.4%) had type 1 diabetes mellitus and 153 (71.2%) had type 2 diabetes mellitus. One (0.5%) patient had steroid diabetes.

### Factor analysis and Cronbach's $\alpha$

Table 2 lists the 21 items in the ITSS and the scores from the analysis set, while Table 3 lists the factor loadings resulting from the factor analysis; here, we assigned each item to a factor – if its factor of loading was  $\geq 0.3$ . A total of 20 items showed clear results. However, item 16 had factor loadings of 0.423 for factor 1 and 0.377 for factor 2; we determined that item 16 should be included in factor 2, which comprises questions about insulin titration adjustments. Factor analysis yielded the following groupings: factor 1, 12 items (items 1–6, 9–11, 14, 17 and 18) within a domain regarding confidence about the insulin injection procedure; factor 2, four items (items 7, 8, 15 and 16) regarding confidence with insulin titration; factor 3, three items (items 19–21) regarding confidence with glycemic control; and factor 4, two items (items 12 and 13) regarding confidence in the ability to cope with hypoglycemia. Subsequently, Cronbach's  $\alpha$  coefficients were calculated for the total score and the four candidate domains (Table S1). All  $\alpha$  coefficients

**Table 1** | Patient characteristics

Characteristics	
<i>n</i>	215
Sex (male/female)	110 (51.2)/105 (48.8)
Diabetes type (type 1/type 2/other)	61 (28.4)/153 (71.2)/1 (0.5)
Age (years)	$62.7 \pm 12.8$
HbA1c (NGSP%)	$7.8 \pm 1.0$
HbA1c (mmol/mol)	$62 \pm 11$
Duration of diabetes (years)	$18.9 \pm 10.2$
Duration of insulin therapy (years)	$11.3 \pm 9.1$
Dosage of insulin (units/day)	$29.9 \pm 17.4$
Insulin injections (times/day)	$3.0 \pm 1.3$
Complications	
Neuropathy	87 (40.5)
Nephropathy	94 (43.7)
Retinopathy	105 (48.8)
Arteriosclerotic disease	43 (20.0)
Coronary artery disease	26 (12.5)
Cerebrovascular disease	17 (8.2)
Peripheral arterial disease	5 (2.4)

Data are presented as numbers (%) or mean  $\pm$  standard deviation. HbA1c, glycosylated hemoglobin; NGSP, National Glycohemoglobin Standardization Program.

exceeded 0.80, showing good internal consistency in the candidate domains.

**Reproducibility test**

Of the 222 enrolled patients, 62 were assigned to reproducibility testing. The final reproducibility analysis set comprised of 59 of these patients from whom two sets of questionnaires were collected (Figure S1). The weighted  $\kappa$  statistics for the reproducibility analysis set (Table S2) ranged from 0.45 to 0.80; 18 of 21 items received a value of  $\geq 0.60$ , whereas the other three items had values of 0.45, 0.55 and 0.59. The former 18 items showed good reproducibility, whereas the latter showed moderate reproducibility; in summary, none of the items showed unsatisfactory reproducibility. The intraclass correlation coefficients for all items exceeded 0.88 (Table S3), showing good reproducibility for both the total score and the candidate domains.

**Concurrent validity**

The results of correlation analysis between ITSS scores and DTSQ and PAID scores are shown in Table 4. There were significant, positive correlations (0.26–0.53) between DTSQ total score and ITSS scores. In contrast, negative correlations were observed between ITSS domain 3 and DTSQ Q2, and between ITSS total score and DTSQ Q2 (–0.40 and –0.18, respectively). Furthermore, ITSS domain 3 correlated positively

