Assessment of the impact of type 2 diabetes on the quality of life by Audit of Diabetes-Dependent Quality-of-Life (ADDQoL-19)

Boryana Angelova Levterova, Maria Orbetzova, Georgi Levterov, Donka Dimitrova and Plamen Todorov

Department of Health Management and Healthcare Economics, Faculty of Public Health, Medical University of Plovdiv, Plovdiv, Bulgaria; Second Department of Internal Diseases, Medical Faculty, Medical University of Plovdiv, Plovdiv, Bulgaria; Clinic of Endocrinology and Metabolic Diseases, University Hospital "Kaspela" Ltd., Plovdiv, Bulgaria; Department of Propaedeutics of Internal Diseases, Medical Faculty, Medical University of Plovdiv, Plovdiv, Bulgaria

ABSTRACT
Together with the epidemic prevalence of diabetes mellitus (DM), the burden of this chronic metabolic disorder has serious impact on the quality of life of patients and reduces their life span. The objective of this study was to assess the impact of type 2 diabetes mellitus (T2DM) on the Quality of Life (QoL) by Audit of Diabetes-Dependent Quality-of-Life (ADDQoL-19). A cross-sectional study of 540 adults with T2DM was carried out. We collected socio-economic, demographic, health status, therapeutic and metabolic control data. The instrument used to measure the quality of life was the ADDQoL-19. The study included 411 adult patients [216 (52.6%) men; mean age 59.9 years]. T2DM had a negative impact on QoL in 36.7% of the participants, whereas 67.1% believed that their life would have been better without the presence of T2DM. The mean 'present QoL' score was: 0.6 (SD: 0.9) and the 'diabetes-related QoL was: −1.8 (SD: 0.8). Diabetes had the most negative average weighted impact on 'freedom to eat' −4.0 (SD: 2.6), and 'family life' −3.9 (SD: 2.7). The results indicate that T2DM has a significant impact on QoL and its assessment is an important tool in the management of this disease. The negative values reflect the general negative impact of diabetes over all 19 examined aspects. These findings are of importance to health professionals and policy makers to identify and implement appropriate interventions in order to achieve better disease management and ultimately to increase the QoL of patients with T2DM.

ARTICLE HISTORY
Received 20 April 2018
Accepted 2 October 2018

KEYWORDS
Type 2 diabetes mellitus (T2DM); quality of life (QoL); Audit of Diabetes-Dependent Quality-of-Life (ADDQoL-19); Bulgaria

Introduction
Diabetes mellitus (DM) is one of the major threats to global health and development in the 21st century worldwide. DM and its related complications are an important cause of disability, premature death and associated healthcare costs. In Europe, DM prevalence is estimated to be 8.8% (58.0 million) of the adult population, including 22.0 million undiagnosed cases, and is expected to amount to over 66.7 million in the year 2045 [1]. The prevalence of patients with diabetes is increasing among all age groups in Bulgaria, mainly due to the rise in overweight and obese people as a consequence of unhealthy diet, and lack of physical activity [2,3]. The prevalence of DM increased from 1.6% in 1990 to 9.6% in 2015 (population ≥20 years of age) and another 3.7% had prediabetes. About 90.4% of all patients had type 2 diabetes mellitus (T2DM) [4,5].

T2DM is a chronic metabolic disorder and together with its complications, this disease has a profound impact on every aspect of patients’ life and reduces the life span. Quality of Life (QoL) is defined as an individual’s subjective perception about ‘how good or bad a person feels his/her life to be’ [6]. QoL as a multi-dimensional construct integrating physical, social and psychological well-being, involves cognitive and emotional elements. Clinical and diagnostic check-ups provide information about the patient’s health status and the progression or regression of his/her condition. Every person perceives their QoL differently and is influenced not only by his/her own physical health, but also by the mental state, the level of dependence on others through service, social relationships, personal beliefs and the relationship with the environment [7,8]. People with DM face many everyday challenges for managing their disease: the need to
monitor their food and beverage intake and to maintain physical activity in order to achieve optimum blood glucose levels. The guidelines for DM care emphasize that one of the primary objectives is to improve QoL [9]. Efforts to prevent complications of diabetes often overlook its treatment and the impact of this condition on the current QoL of a patient. QoL issues are very important because they may strongly predict an individual’s capacity to manage his/her conditions and maintain long-term health and well-being. QoL is a term with a measurable outcome and it is an important indicator of the forecasting of the survival and treatment results, or for the outcome of various health interventions [7,10]. In the context of quality of care, the QoL is one of the most frequently evaluated Patient Reported Outcome Measures (PROMs) [11].

There is no direct approach in assessing QoL. This is why item-measurement theory is applied when trying to evaluate QoL. A number of diabetes-specific questionnaires for QoL have been developed and are in use [12–16]. Disease-specific instruments are recommended for use in conjunction with a generic measure to assess particular problems of any given long-term condition [17,18].

Measuring QoL in patients with T2DM is a widespread practice in many countries. In Bulgaria, there are still only limited studies evaluating diabetes-specific QoL [19]. Therefore, the objective of this cross-sectional study was to assess the impact of diabetes on QoL of Bulgarian patients with type 2 diabetes mellitus (T2DM).

Subjects and methods

Instrument

The participants were asked to fill in the Bulgarian version of Audit of Diabetes-Dependent Quality of Life (ADDQoL-19) and a questionnaire with additional socio-demographic questions. The ADDQoL-19-domain disease-specific instrument was designed and developed by Prof. Bradley et al. [20]. The purpose of this questionnaire is to provide a comprehensive measurement of the diabetes specific quality of life by evaluating the way the individuals perceive their disease and how the disease impacts on their well-being according to various life domains [21]. The ADDQoL begins with two items, assessing ‘present QoL’ and ‘diabetes-dependent QoL’. The first one evaluates the global QoL. ‘In general, my present QoL is’: (excellent/very good/good/neither good nor bad/bad/very bad/extremely bad). The evaluation scale is from +3 (excellent) to −3 (extremely bad). The second question examines the global impact of diabetes on QoL (diabetes-dependent QoL) in the format ‘If I did not have diabetes, my QoL would be’: (very much better/much better/a little better/the same/worse). This domain is evaluated by a scale from +1 (maximum positive effect of the diabetes) to −3 (maximum negative impact of diabetes). The two elements are evaluated separately. Nineteen specific aspects of life follow and they examine: (a) how diabetes affects this aspect and (b) how important this aspect is for the patient’s QoL. The questions are worded in the following manner: ‘If I did not have diabetes, (specific aspects of life) would be’: (very much better/much better/a little better/the same/worse). The impact for each domain is evaluated based on the 5-points Likert scale, from −3 (maximum negative impact of the diabetes) to +1 (maximum positive impact of the diabetes). Then the respondent states how important this aspect is to his/her life (very important—important—somewhat important—not at all important (+3 to 0)). Out of these 19 domains, five ones have an optional answer of ‘not applicable’, i.e. the patient can mark whether a given area is applicable to his/her state or not. The weighted result for each domain is calculated by the multiplication of the evaluation of the impact (impact rating) to the evaluation of importance (importance rating). The Average Weighted Impact (AWI) is evaluated by adding the weighted evaluation for each area and dividing by the number of applicable domains. AWI varies from −9 (maximum negative impact) to +3 (maximum positive impact). Finally, the average weighted result (ADDQoL score) is calculated for the entire scale in all applicable domains. A lower result corresponds to worse QoL [20–22]. The Bulgarian version of the questionnaire shows good psychometric properties [23] and it is available at the authors’ website (https://www.healthpsychologyresearch.com/find-a-questionnaire/audit-diabetes-dependent-quality-life-39).

Study design and participants

This multi-centre cross-sectional study was conducted between March 2014 and March 2015, describing QoL in a group of patients suffering from T2DM. Patients from the endocrinology outpatient clinics in Plovdiv, the second largest region in Bulgaria, were recruited. The eligible patients who were enrolled in the study fulfilled the following criteria: (1) subjects aged over 18 years; (2) duration of T2DM (ICD-10: E11–E14) of at least 1-year according to the available medical records [24]; (3) ability to read and write in Bulgarian. Main
exclusion criteria were as follows: (1) patients with type 1 diabetes, secondary and gestational DM; (2) any mental disease and cognitive impairment; (3) malignant neoplasms and ongoing chemotherapy or radiotherapy; (4) severe illness. A total of 540 individuals were enrolled in the study. We excluded 117 diabetic patients who did not wish to participate. The patients who wished to participate were informed by their physician about the purposes, content and confidentiality related to their participation in the study, and they gave their written informed consent. After informed consent was obtained, all participants were given ADDQoL-19 and an additional questionnaire with socio-demographic characteristics and disease history. When needed, assistance in completing the questionnaire was provided by the patient’s physician, who had been trained in the use of the ADDQoL questionnaire prior to the launch of this study. All data were collected at a single visit by the physicians via medical records review and patient-self-completed questionnaires. Information about the medical history and the duration of the diabetes, glycaemic control and existing complications was also collected from the patients’ medical records.

This study was approved by the Ethics Committee of the Medical University of Plovdiv, Bulgaria (R-1551/13-03-2014).

### Data analysis

Data were analysed using IBM SPSS Statistics-17 (Chicago, IL, USA). The sample data were expressed as frequencies and percentages for categorical variables or by mean values and standard deviation (SD) for continuous variables. After the verification of the normal distribution of the variables, t-test was performed to describe the differences between the means of the groups. p value <0.05 was considered as statistically significant.

### Results and discussion

In total, 540 patients with T2DM were enrolled in this study; 423 individuals gave their written informed consent (response rate of 78.3%). After exclusion of 12 cards with incomplete data, 411 patients were included in the final analysis.

The age groups ranged from 28 to 88 years of age. The mean age of the participants was 59.9 years (SD

| Variables                          | n (%)    | AWI score (SD) | p value |
|------------------------------------|----------|----------------|---------|
| **Gender**                         |          |                |         |
| Males                              | 216 (52.6) | −2.91 (1.64)   | 0.018   |
| Females                            | 195 (47.4) | −3.04 (1.46)   |         |
| **Marital status**                 |          |                |         |
| Married                            | 271 (65.9) | −2.10 (1.60)   | 0.005   |
| Single/widowed/divorced            | 140 (34.1) | −2.91 (1.01)   |         |
| **Education**                      |          |                |         |
| Primary                            | 15 (3.6)  | −2.92 (1.10)   | 0.867   |
| Secondary                          | 298 (72.6) | −3.03 (1.54)   |         |
| College and University             | 98 (23.8)  | −3.26 (1.51)   |         |
| **Ethnicity**                      |          |                |         |
| Bulgarian                         | 296 (72.0) | −2.92 (1.53)   | 0.887   |
| Bulgarian Turkish                 | 65 (15.8)  | −3.25 (1.78)   |         |
| Bulgarian Roma                    | 37 (9.0)   | −3.00 (1.51)   |         |
| Other (Bulgarian Armenian, Bulgarian Jew, etc.) | 13 (3.2) | −3.04 (1.68)   |         |
| **Family history of T2DM**         |          |                |         |
| Employed/self-employed            | 183 (44.5) | −2.89 (1.45)   | 0.406   |
| Unemployed                         | 23 (5.6)   | −3.43 (1.87)   |         |
| Permanently unable to work due to long-term sickness/disability | 41 (10.0) | −2.99 (1.49) | 0.199 |
| Retired                            | 164 (39.9) | −2.99 (1.49)   |         |
| **Perceived economic status**      |          |                |         |
| Poor                               | 124 (30.2) | −2.87 (0.12)   | 0.253   |
| Moderate                           | 139 (33.8) | −2.90 (0.13)   |         |
| Good                               | 148 (36.0) | −3.16 (0.15)   |         |
| **Smoking status**                 |          |                |         |
| Yes                                | 99 (24.1)  | −3.11 (0.16)   | 0.861   |
| No                                 | 312 (75.9) | −2.93 (0.09)   |         |
| **Mean (SD) Range**                |          |                |         |
| Age (years)                        | 59.9 (11.6) | 28–88          | 0.058   |
| HbA1c (%)                          | 8.1 (0.8)   | 6.1–10.8       | 0.001   |
| BMI (kg/m²)                        | 30.9 (5.5)  | 18.6–56.0      | 0.875   |

AWI score, average weighted impact score; HbA1c, glycated haemoglobin; BMI, body mass index.
and it indicates an overall negative impact of DM on QoL in 36.7% of the study participants, whereas 67.1% believed that their life would have been better without the presence of T2DM. The mean AWI score for this population was −2.9 (SD 1.5), where the most negative possible score is −9 and it indicates an overall negative impact of DM on aspects of life of importance for the QoL of patients. A more negative score reflects a greater negative impact of DM on that domain of life. In Bulgarian patients, type 2 DM had the greatest negative impact on ‘freedom to eat’ (mean impact rating: −1.8, SD 0.9) and the least impact on ‘people’s reaction’ (mean −0.9, SD 1.0). After considering weighting, ‘freedom to eat’ (mean −4.0, SD 2.6) was the most affected QoL domain, followed by ‘family life’ (−3.9, SD 2.7) and ‘physically can do’ (−3.7, SD 2.3), whereas ‘people’s reaction’ (mean −1.9, SD 2.4) was the least affected QoL domain. ‘Family life’ was rated as the most important one (mean 2.5, SD 0.6), whereas ‘local or long-distance journeys’ was rated as the least important (mean 1.6, SD 0.7) domain (Table 3).

The ADDQoL instrument includes five domains that respondents can choose not to answer. If no answer was provided, the ADDQoL score was calculated without these domains. Our analysis of the item response patterns showed that three domains (‘working life’, ‘holidays’ and ‘sex life’) accounted for a large majority of those identified as not applicable (N/A). Among these, ‘working life’ was most often identified as N/A (116, 28.2%).

Despite the fact that DM imposes a serious burden on the individuals and the public healthcare system, there are only a few studies that evaluate the impact of this disease on QoL of the patients in Bulgaria [25–29]. This is the first detailed analysis of the impact of type 2 diabetes mellitus on the QoL using a disease-specific questionnaire, translated and validated in Bulgarian. Additionally, the assessment of QoL using an instrument specifically designed and validated for this purpose further supports the obtained results [30,31]. The majority of respondents in this study belonging to the Bulgarian ethnic group is in line with the distribution of the general population in Bulgaria [32].

In the past decade, ADDQoL is one of the most widely-used instruments to measure diabetes-specific quality of life [33]. On the basis of systematic reviews, the ADDQoL is the method of choice for assessment of diabetes-related QoL. It has good psychometric properties and offers the most promising approach for measuring individuals’ perceptions of the impact of diabetes on their quality of life [12–14,16,17,33–35]. In accordance, the recent guidelines from the American Diabetes Association emphasize the need for a “patient centered” approach in the management of T2DM patients, and QoL has been placed in the centre of the disease management [36]. For evaluation of diabetes care, it is necessary to identify the impact

### Table 2. Clinical characteristics of the study cohort (n = 411).

| Duration of type 2 DM | n (%) | AWI score (SD) | p value |
|-----------------------|-------|---------------|---------|
| <5 years              | 166 (40.6) | −2.86 (1.84) | 0.042  |
| ≥5 years              | 245 (59.4) | −3.14 (1.45) |         |

**Diabetes-related complications**

| Disorder                      | n (%) | AWI score (SD) | p value |
|-------------------------------|-------|---------------|---------|
| Any complication              | 379 (92.2) | −2.98 (1.54) | 0.016  |
| Diabetic retinopathy          | 59 (14.4)  | −2.99 (0.19) | 0.040  |
| Diabetic nephropathy          | 33 (8.0)   | −3.28 (1.42) | 0.023  |
| Diabetic neuropathy           | 378 (92.0) | −2.98 (1.53) | 0.019  |
| Diabetic foot                 | 15 (3.7)   | −3.08 (0.86) | 0.034  |
| Coronary artery disease       | 188 (45.7) | −3.12 (1.54) | 0.982  |
| Cerebrovascular disease       | 118 (28.7) | −2.92 (1.45) | 0.583  |
| Hypertension                  | 343 (83.5) | −2.98 (0.08) | 0.902  |
| Dyslipidemia                  | 51 (12.4)  | −3.0 (1.74)  | 0.007  |

**Treatment regiments**

| Treatment                      | n (%) | AWI score (SD) | p value |
|-------------------------------|-------|---------------|---------|
| Only diet and/or exercise     | 2 (0.5)   | −2.94 (1.57)  | 0.006  |
| Oral antidiabetic drugs       | 252 (61.3) | −2.85 (1.46) |         |
| Only insulin                  | 46 (11.2)  | −3.08 (1.57)  |         |
| Oral anti-diabetes drugs and insulin | 111 (27.0) | −3.50 (1.97) |         |

AWI score, average weighted impact score.

*The total value exceeds 100% because some participants had more than one complication.

The duration of diabetes was 10.3 (SD 3.8) years and the HbA1c mean level was 8.1% (SD 0.8). Regarding the diabetes complications, 45.7% of the patients had coronary artery disease, 28.7% had a cerebrovascular disease, 14.4% retinopathy, 92% neuropathy and 8% nephropathy. Almost 61.3% (N = 252) of the study participants were on oral anti-diabetic treatment, while 11.2% (N = 46) were on insulin therapy alone. More details about the respondents’ clinical characteristics are shown in Table 2.

T2DM had a negative impact on QoL in 36.7% of the study participants, whereas 67.1% believed that their life would have been better without the presence of T2DM. The ADDQoL score of 209 patients with T2DM was calculated in the range of −9.0 to 0.0 (scaled from −9 to 3). The median ADDQoL score for this population was −2.9. The mean ‘present QoL’ score was 0.6 (SD 0.9) on a scale from 3 to −3, indicating a mean response between ‘neither good nor bad’ and ‘good’. The distributions of responses regarding the ADDQoL items and the weights assigned to impact ratings are shown in Table 3.

The mean AWI score for this population was −2.9 (SD 1.5), where the most negative possible score is −9 and it indicates an overall negative impact of DM on the study cohort (n = 411).
of diabetes on QoL. It not only gives us information about patients’ experience of living with diabetes, but also shows us ways in which we can improve diabetes care.

The results in the present study suggest that T2DM has strong influence on the subjects’ QoL. If the average weighted impact score is taken into account, the socio-demographic characteristics such as sex, marital status and disease-related characteristics and co-morbidity were found to be significantly associated with QoL. Among the patients with T2DM, those who are female and unmarried reported a lower average weighted impact score. A number of studies report that QoL is better among men than women with diabetes and among married people [8,37]. The scores representing diabetes-related QoL were significantly lower in the patients with a longer duration of diabetes (>5 years), those with microvascular complications and the patients on insulin regimens. These findings are in agreement with a number of previous studies [20–22,29,38,39]. Evidence shows that the strength of the relationship between diabetic-related complications and QoL might be sensitive to the frequency of diabetic complications, and the impact on domain ‘physically can do’ may be due to their presence [6]. Diabetes complications such as neuropathy lead to a restriction of movement and physical stamina and difficulties in performing everyday activities.

The proper management of diabetes through maintenance of optimal glycaemic control reduces the risk of development of long-term diabetic complications. Early diagnosis and optimal treatment are essential for the prevention of the worsening of the QoL of those patients [36].

ADDQoL reflects the general negative impact of diabetes over all the 19 examined aspects of QoL of the patients with T2DM [6,20–22,37–45]. ADDQoL indicated that the surveyed Bulgarian patients with T2DM felt that their QoL would have been better if they did not have this disease. The greatest negative weighted impact of T2DM observed in the present study was ‘freedom to eat’, which is in line with previous studies [21–22]. This parameter was assessed as important or very important by 83.4% of the patients. The influence of diabetes over the quality of life consists of two interconnected aspects: consequences attributed to stress factors related to the disease and the difficulties with following a strict regimen and therapy [8]. The use of ADDQoL among patients with diabetes showed a strong influence of food limitations on diabetes-related QoL and similar findings have been reported earlier in various countries and populations [6,20,21,36,41–44]. What is more, ‘freedom to eat’ also has a maximum unweight negative assessment. