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Bulgarian version of the Audit of Diabetes-Dependent Quality of Life (ADDQoL-19)

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ABSTRACT
The aims of this study were to translate and culturally adapt the UK English Audit of Diabetes-Dependent Quality of Life version 19 (ADDQoL-19) into Bulgarian and explore the psychometric properties of the ADDQoL-19 BUL. The formalized linguistic procedure was used to develop the Bulgarian version of the ADDQoL-19 BUL. The ADDQoL was assessed for the following: internal consistency (Cronbach’s alpha); test–retest reliability (intraclass correlation coefficient (ICC)); factor structure and known-groups validity (insulin requiring vs. non-insulin requiring, with vs. without diabetes-related complications, overweight/obese vs. not overweight/obese). A total of 423 adults with type 2 diabetes mellitus (T2DM) participated in the study. The mean age was 59.92 years (standard deviation (SD) 11.60, range 28–88 years), and 52.6% were male. Internal consistency (α = 0.922) and the 3-week test–retest stability (intraclass correlation = 0.99) were high. Confirmatory factor analysis indicated that the one-factor structure of the ADDQoL-19 fits moderately (χ² = 230.63, df = 136, p < 0.001, SRMR (Standardized Root Mean Square Residual) of 0.05, RMSEA (Root Mean Square Error of Approximation) of 0.06, CFI (Comparative Fit Index) of 0.95). Standardized coefficients showed that all domains loaded 0.4, except for one item. The total score was negatively associated with HbA1c (r = −0.10; p < 0.05), indicating that lower scores were related to poorer glycaemic control. In conclusion, the Bulgarian version of the ADDQoL-19 has good psychometric properties and provides clinicians and researchers with a useful tool for comprehensive assessment of the quality of life in adults with diabetes mellitus.

Introduction
Diabetes mellitus (DM) is a global public health problem. The world is facing an epidemic of type 2 diabetes mellitus (T2DM): 382 million people have diabetes and the disease is set to rise beyond 592 million in fewer than 25 years [1]. The International Diabetes Federation (IDF) recently reported that the number of people with diabetes in the European Region is estimated to be 9.1% of the adult population and this is expected to increase to over 35.6% by 2035 [2].

Diabetes prevalence is increasing among all age groups in Bulgaria, mainly due to the rise in overweight and obesity, because of unhealthy diet and low physical activity. The rates of DM increased from 8.36% in 2006 up to 9.6% in 2014 (population >20 years of age) as patients with T2DM were 90.4% of all [3–5].

Diabetes has a profound impact on the quality of life (QOL) of patients in terms of physical, social and psychological well-being [6]. QoL is described as a multidimensional construct incorporating an individual’s subjective perception of physical, emotional and social well-being, including both a cognitive component and an emotional component, and it changes over time as a result of various influences [7]. QoL issues are considered important, because they may powerfully predict an individual’s capacity to manage his/her conditions and maintain long-term health and well-being. QoL is increasingly recognized as an important health outcome in its own right, representing the ultimate goal of all health interventions [8,9].

In many countries, valid instruments for measuring patient-reported outcomes (PROMs) in DM have been developed and are widely used in practice [10–14]. Disease-specific instruments are recommended for use in conjunction with a generic measure to assess particular problems of any given long-term condition.
The Audit of Diabetes-Dependent Quality of Life (ADDQoL) questionnaire is a third-generation individualized QoL instrument. It is a disease-specific measure, which is increasingly being used to examine the patient’s perspective of the impact of diabetes on their quality of life across a range of domains. ADDQoL is a valid and reliable questionnaire originally developed in the United Kingdom [15]. What makes this questionnaire unique in relation to others is that patients are able to indicate whether potentially affected domains of life apply to them and to rate their impact together with the perceived importance of each domain for their QoL [16–18]. The ADDQoL is linguistically validated into many languages and is well accepted in different populations, ethnic groups and cultures [10,19–31].

Measuring QoL in patients with T2DM is a widespread practice in many countries. A review of available literature showed that, in Bulgaria, studies evaluating QoL are still quite scarce and disease-specific QoL measures for DM were not available prior to the present work [32–37]. Diabetes imposes a large economic burden on patients, their families and national health systems. Treatment of the disease is very expensive, but the real impact of diabetes is in the treatment of its complications. In Bulgaria, a growing number of patients with DM complicate the work of the health system because of limited financial resources [38,39].

The aims of this study were to translate and culturally adapt the UK English Audit of Diabetes-Dependent Quality of Life version 19 (ADDQoL-19) into Bulgarian and explore the psychometric properties of the Bulgarian version of the 19-item ADDQoL (ADDQoL-19 BUL).

