

Research article

Dimensionality and psychometric properties of the Greek version of the Diabetes Impact and Device Satisfaction (DIDS) scale

Emmanouil S. Benioudakis,^{1,2} Argyroula Kalaitzaki,³ Eleni Karlafti,² Oxana Ahanov,⁴ Elisavet Kapageridou,⁵ Christos Savopoulos,² Triantafyllos Didangelos²

¹*Psychiatric Clinic, General Hospital of Chania, Chania, Crete,*

²*Diabetes Center, 1st Propaedeutic Department of Internal Medicine, Medical School, "AHEPA" University General Hospital, Aristotle University of Thessaloniki, Thessaloniki, Macedonia,*

³*Department of Social Work, Laboratory of Interdisciplinary Approaches to the Enhancement of Quality of Life, Health Sciences Faculty, Hellenic Mediterranean University, Heraklion, Crete,*

⁴*Department of Medicine, National and Kapodistrian University of Athens, Athens,*

⁵*Department of Medicine, Democritus University of Thrace, Thrace, Greece*

ARTICLE HISTORY: Received 29 April 2024/Revised 20 September 2024/Published Online 25 September 2024

ABSTRACT

Type 1 diabetes mellitus (T1D) is a chronic condition with rising prevalence. Exogenous insulin administration is the only treatment for individuals with T1D to prevent diabetes-related complications. Diabetes-related technology has significantly contributed to the management of T1D by reducing the burden of living with diabetes and providing greater flexibility in insulin management during daily activities. This study presents the psychometric properties of the Greek translation of the Diabetes Impact and Device Satisfaction (DIDS) Scale, which assesses satisfaction with the use of an insulin delivery device and the impact of diabetes management on individuals with T1D. A sample of 101 adults with T1D, mostly females (71.3%), with a mean age of 38.4 years (± 11.7), completed the translated Greek version of DIDS (DIDS-Gr). Exploratory factor analysis revealed three factors: 'Device Satisfaction', 'Diabetes Management Impact', and (new factor) 'Device Usability'. The internal consistency indices (Cronbach's alpha) for the subscales were 0.86, 0.71, and 0.60, respectively. Furthermore, convergent validity was demonstrated with moderate to high positive correlations between the DIDS-Grand the Diabetes Quality of Life Brief Clinical Inventory (DQoL-BCI) and its subscales, while divergent validity was also confirmed with weaker correlations with the depression subscale of the Hospital Anxiety and Depression Scale (HADS). Additionally, test-retest reliability and differential validity were present in our study. Therefore, DIDS-Gr is a valid and reliable measure for assessing the impact of diabetes on individuals with T1D and the satisfaction with the use of an insulin delivery device in Greece.

KEYWORDS: Type 1 diabetes mellitus, device satisfaction, diabetes impact, validity, reliability, factor analysis.

Introduction

Type 1 diabetes mellitus (T1D) is a chronic condition with rising prevalence, constituting 5% to 10% of all cases of diabetes mellitus (DM).¹ The main cause of T1D is the autoimmune destruction of β -pancreatic cells, and the only treatment for individuals with T1D is exogenous insulin administration.^{1,2} Lifelong glycaemic control constitutes a primary objective in the management of T1D to prevent diabetes-related complications, such as diabetic ketoacidosis, macrovascular and microvascular complications, and even premature death.^{3,4}

A chronic condition such as T1D requires constant monitoring and regulation to avoid chronic complications.⁵ Managing T1D is a complex task that requires multiple daily injections or the use of a Continuous Subcutaneous Insulin Infusion (CSII). Additionally, it entails regular testing through self-monitoring of blood glucose (SMBG) or continuous glucose monitoring (CGM).^{6,7} Diabetes-related technology has improved dramatically over the last few decades, particularly in the accuracy, reliability, and robustness of CGM devices. These advances now enable the adjustment of insulin dosage for basal insulin, premeal, and correction boluses without requiring additional confirmation from a blood glucose meter.⁶ Moreover, diabetes-related technology provides a sense of safety and security for individuals by avoiding severe hypoglycaemia, preventing diabetic ketoacidosis, and maintaining sugar levels within an appropriate range with minimal fluctuations.^{8,9} Recent reviews have shown that devices that are easy to operate, integrated with intuitive mobile applications, such as insulin pens or smart pens, and CSII therapy, have reduced the burden of living with diabetes and improved the quality of life (QoL).^{10–12} Moreover, in conjunction with pioneering Advanced Hybrid Closed-Loop systems (AHCL), the psychological impact of living with diabetes can be markedly reduced. Automating numerous aspects of insulin delivery results in effectively minimizing the risk of fluctuations, and therefore, in mitigating certain psychological symptoms, such as stress and anxiety of managing T1D, particularly for individuals leading active lifestyles.^{5,13}

