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Original research article

Psychometric properties of the Czech version of the Insulin Delivery System Rating Questionnaire

Lenka Machálková [1] *, Eva Reiterová [1], Monika Durďáková [1], Elena Gurková [2]

[1] *Palacký University in Olomouc, Faculty of Health Sciences, Department of Nursing, Olomouc, Czech Republic*
[2] *University of Presov in Presov, Faculty of Health Care, Department of Nursing, Presov, Slovak Republic*

Abstract
Aim: The study deals with the linguistic validation and selected aspects (constructive validity and reliability) of the Insulin Delivery System Rating Questionnaire (IDSRQ).
Methods: The examined file consisted of 151 patients with type 1 diabetes mellitus. The linguistic and content validation IDSRQ was performed, and the results of the questionnaire and individual subscales were processed via descriptive statistics and factor analysis.
Results: The data was used to calculate the reliability of seven original subscales (0.42–0.92). Construct validity was tested via exploratory and confirmatory factor analysis. Models M1, M2 and M3, were created. For models M2 and M3, the significance of the chi-square test ($p < 0.001$) and FIT indices was calculated. The five-factor model with a reliability of 0.69–0.89 in subscales was identified as the best.
Conclusion: The new version of the questionnaire is in line with the psychometric properties of the original tool, and the extraction of items into a five-factor solution reflects the current assessment of patients' satisfaction with type 1 diabetes mellitus therapy in the Czech environment.

Keywords: Application insulin; Construct validity; Diabetes mellitus; Reliability

Introduction

In 2021, the prevalence of diabetes mellitus (DM) in European countries was on average 9.2%, and this is predicted to rise to 10.4% by 2045 (Sun et al., 2022). The number of diabetic patients is rapidly increasing in the Czech Republic (CR). In 2019, the number of people with DM was more than 1 million, approximately 7% with type 1 diabetes mellitus (T1DM), and insulin (INS) was applied by more than 208,000 people (Institute of Health Information and Statistics of the Czech Republic, 2020). Patients treated in the Czech Republic with T1DM can apply multiple daily injections (MDI) or use continuous subcutaneous insulin infusions (CSII) (Prázný et al., 2019).

In the treatment of T1DM, not only professional counselling, psychological and social support, education, self-management skills, and self-monitoring (Mehta et al., 2021) are applied, but there is also the possibility of effective INS application through technologies. The patient's satisfaction is reflected within social relationships and is associated with a higher level of disease management (Todres et al., 2010). T1DM patients are dependent on lifelong insulin therapy. Insulin can be administered by CSII into the human body via a cannula inserted into the subcutaneous tissue.

Minimal doses are applied for the duration of the day (basal mode), or a dose is applied across time intervals (bolus mode) (Štechová, 2019). Application through CSII is suitable for patients from the point of view of performing daily activities (Prázný et al., 2019). These are physical, work activities, eating, and travelling (Bayrakdar et al., 2014). One of the reasons why patients reject changing the method of INS administration is the constant re-connecting of an insulin pump (Mesbah et al., 2020). Further options include the application of multiple INS injections through insulin pens (MDI). Adherence to MDI is affected by the necessity to apply multiple injections in a day (up to five times a day). Injection application limits daily activities and disrupts life. Furthermore, it is exacerbated by the lack of discretion, pains associated with the application, and the need for psychological support (Kruger et al., 2015; Peyrot et al., 2010). Chronic T1DM disease and any complications that arise can affect the quality of life of a patient (Siboni et al., 2019). Health Related Quality of Life (HRQoL) evaluation is desirable in patients with a chronic disease to identify areas affected by the impact of the disease (Megari, 2013; Siboni et al., 2019), and by a change of therapy (Megari, 2013). Specific evaluation tools and scales are used for subjective assessment of the quality of life (Nair and Kachan, 2017). Peyrot and Rubin (2005) compiled the IDSRQ questionnaire to assess insulin application.