**Table 3** | Factor analysis with four factors

Item no.	Factor loading			
	1	2	3	4
1.	0.646 <sup>†</sup>	0.062	–0.272	0.035
2.	0.632 <sup>†</sup>	0.080	–0.183	–0.002
3.	0.585 <sup>†</sup>	0.008	0.003	–0.056
4.	0.656 <sup>†</sup>	–0.007	0.088	–0.054
5.	0.809 <sup>†</sup>	–0.086	0.097	–0.035
6.	0.800 <sup>†</sup>	–0.134	0.023	0.002
7.	–0.035	0.892 <sup>†</sup>	–0.009	–0.004
8.	–0.019	0.986 <sup>†</sup>	–0.040	–0.032
9.	0.571 <sup>†</sup>	0.125	–0.081	0.067
10.	0.503 <sup>†</sup>	–0.048	0.030	0.084
11.	0.494 <sup>†</sup>	0.158	0.029	–0.006
12.	–0.053	–0.012	–0.030	0.941 <sup>†</sup>
13.	0.129	0.036	0.046	0.773 <sup>†</sup>
14.	0.419 <sup>†</sup>	0.273	0.063	0.150
15.	0.033	0.703 <sup>†</sup>	0.107	0.065
16.	0.423	0.377 <sup>†</sup>	0.072	–0.076
17.	0.539 <sup>†</sup>	–0.011	0.261	0.032
18.	0.692 <sup>†</sup>	–0.031	0.128	0.018
19.	0.025	0.001	0.761 <sup>†</sup>	0.042
20.	–0.120	0.069	0.889 <sup>†</sup>	–0.005
21.	0.050	–0.015	0.785 <sup>†</sup>	–0.034

The principal factor method with four-factor promax rotation was applied.  $n = 207$ . <sup>†</sup>Values of factor loadings in the attributed domain.

**Table 2** | Summary of item scores

Item no.	Item	<i>n</i>	Score
1.	I can turn the dial to set the correct insulin dose (units).	213	6.4 ± 0.8
2.	I can correctly inject insulin into the intended part of my body (e.g., abdomen, thigh).	213	6.3 ± 0.8
3.	I can press the knob on the pen-type injector and wait 5–10 s (depending on the injector type) without removing the needle.	213	6.2 ± 0.9
4.	I can always carry my insulin injection tools when away from home.	213	5.9 ± 1.3
5.	Each day, I can perform the scheduled number of insulin injections.	213	6.3 ± 0.9
6.	Each time, I can inject the dose (units) of insulin prescribed after discussion with my physician.	213	6.4 ± 0.8
7.	I can self-increase the dose (units) of insulin when my blood sugar is high.	213	5.1 ± 1.7
8.	I can decrease the dose (units) of insulin when my blood sugar is low.	213	5.0 ± 1.6
9.	I understand the efficacy of insulin injection as a means of controlling my blood sugar level.	213	6.2 ± 0.9
10.	I can inject insulin when other people are around, without hesitation or needing to find a private location.	212	5.5 ± 1.4
11.	I can discuss the dose (units) of insulin with my physician.	212	5.9 ± 1.0
12.	I can recognize the symptoms of hypoglycemia.	212	5.5 ± 1.3
13.	I can consume glucose (sugar) or do something else to ameliorate my sugar level when I have hypoglycemia.	211	5.7 ± 1.3
14.	I understand what to do when I realize I have missed a scheduled insulin injection.	211	5.4 ± 1.2
15.	I can adjust the dose (units) of insulin when I am ill and have a fever, diarrhea or lack of appetite for food.	212	4.8 ± 1.5
16.	I can adjust the dose (units) of insulin by myself or after consulting with my physician after seeing the result of my self-monitoring of blood glucose levels.	212	5.6 ± 1.1
17.	Each day, I perform the scheduled number of blood sugar measurements.	212	5.6 ± 1.4
18.	I never miss my insulin injection.	212	5.7 ± 1.4
19.	I can maintain a blood glucose level of 130 mg/dL or lower before breakfast.	212	3.8 ± 1.5
20.	I can maintain a blood glucose level of 180 mg/dL or lower after meals.	214	3.6 ± 1.4
21.	I can maintain the target HbA1c level discussed with my physician.	213	3.8 ± 1.3

The scores are shown as mean ± standard deviation. All items were scored on a 7-point scale (1 is the worst, 7 is the best).

with DTSQ Q3 (0.18). All correlations between ITSS scores and PAID scores were negative and significant, with correlation coefficients ranging from  $-0.45$  to  $-0.22$ .

### Discriminant validity

Table 4 shows the results of the correlation analyses for discriminant validity. The type of diabetes mellitus was found to correlate with domains 2 and 3, such that there were higher domain 2 and lower domain 3 scores in type 1 diabetes mellitus compared with type 2 diabetes mellitus. HbA1c correlated negatively with the total and domain 3, whereas age and duration of diabetes correlated positively with the total and domains 1, 3 and 4. The duration of insulin therapy correlated positively with the total and domains 2 and 4. The number of insulin injections/day correlated positively with domain 2 and negatively with domain 3, whereas the daily insulin dosage correlated negatively with domains 1 and 3. The frequency of hypoglycemic episodes was positively associated with domain 2. The subjective evaluation for glycemic control was positively associated with the total, and domains 1, 3 and 4, whereas the quality of communication with the physician was positively associated with the total, and domains 1, 2 and 4. In contrast, ITSS scores did not associate with the frequencies of nocturnal and severe hypoglycemic episodes.