Notwithstanding the diabetes-related technology advancements, few tools exist to assess patients' experience using these. However, balancing optimal health outcomes and satisfaction using such devices is crucial to increasing patients' acceptance, adoption, commitment/adherence rates, and satisfaction with their use. If not evaluating self-reported needs, priorities, and preferences before the design and development of such a

device, patients' perceived easiness, usefulness, and effectiveness of devices in decreasing any burden and improving their quality of life should be evaluated with validated tools.¹⁴ Martin-Delgado et al's (2023) scoping review identified two patient-reported experience measures (PREMs) and 32 patient-reported outcome measures (PROMs) related to type 1 and 2 diabetes. Among those, the Diabetes Injection Device Experience Questionnaire (DID-EQ) measures patients' experiences with using a medical device, and the Treatment Related Impact Measure for Diabetes Device (TRIM-DD) measures the impact of treatment on people with DM.^{15–17} In addition, other instruments such as the Insulin Delivery Satisfaction Survey and the INSPIRE assess either the psychosocial impact of diabetes on daily life or device-related satisfaction.^{18,19} To assess patient's experience related to insulin delivery device interaction (insulin pumps, pens, syringes, etc.), specifically device-related satisfaction, and the impact of diabetes management on an individual's life at the time of device use, Manning and his colleagues in 2020 developed the Diabetes Impact and Device Satisfaction (DIDS) Scale.²⁰ DIDS excels over the other instruments, as it was developed for use with any insulin delivery device and measures both patients' device-using satisfaction and the diabetes management impact on their lives. Moreover, the two-factor DIDS was shown to be a valid and reliable instrument with robust psychometric properties.²⁰

Given the importance of an instrument to measure both satisfaction with the use of a device and diabetes management impact on T1D patients' lives and that to date, there is no such instrument in Greek, the aim of this study was to translate and examine the dimensionality and the psychometric properties of the DIDS Scale in a Greek sample (hereafter referred to as DIDS-Gr).

Material and Method

Procedure

Initially, two independent native speakers translated the DIDS into Greek (forward translation). Subsequently, a bilingual individual performed a backward translation, after which all authors conducted a cultural adaptation of the final version of the questionnaire. A reconciled version of the DIDS was developed. Finally, a psychologist and a diabetologist, both experts in the field, conducted the face validity process. Based on their expertise, they examined the extent to which the DIDS-Gr reflected the constructs of diabetes impact and device satisfaction for people with T1D. Permission to access and use the DIDS was granted. The study has been ap-

proved by the Ethics Committee of Aristotle University of Thessaloniki and has been conducted following the Declaration of Helsinki.

Participants

Adults with T1D were invited to participate in the study by both the Diabetes Center of "AHEPA" General University Hospital of Thessaloniki and associations of individuals with T1D throughout Greece. The announcement described the project and included a Google Form link with additional study information. Participants provided online informed consent regarding their rights (e.g., voluntary participation and anonymity of the process). Exclusion criteria included T1D people under age 18, non-Greek-speaking T1D people, those with other types than T1D diabetes mellitus, and those with T1D duration of 12 months or less. One hundred and one adults with T1D aged between 18 and 57 years ($M=38.4 \pm 11.7$), completed the survey. The majority of the patients were females (71.3%), married (44.6%), employed (69.3%), and with high school or university education (68.3%). Finally, a random subsample of 19 T1D participants voluntarily underwent the cognitive debriefing stage and were retested four weeks later to assess the test-retest reliability of the scale. The detailed sociodemographic characteristics of the test and re-test samples are presented in table 1.

Measures

The Diabetes Impact and Device Satisfaction (DIDS) Scale is a self-report, two-dimensional questionnaire comprising 11 items. It was designed to assess satisfaction and the impact of diabetes management, specifically related to the interaction with insulin delivery devices, including insulin pumps and devices used for Multiple Daily Injection (MDI) therapy, such as pens, smart pens, and syringes. Respondents rate each item on a 10-point Likert scale ranging from 1 to 10, with items 5 and 7 being reverse scored. Seven of the items assess satisfaction related to the insulin delivery device and the remaining four assess the impact of diabetes management. The Cronbach's alpha coefficients of the original version of the DIDS were $\alpha_{\text{Device Satisfaction}}=0.86$ and $\alpha_{\text{Diabetes Impact}}=0.71$.²⁰ The Greek version of the DIDS is available in Supplementary 1.

The Diabetes Quality of Life Brief Clinical Inventory (DQoL-BCI) is a 15-item self-report questionnaire designed to assess the overall Health-Related Quality of Life (HRQoL) for individuals with both type 1 and type 2 diabetes. The DQoL-BCI includes two subscales: 'satisfac-

tion related to therapy and quality of life', which is evaluated on a scale from 1 (very satisfied) to 5 (very unsatisfied), and the 'frequency of negative implications of diabetes therapy' which is evaluated on a scale from 1 (never) to 5 (constantly). Higher scores on DQoL-BCI indicate poorer QoL.²¹ The Greek translation of the DQoL-BCI has demonstrated both good reliability and validity.²² In this study, the DQoL-BCI Cronbach alpha coefficients were $\alpha_{\text{DQoL-BCI total}}=0.83$, $\alpha_{\text{satisfaction}}=0.79$, and $\alpha_{\text{negative implications}}=0.7$.

Hospital Anxiety and Depression Scale (HADS) is a self-report rating scale consisting of 14 items on a 4-point Likert scale. The scale comprises two subscales, "Anxiety" (HADS-A) and "Depression" (HADS-D), each one of which consists of seven items, with scores ranging from 0 to 21. Higher scores indicate higher levels of anxiety or depression.²³ The scale can be used in both hospitalized patients and the general population. The translation of HADS into Greek is both reliable and valid.²⁴ In this study, the HADS Cronbach alpha coefficients were $\alpha_{\text{HADS-A}}=0.84$ and $\alpha_{\text{HADS-D}}=0.81$.

Statistical analysis

Initially, face validity and Content Validity Index (CVI) were assessed. The Greek translation of the DIDS was submitted to a panel of three independent experts in diabetes mellitus, comprising an internist and two psychologists. These experts were tasked with evaluating the items of both scales for content equivalence, using a 3-point Likert scale: 1=necessary, 2=useful but not necessary, and 3 = unnecessary. The total CVI was then calculated by dividing the number of items ranked as 1 (necessary) by the total number of items in each scale (i.e., 11). An unforced exploratory factor analysis (EFA) was conducted using Principal Axis Factoring and both Oblimin and Varimax rotation with Kaiser Normalization to investigate the construct validity of the DIDS-Gr. Sampling adequacy was assessed using the Kaiser-Meyer-Olkin (KMO) test, along with Bartlett's test of sphericity.²⁵ Test-retest reliability was assessed using the intraclass correlation coefficient (ICC) 2-way mixed-effects model for measurements (Type: Absolute Agreement), and internal consistency of the subscales of the DIDS-Gr was evaluated using Cronbach's alpha coefficients.²⁶ Construct validity was investigated by calculating two-tailed Pearson's correlation coefficients among the subscales of DIDS-Gr and the DQoL-BCI total score and its subscales "Satisfaction" and "Negative Impact", as well as the HADS "Anxiety" and "Depression" subscales. Medium-to-high correlations ($|r|>0.4$) were considered indicative of convergent validity, while weaker correlations were considered indicative of discriminant validity.²⁷ Finally, the differential validity

Table 1. Demographic characteristics of the participants.

Characteristics	Total sample (n=101) Mean±SD/N (%)	Re-test sample (n=19) Mean±SD/N (%)
Age (years)	38.4±11.7	35.3±13
Diabetes duration (years)	21.9±11.2	20.5±10
Gender		
Male	29 (28.7)	3 (15.8)
Female	72 (71.3)	16 (84.2)
Educational Level		
Primary and secondary	32 (31.7)	6 (31.6)
University	69 (68.3)	13 (68.4)
Family status		
Unmarried	37 (36.6)	10 (52.6)
Married	45 (44.6)	8 (42.1)
Divorced	5 (5)	1 (5.3)
Other	14 (13.9)	0 (0)
HbA1c (self-report)	7.2±1.4	6.9±1.4
CGM (use)	88 (87.1)	17 (89.5)
Treatment: insulin pump	60 (59.4)	13 (68.4)
Medtronic 640G	12 (20)	3 (23.1)
Medtronic 780G	33 (55)	8 (61.5)
Omnipod Dash	8 (13.3)	1 (7.7)
Other	7 (11.7)	1 (7.7)
Closed-loop	34 (33.7)	9 (47.4)
Employment		
Paid work (employed)	70 (69.3)	12 (63.2)
Unemployed	12 (11.9)	2 (10.5)
Retired	5 (5.0)	0 (0)
Other	14 (13.9)	5 (26.3)
Income status		
Low	21 (20.8)	5 (26.3)
Average	56 (55.4)	10 (52.6)
Good	24 (23.8)	4 (21.1)
Psychosocial characteristics		
DQoL-BCI (Total score)	32.1±8.8	N/A
DQoL- BCI (Satisfaction)	17.2±5.8	N/A
DQoL- BCI (Negative impact)	14.8±4.0	N/A
HADS Depression	4.3±3.5	N/A
HADS Anxiety	6.4±4	N/A

Note: HbA1c: hemoglobin A1c; CGM: Continuous Glucose Monitoring; DQoL-BCI (Total score): Diabetes Quality of Life Brief Clinical Inventory - Total score (15-75); DQoL-BCI (Satisfaction): Diabetes Quality of Life Brief Clinical Inventory - Satisfaction (8-40); DQoL-BCI (Negative impact): Diabetes Quality of Life Brief Clinical Inventory – Satisfaction (7-35); HADS Depression: Hospital Anxiety and Depression Scale - Depression (0-21); HADS Anxiety: Hospital Anxiety and Depression Scale – Anxiety (0-21); N/A: Not Applicable

(known groups method) was assessed by independent samples t-test between AHCL users and the rest of the sample (MDI or CSII users).²⁸ The effect size was calculated according to Cohen's guidelines.²⁹ The significance

level was set at $p < 0.05$. All analyses were conducted using SPSS version 26 (SPSS Inc., Chicago, IL, USA), while the parallel analysis was carried out using Monte Carlo PCA for Parallel Analysis.

Results

Translation, cultural adaptation, face validity, and cognitive debriefing

During the translation process, any discrepancies that arose were discussed and resolved, resulting in a consensus version in Greek, and the cultural adaptation process was reviewed by all authors. Following this, the panel of experts who conducted the face validity found that the DIDS-Gr scale reflected the diabetes impact and device satisfaction among people with DM. Cognitive debriefing was assessed through interviews with 19 volunteers. Participants first completed the DIDS-Gr and were then interviewed to assess the clarity and comprehensiveness of the scale instructions and items.