* **Corresponding author:** Lenka Machálková, Palacký University in Olomouc, Faculty of Health Sciences, Department of Nursing, Hněvotínská 3, 775 15 Olomouc, Czech Republic; e-mail: lenka.machalkova@upol.cz
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The aim of this study was the linguistic and content validation and selected aspects of psychometric validation (construct validity, reliability) of the IDSRQ questionnaire for the Czech environment.

Materials and methods

Group of respondents

A purposive sampling method was chosen to select respondents (Creswell and Creswell, 2018) and inclusion criteria were set: age 18 years or older, T1DM disease, treatment with CSII or MDI for at least 1 year (Bayrakdar et al., 2014; Peyrot and Rubin, 2005), and consent to participate in the study. Exclusion criteria included patients with type 2 diabetes mellitus, younger than 18 years, hearing impaired, and speech impaired.

IDSRQ Assessment

The IDSRQ questionnaire by Peyrot and Rubin (2005) can be used to assess patient satisfaction with DM treatment and the impact of specific treatments according to INS application. Based on the content of the specified items, the IDSRQ tool is more sensitive to capturing the patients' perception of aspects of treatment. The questionnaire is composed of items divided into seven subscales according to their content. Treatment Satisfaction (15 items), Treatment Interference with Daily Activities (11 items), and Clinical Effectiveness of Treatment (9 items) subscales contain questions that specifically focus on the method of insulin administration. The subscales, such as Diabetes Concerns (6 items), Social Burden (7 items) and Psychological Wellbeing (15 items) contain more generic questions. The Overall Preference of Treatment subscale (4 items) is focused on treatment assessments. For each subscale, respondents reported their ratings using variations of a 4-point Likert scale, from 1 (completely satisfied, very satisfied, constantly satisfied) to 4 (completely dissatisfied, not at all satisfied, never satisfied). The questionnaire also includes patient clinical characteristics (*e.g.*, age, gender, age at diagnosis of diabetes, age at the start of insulin use, and duration of insulin administration).

Data collection took place from 11/2020 to 3/2021.

Language validation and the results of the cultural adaptation of IDSRQ tool to the Czech language

Linguistic validation

In nursing environments, assessment and measurement tools are emerging in English-speaking dominant countries and other sociocultural backgrounds. To use a specific tool, a linguistic translation, and adaptation into another target language according to a set of recommended procedures for linguistic validation is necessary. Careful preparation and planning of a methodologically suitable procedure are necessary for the translation, adaptation, and cross-cultural use of a particular tool in other countries. For the translation, the methodology of Wild et al. (2005) was used to highlight the different stages within the translation process. The translation of the tool aims to produce a version in another language (Czech in this study) according to the criteria for translation: respecting the cultural context of the translation and the meaning of particular words, phrases, and expressions (Sousa and Rojjanasrirat, 2011; Wild et al., 2005).

The validation process of IDSRQ was initiated after obtaining the original version of the tool, consent for use, translating of the tool into the Czech language, and application of the research study by Peyrot and Rubin (2005). The first step of the validation process involved approaching translators and the persons interested in the validation process and obtaining their consent for collaboration. Step two involved translation by three independent translators into the target language. The persons were living in the Czech Republic; one was a professional translator, another a native speaker, and one an expert in the field. In step 3, a comparison and consensus of the three Czech versions were made with the participation of a professional translator, a researcher, and an expert in the field. Simultaneously, the appropriateness of the content and the meaning of the translation were assessed, and phrases were eliminated based on cultural aspects and suitability of inclusion. On the recommendation of the expert in the field, the variant "Needleless Injector" was excluded from the insulin delivery system, as it is not offered in the Czech Republic. In step 4 of the process, a reverse translation from Czech to English was performed by three independent translators (a professional translator, a native speaker, an expert in the field), and three versions in English were obtained. The comparison with the original tool version was carried out in step 5 of the process. The translated versions were compared and evaluated with the original tool by the researcher, the expert in the field, and the translator.

Content validity

In step 6, the working Czech version of IDSRQ-CZ questionnaire was assessed by a team of experts (nursing academic, researcher, and translator). In step 7, cognitive debriefing was carried out to determine the level of comprehensibility and cognitive equivalence of the translation of the tool in 10 adult patients with T1DM living in the Czech Republic. Based on their comments, minor adjustments were made (step 8 of the process). A misunderstanding was identified for questions within the respondent's clinical characteristics. A response option "continuous blood sugar monitoring (sensor)" was added to the question on the frequency of blood sugar monitoring. In the question of what type of INS you use, there was a change from a closed to an open question, allowing the respondent to indicate the specific type of INS used. There was a misunderstanding of items in the Treatment Interference with Daily Activities and Clinical Effectiveness of Treatment subscales. Items were reworded maintaining the original content. The validation process included proofreading and editing the translation of the tool in the Czech language and checking for stylistic and linguistic correctness (step 9). The last step (step 10) resulted in the creation of the Czech version of the questionnaire "Method of insulin administration – evaluation questionnaire". The final adjustments, including the numerical designation of the items (1 to 67) and the correction of the questionnaire were carried out by the researcher, a university expert in the Czech language, and a translator. For the research in this study, the IDSRQ questionnaire in the Czech version was supplemented with sociodemographic information (education, marital status, family background of the respondent). To conclude the whole process, content validity of the tool was performed.

Content validity index (CVI)

A total of 5 nurses with a minimum of 10 years of experience in diabetes evaluated the Czech version of the IDSRQ tool for content validity. The experts rated the items using a Likert-type scale with options ranging from 1 (not relevant) to 4 (highly relevant). According to Kline (2011), the content validity index (CVI) should be interpreted as follows: 0.90 (excellent), 0.80 (very good), and 0.70 (sufficient). The range of

expert agreement in this study was 0.81 to 0.97. The lowest admissible value of 0.78 (Polit et al., 2007) for individual items (I-CVI) was not obtained for any item (I-CVI = 0.8–1.0). The S-CVI/Ave score, which is calculated as the average of the I-CVI between the scale items was 0.91, which Polit et al. (2007) rated as excellent. No adjustments to the instrument were made due to these findings, and content validity was guaranteed.

Statistical analysis

The statistical software IBM SPSS version 24, Statistica.cz version – 12, Microsoft Excel, and Jamovi 2.2.5 programme were used to process the statistical data.

Descriptive statistics

The results of anamnestic data were processed using descriptive statistics (%, mean, standard deviation). Multi-item subscales in the questionnaire were evaluated individually. The Total Treatment Preference subscale (3–4 items) was analysed from two perspectives, based on the number of items included according to the author's methodology.

Construct validity

Exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) were used to confirm construct validity (Hendl and Remr, 2017). Using EFA, three models (M1, M2, M3) with a different number of items were created. Factor analysis (FA) was conducted on the questionnaire items to identify a reduced number of common factors. Based on eigenvalues >1 and a scatter plot, the required number of factors was identified (Williams et al., 2010), and the first M1 model was developed. Two more variants of the models (M2, M3) were built within the CFA. For each M2, M3 model variant, the CFA coefficients Comparative fit index (CFI), Tucker–Levis index (TLI), and Standardized Root Mean Square Residual (RMSEA) were calculated. Based on the values found, M3 was selected as the best fitting model. Pearson's correlation coefficient was used to assess the relationships between the factors in the M3 model.

Reliability

In this study, the psychometric analysis of the questionnaire was also conducted from the perspective of reliability analysis. In terms of reliability, an analysis was conducted to analyse the internal consistency of the questionnaire by calculating the Cronbach's alpha coefficient for all items and for items in each subscale.

Results

Group of respondents

The final sample consisted of 151 (100%) respondents with T1DM, with an average age of 38.9 (SD = 13.1). The average age at the beginning of INS use was 18.1 (SD = 13.1). INS administration using CSII was used by 92 (61%) of respondents, and MDI by 59 (39%). The sample consisted of 69 (45.7%) men and 82 (54.3%) women (Table 1). The respondents' education was predominantly secondary school diplomas (46.4%) and university degrees (21.2%). 50.9 % were married, and 39 % were single. 41% lived with a spouse and children, and 21.9% lived with their partner.

Reliability of the original distribution of items into 7 subscales of IDSRQ

Reliability of the obtained data was calculated using Cronbach's alpha. The reliability for the questionnaire items (1–67) was 0.67. Reliability was also calculated for each subscale of the original questionnaire (Peyrot and Rubin, 2005). Except for the psychological well-being subscale, all others showed good to very good reliability (Table 2).

Table 1. Descriptive statistics of the file (*N* = 151)

Variable	CSII	MDI
Women (%)	49 (60)	33 (40)
Men (%)	43(62)	26 (38)
Age in years (Ø ± SD)	38.16 ± 10.24	40 ± 16.73
Length of INS use in years (Ø ± SD)	12.23 ± 5.72	17.93 ± 8.99
Age at beginning of INS use (Ø ± SD)	14.71 ± 6.43	17.23 ± 11.21
Age at T1DM diagnosis (Ø ± SD)	15.99 ± 8.51	20.2 ± 16.13

Note: CSII – insulin pump; MDI – pen; INS – insulin; T1DM – type 1 diabetes mellitus; Ø – average value; SD – standard deviation.

Table 2. Cronbach alpha values in individual subscales by Peyrot and Rubin (2005)

Subscale	*N*	C_α
Treatment satisfaction	15	0.92
Daily activity interference	11	0.89
Clinical efficacy	9	0.89
Diabetes worries	6	0.79
Social burden	7	0.75
Psychological well-being	15	0.42
Overall preference (4)	4	0.79
Overall preference (3)	3	0.84

Note: N – number of items, C_α – Cronbach alpha.

Construct validity

Construct validity was tested using EFA and CFA. The prerequisites for using EFA were met. The Kaiser–Meyer–Olkin (KMO) measure of selection adequacy indicates a suitable model for the use of EFA. The KMO value = 0.82 is above the recommended value of 0.60 (Kaiser, 1974). Bartlett's test of sphericity for the 67 items of the questionnaire (χ^2 = 7378[2346]) comes out as highly significant ($p < 0.001$) and rejects the null hypothesis of no correlation between items. On the basis of eigenvalues >1 obtained by the principal component method and the scatter plot (Fig. 1), the existence of a six-factor solution to our model was predicted to explain 51.6% of the total variability in the original variables.

In the six-factor M1 model, factors F1–F6 were extracted with the items listed in Table 3. Furthermore, an M2 model was constructed for the 5 factors with the omission of questionnaire item 67 (Table 3). This item clearly does not belong in the questionnaire as it was separated into one subscale and is out of context with the other items. The purpose of the item was to determine whether the respondent had previously used any method of insulin administration other than the current one. The item does not ascertain current issues with INS administration and is more informative for the researcher. It was discarded during the development of the five-factor model. In this study, the five-factor model included 48.7% of the variability. The first factor explained 12.2% of the variance, the second factor explained 12.1% of the variance, the third factor explained 9.9% of the variance, the fourth factor explained 7.3% of the variance, and the fifth factor explained 7.2% of the variance.