Table 5 presents a subgroup analysis of ITSS total scores. Significant differences were observed among subgroups stratified by the duration of diabetes, allowance/instruction of insulin self-titration and neuropathy. Trend tests for three or more subgroups identified significant trends in HbA1c, subjective evaluation of glycemic control and quality of communication with the physician. Patients with a higher ITSS total score tended to have a lower HbA1c, better subjective evaluation of glycemic control and better communication with their physician.

### Predictive validity

We asked 130 patients to answer a question regarding their insulin injection implementation status 6 months later. The available responses from 114 patients (Figure S2) were subjected to a correlation analysis (Table 4). The implementation status significantly positively correlated with the total score, and domains 1, 2 and 4.

### DISCUSSION

In the present study, we developed and validated the ITSS questionnaire, which we intend for use as a measure of patients' self-efficacy regarding insulin therapy. Good construct validity and internal consistency of the 21 items were confirmed. The items

**Table 4** | Correlations of Insulin Therapy Self-efficacy Scale scores with other parameters

	ITSS scores				
	D1	D2	D3	D4	Total
Other QOL scores					
DTSQ total (treatment satisfaction)	0.53***	0.31***	0.26***	0.32***	0.49***
DTSQ Q2 (hyperglycemia)	-0.11	-0.06	-0.40***	-0.08	-0.18**
DTSQ Q3 (hypoglycemia)	0.01	0.11	0.18**	0.08	0.09
PAID	-0.45***	-0.24***	-0.22**	-0.32***	-0.43***
Patient characteristics					
Type of diabetes mellitus	-0.06	-0.27***	0.14*	0.01	-0.10
HbA1c	-0.11	-0.01	-0.39***	-0.01	-0.18**
Age	0.21**	-0.04	0.23***	0.22**	0.18**
Duration of diabetes	0.20**	0.11	0.17*	0.20**	0.20**
Duration of insulin therapy	0.11	0.27***	-0.06	0.22**	0.17*
No. insulin injections/day	-0.08	0.16*	-0.17*	-0.01	0.00
Dosage of insulin/day	-0.16*	0.02	-0.16*	-0.02	-0.12
Patient experiences					
Frequency of hypoglycemic episode	0.03	0.25***	-0.06	0.04	0.11
Frequency of nocturnal hypoglycemic episode	-0.09	0.11	-0.01	-0.02	-0.02
Frequency of severe hypoglycemic episode	0.01	0.12	-0.08	-0.09	0.01
Subjective evaluation for glycemic control	0.19**	0.05	0.46***	0.14*	0.24***
Communication with physician	0.39***	0.27***	0.12	0.27***	0.36***
Implementation score					
Implementation score	0.43***	0.30**	0.12	0.23*	0.44***

Spearman's rank correlation coefficients are shown; \* $P < 0.05$ , \*\* $P < 0.01$ , \*\*\* $P < 0.001$ . D1, domain 1 regarding 'confidence about the insulin injection procedure'; D2, domain 2 regarding 'confidence with insulin titration'; D3, domain 3 regarding 'confidence with glycemic control'; D4, regarding 'confidence in the ability to cope with hypoglycemia'; DTSQ, Diabetes Treatment Satisfaction Questionnaire; HbA1c, glycosylated hemoglobin; ITSS, Insulin Therapy Self-efficacy Scale; PAID, Problem Areas in Diabetes Questionnaire; QOL, quality of life.