Content validity

An agreement of 90% was found among the panel of experts, which is an acceptable index.²⁰ Item No.10 "How often do you worry about going low?" was unanimously assessed as 'useful but not necessary'.

Structural validity

Initially, a Confirmatory Factor Analysis (CFA) was conducted to assess the proposed two-factor structure (Supplementary 2); however, two items (5 and 7) loaded below 0.4.31 Additionally, the model fit indices did not meet the acceptable criteria: $\chi^2(43)=100.9$, $p<0.001$, $\chi^2/df=2.346$, $GFI=0.853$, $TLI=0.801$, $CFI=0.845$, $RMSEA=0.116$, and $SRMR=0.0921$. Consequently, we proceeded with an Exploratory Factor Analysis (EFA) to further investigate the underlying structure of the data.

An unforced (EFA) was conducted using the Principal Axis Factoring method for factor extraction, employing both oblique rotation (Direct Oblimin) and orthogonal rotation (Varimax) rotation. Additionally, a cut-off of ≥ 0.45 was applied to identify meaningful factor loadings using the latent root criterion, retaining factors with Eigenvalues greater than 1.0. A three-factor structure was identified and confirmed by both rotations and the parallel analysis (Supplementary 2), with the extracted factors explaining 63.4% of the total variance. KMO coefficient was equal to 0.767 and Barlett χ^2 value was 408.5 ($p<0.001$). The final communality estimates after rotation were high for all items (>0.36) except items No.5 (0.27) and No.10 (0.23). All factor loadings exceeded 0.45, ranging from 0.45 to 0.80. The 11 items were allocated in three factors: "Device Satisfaction" (1,2,4,6); "Diabetes Management Impact" (8,9,10,11); and (new factor) "Device Usability" (3,5,7). The three-dimensional structure of the DIDS-Gr is presented in table 2.

Descriptive statistics of the DIDS-Gr and AHCL differences

The mean scores of the subscales "Device Satisfaction", "Diabetes Management Impact", and "Device Usability" of the DIDS-Gr were $33.7 (\pm 5.9)$, $14.8 (\pm 6.5)$, and $26.5 (\pm 4.3)$, respectively. Of the total sample, 34 participants (33.7%) used the pioneer AHCL technology. Statistically significant differences were found in favor of the AHCL users in the subscales "Device Satisfaction" (36.1 ± 4.9 vs 32.5 ± 6.0 ; $t(99) 2.99$, $p=0.003$, $d=0.65$) and the "Diabetes Management Impact" (12.6 ± 5.3 vs 15.9 ± 6.9 ; $t(99) -2.38$, $p=0.019$, $d=0.53$) compared to the rest of the sample.

Test-retest reliability

The ICC values for the 19 volunteers who were retested four weeks later were as follows: "Device Satisfaction" subscale: 0.88 ($p<0.001$); "Diabetes Management Impact" subscale: 0.81 ($p=0.001$); and Device Usability" (new subscale) >0.90 ($p<0.001$).

Internal consistency

The Cronbach's alpha coefficients for the subscales of the 11-item DIDS-Gr were as follows: "Device Satisfaction" 0.86; "Diabetes Management Impact" 0.71; and (new factor) "Device Usability" 0.60, whereas when calculated specifically for the sub-sample of those using insulin pump therapy ($n=60$), Cronbach's alpha coefficient increased to 0.69. Inter-items correlations, means, and standard deviations of the 11 items of the DIDS-Gr, as well as Cronbach's alpha if the item is deleted are presented in Supplementary 2.

Construct validity

Convergent validity was supported by positive correlations between the "Diabetes Management Impact" subscale of the DIDS-Gr and both the subscales and the total score of DQoL-BCI and by negative correlations between the "Device Satisfaction" subscale of the DIDS-Gr and the "Total score" and "Satisfaction" subscale of the DQoL-BCI (because low scores indicate greater satisfaction, a negative sign reflect a correlation between the variables). In addition, divergent validity was confirmed by weak negative correlations between the "Depression" subscale of the HADS and both the "Device Satisfaction" and "Device Usability" subscales of the DIDS-Gr. The correlations are presented in table 3.

Discussion

This study reports the translation, cultural adaptation, and psychometric properties of the DIDS in the Greek

Table 2. The three-factor solution extracted by the Exploratory factor analysis and the internal consistency reliability of the three factors of DIDS- Gr

	three-factor solution ^a		
	Device Satisfaction	Diabetes Management Impact	Device Usability
My current insulin delivery device helps me feel more in control of my diabetes ⁶	0.806		
How much do you trust your insulin delivery device? ²	0.773		
How satisfied are you with your insulin delivery device? ¹	0.731		
My current insulin delivery device helps me have good blood glucose control ⁴	0.708		
How often do you have a bad night sleep due to diabetes? ⁸		0.737	
How often do you wake up at night to treat a low blood glucose? ⁹		0.691	
How often do you worry about going low? ¹⁰		0.463	
How often do you miss work, school, chores, or other responsibilities due to diabetes? ¹¹		0.456	
My current insulin delivery device is too complicated ⁷			0.680
My current insulin delivery device is easy to use ³			0.602
My current insulin delivery device is a hassle to use ⁵			0.458
Score range	4–40	4–40	3–30
Mean±sd	33.7±5.9	14.8±6.5	26.5±4.3
Eigenvalue	4.2	1.5	1.27
% variance explained	38.21	13.7	11.56
Cronbach's alpha	0.86	0.71	0.6

Note: a Unforced three-factor solution with principal components analysis and Varimax rotation; Factor loadings ≥ 0.45 are presented

language (i.e., DIDS-Gr). The DIDS-Gr was validated, and the 11-item scale proved to be an acceptable, reliable, and valid tool for assessing satisfaction with the use of an insulin delivery device and the impact of diabetes on individuals with T1D in Greece.