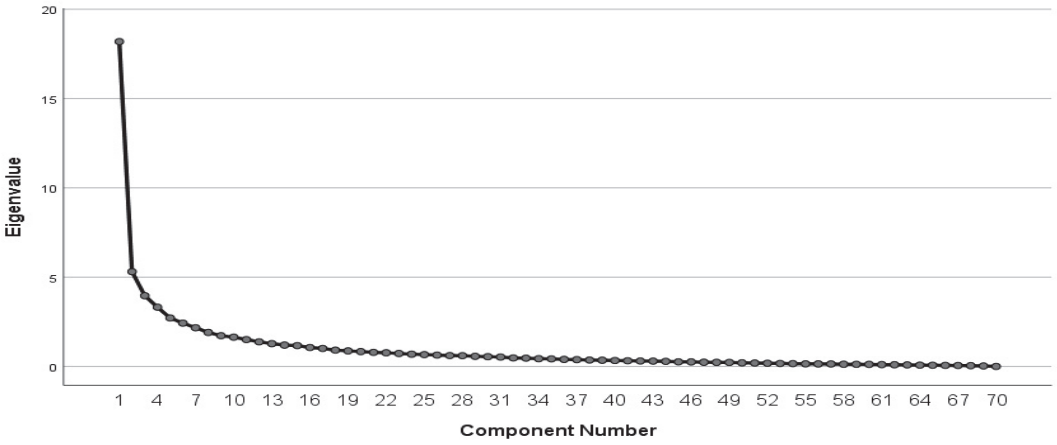

Fig. 1. Scree Plot

Table 3. Distribution of the questionnaire items into subscales of M1 and M2 model

Factor	Six-factor model M1	Five-factor model M2
F1	1–15, 29, 30, 33, 34, 40, 63–67	1–15, 26, 40, 47, 48, 64, 65
F2	27, 28, 31, 32, 35, 49–57, 61	27–35, 49–56, 61, 63
F3	16–26	16–25
F4	36–39, 42, 43, 46, 58–60, 41	36, 38, 41–46, 66
F5	67	37, 39, 57–60, 62
F6	44, 45, 47, 48, 62	–

Note: F1–F6 subscales of the model.

A chi-square test was calculated on the M2 model with a value of 4660 [2069], $p < 0.001$ and FIT index values (Table 4). To improve the chi-square and FIT indices values, an M3 model was created in which new relationships between factors and some variables were found using modification indices. The chi-square value was reduced to 4379[2057], $p < 0.001$. The FIT index values have improved (Table 4), but do not reach the desired level of 0.9. Estimates of the correlations between factors are shown in Table 5. High correlations were found between factors F2 and F5 (0.96) and between factors F4 and F5 (0.92) – Table 5.

Based on the FIT indices (Table 4), a five-factor distribution was confirmed with the following description of the factors (Table 6): F1 labelled Satisfaction – the main item was satisfaction with the current method of administration of INS, how often the respondent worries about being alone at home, how true is the statement that he does not get along with his doctor, that he has to visit the doctor often to control his diabetes, whether he wants to change the method of administration. F2 labelled Positivity – the main aim was to find out how the respondent's current method of INS administration helps with keeping blood sugar stable, having control over blood sugar, preventing low blood sugar, avoiding hospital visits for poor control, not gaining weight, and also questions of psychological wellbeing, frequency of feelings (vitality, good mood, control over one's own body, being able to do what one wants, normal life, whether diabetes limits them). F3 labelled Obstacles – the main question focuses on the issue of the current way of administering INS in the context of carrying out daily activities (dressing, eating, sleeping, self-care when travelling, sex, exercise). F4 labelled Worries – the questions aimed to find out whether the respondent is worried about the onset of complications, low blood sugar, travelling, and also the truth of statements in the context of social burden (the concerns of family and friends about complications surrounding the condition and about control of diabetes), whether the respondent would recommend the INS method of administration to others. F5 labelled Emotions – aimed at discovering whether

Table 4. FIT indices

Fit index	Required value	M2	M3
CFI	>0.9	0.58	0.62
TLI	>0.9	0.56	0.61
RMSEA	<0.1	0.09	0.09

Note: CFI – Comparative fit index, TLI – Tucker-Levis index, RMSEA – Standardized Root Mean Square Residual (Vandenberg and Lance, 2000).

Table 5. Estimated correlations with intervals of reliability among five factors in the M3 model

Factors	F1	F2	F3	F4	F5
F1	1	0.605***	0.408***	0.562***	0.53***
F2		1	0.531***	0.89***	0.959***
F3			1	0.58***	0.539***
F4				1	0.917***
F5					1

Note: F1–F5 extracted factors, *** statistical significance to $p < 0.001$.

the respondent worried about unpredictable/high blood sugar, was anxious, stressed, burnt out, or experienced mood swings. The reliability of individual factors for five-factor solution was calculated via Cronbach's alpha = 0.72–0.89, which is satisfactory (Table 6).

Table 6. Reliability for a five-factor solution in individual factors and the total score

Factor	*N*	C_α
F1 Satisfaction	21	0.84
F2 Positivity	19	0.89
F3 Obstacles	10	0.89
F4 Worries	9	0.72
F5 Emotions	7	0.82
Total score	66	0.69

Note: F1–F5 model factors, *N* – number of items, C_α – Cronbach alpha.

Discussion

The aim of the study was the linguistic and content validation of the IDSRQ instrument, including the evaluation of the psychometric properties of its Czech version, which comprised the verification of construct validity and reliability.

The linguistic validation of the IDSRQ instrument into Czech language was carried out according to the methodology of Wild et al. (2005) and Sousa and Rojjanasritat (2011). As part of the validity, the CVI of the Czech IDSRQ instrument was performed, which reached a value of 0.89. Compared to the study by Coelho et al. (2021), this value is higher than the CVI of the Brazilian version of the IDSRQ instrument (0.87).

To evaluate the reliability of the analysed IDSRQ questionnaire for the Czech environment, internal consistency analysis was used with the calculation of Cronbach's alpha. In the original validation study by Peyrot and Rubin (2005), the reliability for a set of respondents with T1DM and T2DM in individual subscales 1–7 was based on Cronbach's alpha values of 0.67–0.92. The results of this study present processed data for respondents with T1DM only, as do the results of the Coelho et al. (2021) study. In that study, Cronbach's alpha values ranged from 0.42–0.92. The lowest Cronbach's alpha value of 0.42 was for the psychological well-being subscale, and a low Cronbach's alpha value of 0.288 in the same subscale was also reported by Coelho et al. (2021). In the study by Coelho et al. (2021), the Cronbach's alpha values in the seven subscales ranged from 0.288 to 0.906. The Cronbach's alpha values were similar to the present study (0.42 to 0.92). In Peyrot and Rubin's (2005) study, overall treatment preference was analysed in two ways: 1. with an item comparing current and previous treatment strategies based on four items (Cronbach's alpha = 0.67); 2. without an item in the number of three items (Cronbach's alpha = 0.77). The same analysis was used in this study with results for four items (Cronbach's alpha = 0.79) and for three items (Cronbach's alpha = 0.84). These are more satisfactory reliability coefficient values for this study's data. The higher internal consistency of the tool may have been influenced by narrow selection (T1DM patients only were included). The study of Peyrot and Rubin (2005), which had a representation of respondents with T1DM and T2DM, divided the questionnaire into 7 subscales with descriptions of Treatment Satisfaction (15 items), Daily Activity Interference (11 items), Clinical Efficacy (9 items), Diabetes Worries (6 items), Social Burden (7 items), Psychological Wellbeing (15 items), and Overall Preference (3, 4 items).