**Table 5** | Insulin Therapy Self-efficacy Scale total scores in the subgroup analyses

Factors	n	Score	P-value
Type of diabetes mellitus			
Type 1	61	76.1 ± 10.6	0.14
Type 2	145	73.6 ± 12.6	
HbA1c			
<Median	95	76.2 ± 11.9	0.07
≥Median	108	73.1 ± 12.2	
HbA1c			
<7%	33	77.7 ± 12.4	0.020
≥7%, <8%	90	75.1 ± 12.1	
≥8%	80	72.6 ± 11.9	
Age			
<Median	100	73.0 ± 12.8	0.11
≥Median	107	75.7 ± 11.4	
Age (years)			
<65	96	72.7 ± 12.8	0.06
≥65	111	75.9 ± 11.4	
Duration of diabetes			
<Median	96	71.4 ± 12.3	0.001
≥Median	109	76.8 ± 11.5	
Duration of insulin therapy			
<Median	93	73.5 ± 12.2	0.29
≥Median	111	75.3 ± 12.2	
Insulin injections/day			
<Median	92	75.0 ± 11.9	0.50
≥Median	115	73.9 ± 12.3	
Dosage of insulin/day			
<Median	99	75.5 ± 12.7	0.20
≥Median	108	73.4 ± 11.6	
Sex			
Male	105	74.9 ± 12.4	0.59
Female	102	73.9 ± 11.8	
Allowance/instruction for insulin self-titration			
Yes	147	75.7 ± 11.8	0.014
No	60	71.2 ± 12.4	
Neuropathy			
Yes	84	76.9 ± 10.1	0.010
No	101	72.3 ± 13.4	
Nephropathy			
Yes	91	74.4 ± 12.0	0.98
No	116	74.4 ± 12.3	
Retinopathy			
Yes	100	75.9 ± 11.7	0.09
No	99	73.0 ± 12.4	
Arteriosclerotic disease			
Yes	40	77.5 ± 11.6	0.08
No	160	73.8 ± 12.1	
Hypoglycemia			
Yes	102	75.2 ± 11.4	0.35
No	103	73.7 ± 12.9	
Nocturnal hypoglycemia			
Yes	39	74.0 ± 11.9	0.78
No	166	74.6 ± 12.3	

**Table 5** (Continued)

Factors	n	Score	P-value
Severe hypoglycemia			
Yes	6	75.4 ± 7.1	0.85
No	199	74.4 ± 12.3	
Subjective evaluation of glycemic control			
Very good	9	81.1 ± 8.2	<0.001
Good	81	77.0 ± 12.5	
Neither	76	72.6 ± 12.4	
Bad	33	69.8 ± 10.0	
Very bad	6	74.7 ± 9.4	
Quality of communication with physician			
Well	114	77.8 ± 11.7	<0.001
Somewhat	69	71.9 ± 10.9	
Neither	17	67.6 ± 11.2	
Not much	5	55.6 ± 9.8	
Not at all	0	–	

Data are expressed as mean ± standard deviation. The *t*-test was used for subgroup comparisons of two categories, whereas the Jonckheere–Terpstra trend test was used for subgroup comparisons of three or more categories. HbA1c, glycosylated hemoglobin; ITSS, Insulin Therapy Self-efficacy Scale.

were classified into four factors, namely the domains of ‘confidence about the insulin injection procedure,’ ‘confidence with insulin titration,’ ‘confidence with glycemic control’ and ‘confidence in the ability to cope with hypoglycemia.’ We also confirmed the tool has good reproducibility.

In subsequent analyses for concurrent validity, the positive correlations of ITSS scores with DTSQ total score showed that patients with a higher level of treatment satisfaction tended to exhibit better self-efficacy. Furthermore, negative correlations of DTSQ Q2 with ITSS domain 3 and total scores showed that patients with a higher level of confidence with glycemic control tended to experience fewer concerns about hyperglycemia. Finally, the negative correlations of ITSS scores with PAID score showed that patients with better self-efficacy and confidence tend to experience less diabetes-related distress. In summary, the ITSS questionnaire provides a good reflection of a patient’s psychological perception regarding insulin therapy and shows good concurrent validity.

The ITSS total score was also found to correlate with important clinical indicators, and patient characteristics and experiences. Notably, the ITSS total score and domain 3 correlated negatively with HbA1c, an objective index of glycemic control. Similar negative correlations between self-efficacy and objective indices of glycemic control have been reported in studies of other self-efficacy questionnaires, such as the Diabetes Management Self-Efficacy Scale<sup>13,21,22</sup>, Confidence in Diabetes Self-Care<sup>17</sup> and Diabetes Self-Efficacy Scale<sup>23</sup>. However, the ITSS, and particularly domain 3, is a good indicator of objective glycemic index, even in comparison with these other tools.