Initially, we conducted a CFA to validate the original two-factor structure of the DIDS. However, the results were unsatisfactory, prompting us to perform two separate Exploratory Factor Analyses (EFA) using Varimax and Direct Oblimin rotations, in line with the approach used during the development of the DIDS.²⁰ As the differences between the two solutions were negligible, we presented the orthogonal rotation (Varimax), following Pedhazur and Schmelkin's strategy.^{20,32} Unlike the original DIDS, the EFA of our study identified three factors, two of which were similar to the original DIDS, and thus the original naming was retained. These were: "Device Satisfaction" (four items, in contrast to seven of the original DIDS) and "Diabetes Management Impact" (four items, same as the original). The new factor of the DIDS-Gr, consisting of three items (3: 'My current insulin delivery device is easy to use', 5: 'My current insulin delivery

device is a hassle to use', and 7: 'My current insulin delivery device is too complicated'), refers to the usability of the device, and it was named "Device Usability". We believe that the items of the 'new factor' refer primarily on insulin pump therapy users since there were no participants in our study using a smart pen device; the low factor loadings of these three items (i.e., 3, 5, and 7) when the EFA was conducted exclusively among MDI users in Manning's study and the increase of the Cronbach's alpha value in this study when calculated separately in the sub-group of pump therapy users ascertain this assertion.²⁰

The three-factor structure of the DIDS-Gr demonstrated satisfactory psychometric properties, as indicated by acceptable Cronbach's alphas and test-retest reliabilities. The alpha reliability for the "Diabetes Management Impact" subscale was comparable to that of the original version,²⁰ while the "new subscale" showed acceptable reliability among insulin pump users. The correlations between the DIDS-Gr and DQoL-BCI were consistent with expectations, supporting both the convergent and divergent validity of the DIDS-Gr. In the absence

Table 3. Correlations of the subscales of DIDS-Gr with validity measures.

	Device Satisfaction	Diabetes Management Impact	Device Usability ^a
DQoL-BCI (Total score)	−0.583**	0.673**	−0.458**
DQoL- BCI (Satisfaction)	−0.616**	0.519**	−0.397**
DQoL- BCI (Negative impact)	−0.381**	0.722**	−0.427**
HADS Depression	−0.214*	0.389**	−0.243*
HADS Anxiety	−0.363**	0.417**	−0.159

Note: a New subscale, *p<0.05, **p<0.01

of similar analyses in the original article of its development, our findings align with existing literature, which demonstrates positive correlations between the use of advanced diabetes-related technology and (QoL).^{20,33,34} Divergent validity was as expected, as individuals with T1D are at a higher risk of depression compared to the general population, regardless of whether they use an MDI or an insulin pump therapy.^{35–37}

Furthermore, the DIDS-Gr showed differential validity between the AHCL users and non-AHCL users, such as MDI and CSII users. The AHCL system provides automated basal and bolus insulin correction. It utilizes a model-based adaptive algorithm with an insulin feedback module, delivering insulin micro boluses with additional safety features for the user. This results in an increase in the time users spend in euglycaemia.^{38,39} Thus, it was reasonable to expect differences in favor of the AHCL users in the “Device Satisfaction” and “Diabetes Management Impact” subscales of DIDS-Gr.

The findings of the present study suggest that the DIDS-Gr is a valid and reliable measure for assessing satisfaction with the use of an insulin delivery device and the impact of T1D management on individuals in Greece. Key strengths of the present study include the rigorous validation process, the longitudinal design that allowed for test-retest reliability, and the examination of convergent, discriminant, and differential validity. Having one instrument for assessing three aspects of device use is another strength of this study. There are, however, some limitations that need to be acknowledged, such as the relatively small sample size that did not allow for separated EFAs among MDI and CSII users, and the fact that more women with T1D than men responded to the survey. Future studies should confirm the three-factor mod-

el that emerged from this survey and compare it across samples using different insulin pump devices.

Conclusion and implications

This study resulted in the availability of a short, quick, and easy-to-use instrument in Greek for measuring T1D patients’ experiences and satisfaction with the use of an insulin delivery device and the impact of diabetes management on their lives, which is acceptable, valid, and reliable. The psychometric validation of the DIDS-Gr indicated a three-factor construct (“Device Satisfaction”, “Diabetes Management Impact”, and “Device Usability”) with high internal consistency reliability, and satisfactory convergent, discriminant, and differential validity. The implications of this study could guide the development of improved devices and tailored solutions taking into consideration patients’ perceptions and satisfaction with their use, whereas interventions could be also developed and implemented to promote device engagement, adherence, and satisfaction. Achieving optimal health outcomes and satisfaction with device use is the cornerstone of patient’s decrease of attrition in device use, an increase in engagement, and consequently, improve their quality of life and increase their well-being.