In our research, which only included respondents with T1DM, the questionnaire items were extracted into 5 subscales: Satisfaction (21 items), Positivity (19 items), Obstacles (11 items), Worries (9 items), and Emotions (7 items). Relationships between other items and factors were also incorporated in the M3 model. The chi-square test value for the M2 model was = 4660, $p < 0.001$, and for the M3 model it was reduced to 4379, $p < 0.001$. Although they did not reach the desired values, the fit indices CFI and TLI came out better for the M3 model compared to M2, (CFI for M2 = 0.58, for M3 = 0.62; TLI for M2 = 0.56, for M3 = 0.61). The magnitude of the RMSEA index for M2 = 0.09 and for M3 = 0.09 met the required value of <0.1. Based on the better values of the FIT indices and the correlations between factors, in this study the M3 model can be considered suitable for respondents with T1DM.

Implications for nursing

The significance of this study lies in the initial use of the IDSRQ in clinical practice in the Czech Republic. Based on the current values found in respondents with T1DM, it is possible to adequately respond and plan care for patients with T1DM treated with insulin (CSII, MDI). This will make professional care even more individualized. It would be useful to implement further research using the IDSRQ questionnaire for different groups of DM patients of different age groups.

In further investigations, we recommend using the tool in, for example, a group of adult patients with T2DM, children, or adolescents with T1DM. Research can also be carried out according to the method of insulin administration – pen, pump, syringe, inhalation. It might also be beneficial to conduct research in specific diseases in conjunction with diabetes (*e.g.*, stoma patients).

Limitations

A limitation of the study was that only respondents with T1DM who injected insulin using CSII or MDI were included, regardless of the incidence of complications. The small number of respondents was another limitation (especially for the use of CFA) and only respondents from the Moravia region within the Czech Republic were included. Another limitation was the sporadic occurrence of research on the IDSRQ questionnaire, and no studies in adult respondents in which CFA was used were found. Therefore, the questionnaire was subjected to further examination for construct validity.

Conclusion

Based on the results of the study, the IDSRQ questionnaire was shown to be a suitable tool for assessing T1DM patient satisfaction with CSII or MDI insulin administration in the Czech environment. The extraction of IDSRQ items into five subscales in the proposed M2 and M3 models reflects the current assessment of T1DM patient satisfaction based on CSII, MDI insulin administration. Further psychometric analysis of this tool on a larger sample of respondents of different age groups would be appropriate.

Ethical considerations

The research was approved by the Ethical Committee of the Faculty of Health Sciences of Palacký University in Olomouc (No. 109734/1050S-2020). Informed consent to include the respondents in the research included an explanation and was part of the questionnaires in paper form. Respondents' participation in the research was anonymous and voluntary, and they could withdraw from the research at any time as indicated in the informed consent.

Ethical aspects and conflict of interests

The authors have no conflict of interests to declare.

Psychometrické vlastnosti české verze Insulin Delivery System Rating Questionnaire

Souhrn

Cíl: Studie se zabývá lingvistickou validací a vybranými aspekty (konstruktové validity a reliability) dotazníku hodnocení inzulinového aplikačního systému (IDSRQ).

Metodika: Zkoumaný soubor tvořilo 151 pacientů s diabetem mellitem 1. typu. Byla provedena jazyková a obsahová validace IDSRQ. Výsledky dotazníku a jednotlivých subškál byly zpracovány pomocí deskriptivní statistiky a faktorové analýzy.

Výsledky: Data byla použita k výpočtu reliability sedmi původních subškál (0,42–0,92). Platnost konstruktu byla testována pomocí explorační a konfirmační faktorové analýzy. Byly vytvořeny modely M1, M2 a M3. Pro modely M2 a M3 byla vypočtena významnost chí-kvadrát testu (p < 0,001) a FIT indexů. Jako nejlepší byl označen pětifaktorový model se spolehlivostí 0,69–0,89 v subškálách.

Závěr: Nová verze dotazníku je v souladu s psychometrickými vlastnostmi původního nástroje a extrakce položek do pětifaktorového řešení odráží aktuální hodnocení spokojenosti pacientů s léčbou diabetu mellitu 1. typu v českém prostředí.

Klíčová slova: aplikace inzulinu; diabetes mellitus; konstruktová validita; reliabilita

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