**Subjects and methods**

**Instrument**

The ADDQoL is a 19-domain disease-specific instrument that attempts to evaluate comprehensively diabetes-specific QoL by assessing how individuals perceive diabetes. How the disease is interfering with their well-being or, contrarily, how diabetes may be having a positive effect on some aspects of life [15].

The ADDQoL allows the respondents to indicate aspects of life that are not applicable (N/A) to them, rate the amount of impact of diabetes, positive or negative, on the applicable aspects of life, and rate the perceived importance of each applicable aspect of life for their QoL. The impact rating is multiplied by the importance rating for each applicable aspect of life to provide weighted impact scores, which can be averaged across all applicable domains to form a single, average-weighted impact (AWI) score [19]. The ADDQoL begins with two items, assessing “present QoL” and “diabetes-dependent QoL”. The subsequent items are concerned with assessing 19 more specific domains. The impact of each domain is scored on a five-point scale (from −3 to 1), and the corresponding importance is rated on a four-point scale (3 to 0). The weighted score of each applicable domain is calculated by multiplying the impact and importance rating ranging from −9 to +3. Of the 19 domains, there are five with N/A options. When these items are said to be N/A, they are scored as such. As a result, domains that are not relevant to respondents are excluded from the mean ADDQoL weighted score. Finally, the mean weighted score is converted to a final score on a 0–100 scale. A higher score indicates a better diabetes-specific QoL [15,18].

**Linguistic validation procedure**

The developers of ADDQoL (Bradley et al. [CB179/26th SEP2012] from the Health Psychology Research Ltd., University of London, Egham, Surrey, UK) were contacted in order to obtain permission for its translation and use. A formalized linguistic validation procedure was applied following the principles of good practice [40].

**Step 1.** Written permission from the authors, Bradley et al., to translate the ADDQoL was obtained.

**Step 2.** **Forward translation.** Two bilingual persons living in Bulgaria with mother tongue Bulgarian, both fluent in English, translated the ADDQoL independently to produce FT1 and FT2 translated from English into Bulgarian. After completion of the FT1/2, the project coordinator (a PhD student), together with the translators, produced a preliminary consensus version of the ADDQoL in Bulgarian (ADDQoL-BUL).

**Step 3.** **Reconciliation.** A consensus meeting addressing any discrepancies in the translations resulted in a reconciled version FT-rev of the ADDQoL. A written report documented the issues addressed and decisions made.

**Steps 4–5.** Version FT-rev was back-translated to English (BT) by one translator trained and working in an English-speaking country (Bulgarian/English). The version was compared with the original English version of the questionnaire as a validity check of semantic and conceptual equivalence. Discrepancies and any unclear wording resulted in revision of the reconciled version. The project manager carried out the review together with the back-translator.

**Step 6.** **Harmonization.** The harmonization committee consisted of linguists, back-translators, a
researcher (PhD student), clinicians (endocrinologist, psychiatrist) and a psychologist. Due to geographical and time issues, the members of the committee met individually with the project manager once and the pre-final version was developed through e-mail correspondence. Discrepancies were resolved by consensus. All reports and drafts of the BT-rev were sent to all members in the harmonization committee to ensure transparency. The original developers were contacted in order to clarify any possible misunderstandings at each stage of the process. The preliminary version and a written report were agreed upon by all the members. Steps 7–8. Test and review of the preliminary version by cognitive interviewing were performed at the University Hospital of Plovdiv. The interviews and the coding of the cognitive interviews were performed by two experienced interviewers, of whom one was the clinical psychologist. Five patients (including two men and three women, aged 38–72 years; duration of T2DM of 1–15 years; education, primary to college) were asked about their view on the impact of diabetes on their lives and the relevance of each item to themselves. In addition, the participants were asked about possible difficulties in understanding the items. Results generated a cognitive debriefing (CD) report. Steps 9–10. The original developer then did a review to ensure the authenticity of the translation. After an agreement was reached, the final version of the Bulgarian ADDQoL was produced.

Study design and participants

The cross-sectional study was conducted at outpatient practices from October 2013 to March 2015. T2DM patients were recruited as respondents from nine randomly selected practices specializing in endocrinology and metabolic diseases (25%) drawn from all practices under contract to the Regional Health Insurance Fund Plovdiv (the second largest region in Bulgaria).

The study was approved by the Research and Ethics Committee of the Medical University–Plovdiv (R-1551/13-03-2014) and performed according to the Declaration of Helsinki. All patients with T2DM were invited to participate in the study (n = 540). Inclusion criteria were as follows: age over 18 years, diagnosed with T2DM for at least 1 year and able to complete a questionnaire written in Bulgarian. We excluded patients with cognitive impairment and severe illness. Of those fulfilling the criteria, 78% (n = 423) gave written informed consent to participate in the study and completed the questionnaire. We examined the test–retest reliability among 41 patients who completed the questionnaire twice with an interval of 3 weeks (response rate 90.24% (n = 37)).