Acknowledgments

The authors would like to acknowledge the study participants.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi: <https://doi.org/10.22365/jpsych.2024.017>

References

1. American Diabetes Association Professional Practice Committee.
2. Diagnosis and Classification of Diabetes: Standards of Care in Diabetes-2024. *Diabetes Care* 2024, 47:S20–S42, doi: 10.2337/dc24-S002
2. International Diabetes Federation. *IDF Diabetes Atlas*. 10th ed. International Diabetes Federation, Brussels, Belgium, 2021
3. American Diabetes Association Professional Practice Committee.
6. Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes-2024. *Diabetes Care* 2024, 47:S111–S125, doi: 10.2337/dc24-S006

4. Longendyke R, Grundman JB, Majidi S. Acute and Chronic Adverse Outcomes of Type 1 Diabetes. *Endocrinol Metab Clin North Am* 2024, 53:123–133, doi: 10.1016/j.ecl.2023.09.004
5. Choudhary P, Kolassa R, Keuthage W, Kroeger J, Thivolet C, Evans M et al. Advanced hybrid closed loop therapy versus conventional treatment in adults with type 1 diabetes (ADAPT): a randomised controlled study. *Lancet Diabetes Endocrinol* 2022, 10:720–731, doi: 10.1016/S2213-8587(22)00212-1
6. Rodbard D. Continuous Glucose Monitoring: A Review of Recent Studies Demonstrating Improved Glycemic Outcomes. *Diabetes Technol Ther* 2017, 19:S25–S37, doi: 10.1089/dia.2017.0035
7. Dicembrini I, Cosentino C, Monami M, Mannucci E, Pala L. Effects of real-time continuous glucose monitoring in type 1 diabetes: a meta-analysis of randomized controlled trials. *Acta Diabetol* 2021, 58:401–410, doi: 10.1007/s00592-020-01589-3
8. Mauricio D, Alonso N, Gratacòs M. Chronic Diabetes Complications: The Need to Move beyond Classical Concepts. *Trends Endocrinol Metab* 2020, 31:287–295, doi: 10.1016/j.tem.2020.01.007
9. Breton MD, Patek SD, Lv D, Schertz E, Robic J, Pinnata J et al. Continuous Glucose Monitoring and Insulin Informed Advisory System with Automated Titration and Dosing of Insulin Reduces Glucose Variability in Type Diabetes Mellitus. *Diabetes Technol Ther* 2018, 20:S31–S40, doi: 10.1089/dia.2018.0079
10. Cappon G, Vettoretti M, Sparacino G, Facchinetti A. Continuous Glucose Monitoring Sensors for Diabetes Management: A Review of Technologies and Applications. *Diabetes Metab J* 2019, 43:383–397, doi: 10.4093/dmj.2019.0121
11. Heinemann L, Schnell O, Gehr B, Schloot NC, Görgens SW, Görgen C. Digital Diabetes Management: A Literature Review of Smart Insulin Pens. *J Diabetes Sci Technol* 2022, 16:587–595, doi: 10.1177/1932296820983863
12. Jendle J, Reznik Y. Use of insulin pumps and closed-loop systems among people living with diabetes: A narrative review of clinical and cost-effectiveness to enable access to technology and meet the needs of payers. *Diabetes Obes Metab* 2023, 25:21–32, doi: 10.1111/dom
13. Yuan CY, Kong YW, Amooore T, Brown K, Grosman B, Jenkins A et al. Improved Satisfaction While Maintaining Safety and High Time in Range (TIR) With a Medtronic Investigational Enhanced Advanced Hybrid Closed-Loop (e-AHCL) System. *Diabetes Care* 2024, 47:747–755, doi: 10.2337/dc23-2217
14. Kalaitzaki A, Rovithis M, Dimitropoulos A, Koukouli S, Linardakis M, Katsiri E et al. Promoting Self-Management and Independent Living of Older Individuals with Chronic Diseases through Technology: A Study of Self-Reported Needs, Priorities, and Preferences. *Medicina (Kaunas)* 2023, 59:1493, doi: 10.3390/medicina59081493
15. Martin-Delgado J, Guilbert M, Mira-Solves J. Patient-Reported Experience and Outcome Measures in People Living with Diabetes: A Scoping Review of Instruments. *Patient* 2021, 14:759–773, doi: 10.1007/s40271-021-00526-y
16. Matza LS, Boye KS, Stewart KD, Paczkowski R, Jordan J, Murray LT. Development of the Diabetes Injection Device Experience Questionnaire (DID-EQ) and Diabetes Injection Device Preference Questionnaire (DID-PQ). *J Patient Rep Outcomes* 2018, 2:43, doi: 10.1186/s41687-018-0068-z
17. Brod M, Hammer M, Christensen T, Lessard S, Bushnell DM. Understanding and assessing the impact of treatment in diabetes: the Treatment-Related Impact Measures for Diabetes and Devices (TRIM-Diabetes and TRIM-Diabetes Device). *Health Qual Life Outcomes* 2009, 7:83, doi: 10.1186/1477-7525-7-83
18. Polonsky WH, Fisher L, Hessler D, Edelman SV. Development of a New Measure for Assessing Insulin Delivery Device Satisfaction in Patients with Type 1 and Type 2 Diabetes. *Diabetes Technol Ther* 2015, 17:773–779, doi: 10.1089/dia.2015.0140
19. Weissberg-Benchell J, Shapiro JB, Hood K, Laffel LM, Naranjo D, Miller K et al. Assessing patient-reported outcomes for automated insulin delivery systems: the psychometric properties of the INSPIRE measures. *Diabet Med* 2019, 36:644–652, doi: 10.1111/dme.13930
20. Manning ML, Singh H, Stoner K, Habif S. The Development and Psychometric Validation of the Diabetes Impact and Device Satisfaction Scale for Individuals with Type 1 Diabetes. *J Diabetes Sci Technol* 2020, 14:309–317, doi: 10.1177/1932296819897976
21. Burroughs TE, Desikan R, Waterman BM, Gilin D, McGill J. Development and validation of the diabetes quality of life brief clinical inventory. *Diabetes Spectr* 2004, 17:41–9, <http://dx.doi.org/10.2337/diaspect.17.1.41>
22. Rekleiti M, Souliotis K, Sarafis P, Kyriazis I, Tsironi M. Measuring the reliability and validity of the Greek edition of the Diabetes Quality of Life Brief Clinical Inventory. *Diabetes Res Clin Pract* 2018, 140:61–71, doi: 10.1016/j.diabres.2018.01.019
23. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983, 67:361–370, doi: 10.1111/j.1600-0447.1983.tb09716.x
24. Michopoulos I, Kalkavoura C, Michalopoulou P, Fineti K, Kalemi G, Psarra M et al. [Hospital anxiety and depression scale (HADS): Validation in a Greek general hospital sample]. *Psychiatriki* 2007, 18:217–224. Greek, Modern, PMID: 22466626
25. Hair JF, Anderson RE, Black WC. Multivariate Data Analysis. 7th ed. Pearson, New York, 2014.
26. Koo TK, Li MY. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. *J Chiropr Med* 2016, 15:155–163, doi: 10.1016/j.jcm.2016.02.012
27. Kaplan RM, Bush JW, Berry CC. Health status: types of validity and the index of well-being. *Health Serv Res* 1976, 11:478–507, PMID: 1030700
28. Katzell RA, Dyer FJ. Differential validity revived. *Journal of Applied Psychology* 1977, 62:137145, doi: 10.1037/0021-9010.62.2.137
29. Cohen J. Statistical Power Analysis for the Behavioral Sciences. Hillsdale, NJ: Lawrence Erlbaum Associates, Publishers, New York, 1988
30. Davis LL. Instrument review: Getting the most from a panel of experts. In *Applied Nursing Research* 1992, 5:194–197, doi: 10.1016/s0897-1897(05)80008-4
31. Cheung GW, Cooper-Thomas HD, Lau RS, Wang LC. Reporting reliability, convergent and discriminant validity with structural equation modeling: A review and best-practice recommendations. *Asia Pac J Manag* 2024, 41:745–783, <https://doi.org/10.1007/s10490-023-09871-y>
32. Pedhazur EJ, Schmelkin LP. *Measurement, Design, and Analysis: An Integrated Approach*. Student ed., Lawrence Erlbaum Associates, Inc, New Jersey, 1991
33. Isaacs D, Kruger DF, Shoger E, Chawla H. Patient Perceptions of Satisfaction and Quality of Life Regarding Use of a Novel Insulin Delivery Device. *Clin Diabetes* 2023, 41:198–207, doi: 10.2337/cd22-0034
34. Elian V, Popovici V, Ozon EA, Musuc AM, Fița AC, Rusu E et al. Current Technologies for Managing Type 1 Diabetes Mellitus and

- Their Impact on Quality of Life-A Narrative Review. *Life* (Basel) 2023, 13:1663, doi: 10.3390/life13081663
35. Peyrot M, Rubin RR. Levels and risks of depression and anxiety symptomatology among diabetic adults. *Diabetes Care* 1997, 20:585–90, doi: 10.2337/diacare.20.4.585
36. Benioudakis ES, Karlafti E, Kalaitzaki A, Didangelos T. [Depressive symptoms and insulin pump therapy in people with type 1 diabetes mellitus: A systematic review]. *Psychiatriki* 2023, 34:133–142, Greek, Modern, doi: 10.22365/jpsych.2022.058
37. Tsarkova P, Chakarova N, Dimova R, Grozeva G, Todorova A, Serdarova M et al. CSII is related to more stable glycemia in adults with type 1 diabetes. *Endocrine* 2022, 75:776–780, doi: 10.1007/s12020-021-02913-9
38. Benioudakis ES, Karlafti E, Kalaitzaki A, Kalpou MA, Georgiou ED, Savopoulos C, Didangelos T. Comparison of the Sensor-Augmented Pump System with the Advanced Hybrid Closed-Loop Delivery System: Quality of Life, Diabetes Distress, and Glycaemic Outcomes in a Real-Life Context. *Curr Diabetes Rev* 2024, 20:e310523217505, doi: 10.2174/1573399820666230531161858
39. Templer S. Closed-Loop Insulin Delivery Systems: Past, Present, and Future Directions. *Front Endocrinol* (Lausanne) 2022,13:919942, doi: 10.3389/fendo.2022.919942

Ερευνητική εργασία

Διαστάσεις και ψυχομετρικές ιδιότητες της ελληνικής έκδοσης της Κλίμακας των Επιπτώσεων του Διαβήτη και της Ικανοποίησης από τη Συσκευή Χορήγησης Ινσουλίνης

Εμμανουήλ Σ. Μπενιουδάκης,^{1,2} Αργυρούλα Καλαϊτζάκη,³ Ελένη Καρλάφτη,² Οξάνα Αχάνοβ,⁴ Ελισάβετ Καπαγερίδου,⁵ Χρήστος Σαββόπουλος,² Τριαντάφυλλος Διδάγγελος²

¹Ψυχιατρική Κλινική, Γενικό Νοσοκομείο Χανίων,

²Διαβητολογικό Κέντρο, Α΄ Προπαιδευτική Παθολογική Κλινική, Πανεπιστημιακό Γενικό Νοσοκομείο «ΑΧΕΠΑ», Αριστοτέλειο Πανεπιστήμιο Θεσσαλονίκης, Θεσσαλονίκη, Μακεδονία,

³Εργαστήριο Διεπιστημονικής Προσέγγισης για τη Βελτίωση της Ποιότητας Ζωής, Τμήμα Κοινωνικής Εργασίας, Ελληνικό Μεσογειακό Πανεπιστήμιο, Ηράκλειο, Κρήτη,

⁴Τμήμα Ιατρικής, Εθνικό και Καποδιστριακό Πανεπιστήμιο Αθηνών, Αθήνα,

⁵Τμήμα Ιατρικής, Δημοκρίτειο Πανεπιστήμιο Θράκης, Θράκη

ΙΣΤΟΡΙΚΟ ΑΡΘΡΟΥ: Παραλήφθηκε 29 Απριλίου 2024/Αναθεωρήθηκε 20 Σεπτεμβρίου 2024/Δημοσιεύθηκε Διαδικτυακά 25 Σεπτεμβρίου 2024

ΠΕΡΙΛΗΨΗ

Ο σακχαρώδης διαβήτης τύπου 1 (ΣΔ1) είναι μια χρόνια πάθηση με διαρκώς αυξανόμενο επιπολασμό. Η μόνη θεραπεία για άτομα με ΣΔ1 για την πρόληψη πιθανών επιπλοκών που σχετίζονται με τον σακχαρώδη διαβήτη (ΣΔ) είναι η εξωγενής χορήγηση ινσουλίνης. Η τεχνολογία που συνδέεται με τον ΣΔ έχει συμβάλει σημαντικά στη διαχείρισή του, μειώνοντας την επιβάρυνση που συνδέεται με τον ΣΔ και παρέχοντας παράλληλα μεγαλύτερη ευελιξία στη διαχείριση της ινσουλίνης κατά τη διάρκεια των καθημερινών δραστηριοτήτων. Σε αυτή την εργασία παρουσιάζονται οι βασικές ψυχομετρικές ιδιότητες της ελληνικής μετάφρασης του ερωτηματολογίου Diabetes Impact and Device Satisfaction (DIDS), το οποίο αξιολογεί την ικανοποίηση των ατόμων με ΣΔ1 από τη χρήση μιας συσκευής χορήγησης ινσουλίνης και τις επιπτώσεις της διαχείρισης του ΣΔ. Ένα δείγμα 101 ενηλίκων με ΣΔ1, αποτελούμενο κυρίως από γυναίκες (71,3%), με μέση ηλικία τα 38,4 έτη ($\pm 11,7$), συμπλήρωσε τη μεταφρασμένη ελληνική έκδοση του DIDS (DIDS-Gr). Η διερευνητική παραγοντική ανάλυση αποκάλυψε ένα μοντέλο τριών παραγόντων: «ικανοποίηση από τη συσκευή», «Επιπτώσεις της διαχείρισης του διαβήτη» και «Χρηστικότητα της συσκευής». Οι δείκτες εσωτερικής συνοχής (Cronbach alpha) για τις υποκλίμακες ήταν 0,86, 0,72 και 0,60, αντίστοιχα. Επιπλέον, η συγκλίνουσα εγκυρότητα επιβεβαιώθηκε με μέτριες έως υψηλές θετικές συσχετίσεις μεταξύ του DIDS-Gr και του DQoL-BCI και των υποκλιμάκων του («ικανοποίηση» και «αρνητική επίδραση»), ενώ η αποκλίνουσα εγκυρότητα επιβεβαιώθηκε με χαμηλές συσχετίσεις με την υποκλίμακα της κατάθλιψης του HADS. Τέλος, μέσα από τη μελέτη αναδείχθηκε η αξιοπιστία των επαναληπτικών μετρήσεων και η διαφορική εγκυρότητα. Επομένως, το DIDS-Gr είναι ένα έγκυρο και αξιόπιστο εργαλείο για την αξιολόγηση της ικανοποίησης από τη χρήση συσκευής χορήγησης ινσουλίνης και των επιπτώσεων του διαβήτη σε άτομα με ΣΔ1 στην Ελλάδα.

ΛΕΞΕΙΣ ΕΥΡΕΤΗΡΙΟΥ: Σακχαρώδης διαβήτης τύπου 1, επιπτώσεις του διαβήτη, ικανοποίηση από τη συσκευή, εγκυρότητα, αξιοπιστία, ανάλυση παραγόντων.