Furthermore, the ITSS was shown to provide a good reflection of patients' subjective self-evaluations of glycemic control. By contrast, domain 4, which addresses 'confidence in the ability to cope with hypoglycemia,' did not correlate with the frequency of any type of hypoglycemic episode. It was influenced by age, duration of diabetes, duration of insulin therapy, quality of communication with the physician and, interestingly, the subjective evaluation of glycemic control. This last correlation suggests that the patient's awareness of good glycemic control and active self-involvement in glycemic control requires confidence in one's ability to cope with hypoglycemia.

Similarly, patients with longer duration of diabetes mellitus and insulin therapy had higher total ITSS scores, suggesting that confidence increases with the length of experience with insulin therapy. Good quality of communication with a physician was also found to correlate with ITSS scores, suggesting that either good communication increases a patient's confidence or more confident patients communicate better with physicians. Regardless, good communication with the physician is important to a patient's confidence with insulin therapy and, therefore, the future success of insulin treatment. The ITSS reflects the patients' confidence and self-efficacy regarding multiple aspects of insulin therapy, with good discriminant validity.

We confirmed that the ITSS was a good predictor of future behavior by testing implementation status after 6 months. Accordingly, the ITSS will be useful for the evaluation and prediction of patients' future therapeutic success. In particular, patients' confidence regarding the insulin injection procedure and insulin titration is suggested to be important for their implementation of insulin injection therapy.

We note that several questionnaires with diabetes therapy-related self-efficacy scales have been developed<sup>13–18</sup>. These questionnaires comprise items related to general self-management, diet therapy, exercise therapy, medication, weight management and foot care. One such questionnaire, Confidence in Diabetes Self-Care, was developed for patients with type 1 diabetes mellitus and comprises of 20 items, including three related to insulin therapy<sup>17</sup>. Another scale, Insulin Management Diabetes Self-Efficacy Scale, was developed for patients using insulin therapy and has 28 items, including 11 insulin subscale items<sup>15</sup>. Self-Efficacy for Diabetes is a scale developed for adolescents with insulin-dependent diabetes mellitus (mean age  $13.4 \pm 4.5$  years)<sup>14</sup>. The ITSS was developed to address patients with both type 1 diabetes mellitus and type 2 diabetes mellitus over a wide range of ages (23–84 years), and covers items addressed by the Insulin Management Diabetes Self-Efficacy Scale insulin subscale and more detailed items regarding the entire process related to insulin therapy.

Several limitations in the present study should be noted. First, this study was carried out at two institutions, and therefore, the possibility of sample bias cannot be excluded. However, we broadly and consecutively enrolled patients who received insulin therapy, and the participants were demographically diverse in terms of sex, age, diabetes type, disease

duration, insulin therapy duration and complications. Second, all participants were Japanese, and therefore, we could not evaluate the influences of ethnicity, race and/or region. Third, this questionnaire was developed in Japanese. Accordingly, the validity and reliability of versions translated into different languages should be further evaluated in populations of non-Japanese patients.

Insulin therapy is a powerful and essential component of diabetes treatment, but it cannot be considered a perfect therapy, given its association with issues such as hypoglycemia, weight increases and the burden of self-management of daily therapeutic injections for a long duration. Newer second-generation, basal insulin formulas might overcome some of the limitations; however, patient education and empowerment remain important elements. To improve the success of insulin therapy, physicians must determine the sources and nature of the problems faced by patients. The ITSS questionnaire will help physicians to identify and resolve these underlying issues with insulin therapy, and provide support to patients to increase their self-confidence. We believe that our questionnaire will help patients and physicians achieve success with insulin therapy.

The ITSS is a reliable and valid insulin therapy-specific self-efficacy scale that can assess a patient's self-efficacy and confidence in four domains regarding the insulin injection procedure, insulin titration, glycemic control and the ability to cope with hypoglycemia. Furthermore, the ITSS can predict a patient's future adherence to insulin therapy. These characteristics will ensure the clinical usefulness of the ITSS as a measure of patient self-efficacy and will lead to future treatment success.

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

**Figure S1** | Flowchart of the analysis set and reproducibility analysis set in the phase 3 study.

**Figure S2** | Flowchart for the implementation analysis set in the phase 3 study.

**Table S1** | Domain scores and Cronbach's  $\alpha$  coefficients.

**Table S2** | Reproducibility analysis test.

**Table S3** | Intraclass correlation coefficient.