The respondents were asked to complete the ADDQoL-19 BUL and questions on socio-demographic information. We collected clinical parameters data and laboratory measurements.

Data analysis

We performed statistical analysis of reliability and construct validity using AMOS and SPSS. Cronbach’s alpha was used to determine internal consistency [41]. Confirmatory factor analysis (CFA) was performed to examine the assumed single-factor construct of the ADDQoL-19 intraclass correlation coefficient (ICC) and Bland–Altman plot was used to examine the test–retest stability. We examined convergent validity using Pearson’s correlations (r). Statistical significance was set at p < 0.05 for the data analysis, and p < 0.01 or p < 0.001 was also reported where applicable. Patients with six or more missing items in the ADDQoL were excluded from all analyses.

Results and discussion

A total of 423 adults with T2DM participated in the study. We further excluded another 12 respondents who missed out more than six items in QoL and AWI scores on the ADDQoL. Hence, the final number of responses analyzed was 411. The mean age was 59.92 years (standard deviation (SD) 11.60, range 28–88 years), 53% were males, 72% Bulgarian ethnic group, 59% were with diabetes duration of over 5 years, the mean HbA1c was 8.1 (SD 0.85) and 38% used insulin. The characteristics of the respondents are shown in Table 1.

It is becoming acknowledged that PROMs are replacing the focus from classical outcomes for clinical decision-making. They should be the basis of person-centred decision-making founded on valid, reliable and clinically useful measurement delivered by the patient to the health care providers. Physicians need more education and further research to improve the ability to interpret and apply PROMs and QoL outcome. This ability is viewed as having an unreleased potential to contribute to a better understanding of patients well-being [42]. The ADDQoL is a diabetes-specific scale widely used around the world [10–14,34,43]. We were the first to introduce and develop the Bulgarian version of ADDQoL-19 (ADDQoL-19 BUL). Although diabetes is known to be a serious burden on the Bulgarian public health
system, the studies on the impact of diabetes on the patients’ QoL are still scarce [32,35–39,44].

The final version of the Bulgarian ADDQoL was produced as a five-point Likert scale including 19 domain-specific items with five options for each impact rating scale and the same four options for each importance rating scale as shown in Table S1 (Online Supplement).

The mean present QoL score was 0.59 (SD 0.90) on a scale from 3 to −3 indicating a mean response between ‘neither good nor bad’ and ‘good’. The diabetes-related QoL mean score was −1.80 (SD 0.80), where the most negative possible score would be −3 and −2 would indicate that QoL would be ‘much better’ if the person did not have diabetes. Overall, the presence of diabetes negatively affected all 19 ADDQoL domains.

The perception of QoL among Bulgarian patients with DM has been well demonstrated by several local studies [32,35–37]. The relevance of the 19 domains to the Bulgarian diabetes patients was confirmed by two local diabetes experts and respondents during the CD. The results suggested that the items can be used in the Bulgarian version without modification other than translation. The robustness of our findings is also strengthened because the procedure was performed according to the principles of good practice and the guidelines of the developers of the instrument [40].

Some phrases in the ADDQoL that were particularly difficult to translate into Bulgarian included ‘management’, ‘local or long-distance journeys’, ‘physically can do’, ‘close personal relationship’, ‘depend on others’ and ‘freedom to eat’. The equivalence of intensity across the adverbs scale was a challenging issue. The challenge of achieving semantic equivalence with these phrases was overcome through many rounds of discussion between the translators and developers, as well as CD among the patients.

Cronbach’s alpha indicates a measure of internal consistency. In this study, the Cronbach’s alpha for the overall items was 0.92, which indicated excellent reliability. CFA indicated that a one-factor structure fitted moderately ($\chi^2 = 230.63, df = 136, p < 0.001, SRMR$ (Standardized Root Mean Square Residual) of 0.05, $RMSEA$ (Root Mean Square Error of Approximation) of 0.06, $CFI$ (Comparative Fit Index) of 0.95). Standardized coefficients showed that all domains loaded more than 0.4 on a single dimension, except for one item (freedom to drink).

In the original version, a high internal consistency was reported, and an exploratory factor analysis with a forced one-factor solution showed that all domains loaded >0.40. Compared with the acceptable level of a good comparative fit index in confirmatory factor analyses of 0.95 or higher and our study also indicated moderate support for a one-factor structure [45].

As for the known-group validity, the results showed that the participants who required insulin, experienced DM-related complications or obesity reported lower present QoL, diabetes-dependent QoL and AWI scores than the participants who did not, but in the obesity groups, the differences were not statistically significant (Table 2).

The subsample used to explore the test–retest reliability had higher prevalence of males (64.86%), but otherwise did not differ from the rest of the participants in terms of age (mean 58.9, SD 9.5), BMI (mean 31.1, SD

### Table 1. Characteristics of participants.

| Characteristics                  | n   | %    |
|----------------------------------|-----|------|
| Sex                              |     |      |
| Male                             | 216 | 52.55|
| Marital status                   |     |      |
| Married                          | 271 | 65.94|
| Single/Widowed/Divorced          | 140 | 34.06|
| Education                        |     |      |
| Primary education                | 15  | 3.65 |
| Secondary education              | 298 | 72.50|
| College and Higher               | 98  | 23.85|
| Ethnicity                        |     |      |
| Bulgarian                        | 296 | 72.02|
| Other Bulgarian ethnic group     | 115 | 27.98|
| Diabetes duration > 5 years      | 244 | 59.37|
| Complications                    | 379 | 92.21|
| DM treatment                     |     |      |
| Diet                             | 2   | 0.49 |
| Oral only                        | 252 | 61.31|
| Oral + insulin injections        | 111 | 27.01|
| Insulin injections               | 46  | 11.19|

### Table 2. Known-groups validity results.

| Participant group | Present QoL score | Diabetes-dependent QoL score | AWI score |
|-------------------|-------------------|-------------------------------|-----------|
| Insulin requiring |                   |                               |           |
| Yes (n = 111)     | 0.52 (0.97)       | −1.88 (0.78)                  | −3.08 (1.57) |
| No (n = 300)      | 0.62 (0.87)       | −1.79 (0.77)                  | −2.43 (1.55) |
| p-Value           | p < 0.05          | p < 0.05                      | p < 0.05  |
| Complications     |                   |                               |           |
| Yes (n = 379)     | 0.56 (0.89)       | −1.84 (0.76)                  | −2.86 (1.75) |
| No (n = 32)       | 1 (0.88)          | −1.50 (0.95)                  | −2.98 (1.54) |
| p-Value           | p < 0.05          | p < 0.05                      | p < 0.05  |
| Obesity (BMI > 30 kg/m²) |       |                               |           |
| Yes (n = 231)     | 0.61 (0.92)       | −1.87 (0.81)                  | −3.05 (1.61) |
| No (n = 175)      | 0.56 (0.87)       | −1.73 (0.73)                  | −2.87 (1.47) |
| p-Value           | p > 0.9           | p > 0.5                       | p > 0.7   |

Data are means (SD) and p-value; n = 411; underweighted were excluded (n = 5).
5.1), HbA1c (mean 8.0, SD 1.0) or other important demographic characteristics.

Only 19 of a total of 41 patients had complete data allowing calculation of AWI scores. The 3-week test–retest reliability of the ADDQoL AWI was high (ICC = 0.999, 95% CI: 0.997, 1.000). Figure 1 shows a Bland–Altman plot of the difference between the test and retest AWI scores. The mean of the difference was 0.01 (SD = 0.06). The 95% limits of agreement (−0.108 to 0.125) contained 89.47% (17 of 19) of the participants. There was no evidence of proportional bias in the Bland–Altman plot (trend: \( B = -0.01 \), \( SE = 0.01 \), \( t = -0.99 \), \( p = 0.338 \)) (Figure 1).

The results of the conceptual equivalence, semantic equivalence and measurement equivalence listed above indicated that a reasonable degree of equivalence was achieved in all areas.

Conclusions

The results from this exploratory study suggest that this Bulgarian version of the ADDQoL has achieved functional equivalence with the original English ADDQoL by demonstrating conceptual equivalence, item equivalence, semantic equivalence, operational equivalence and measurement equivalence. The Bulgarian version of ADDQoL-19 has good psychometric properties and will provide clinicians and researchers with a useful tool for comprehensive assessment of QoL in adults with DM. Our study provides justification for further research with large sample sizes among the patients with T2DM in Bulgaria.

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Disclosure statement

The authors have no conflicts of interest that are directly relevant to the content of the article.

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Figure 1. Bland–Altman plot for the 3-week test–retest reliability of the ADDQoL-19. The y-axis represents the difference between the first-week AWI score and the third-week AWI score. The x-axis represents the average of the first-week total score and the third-week total score. Data are \( n = 19 \); ADDQoL, Audit of Diabetes-Dependent Quality of Life; AWI, average-weighted impact score.
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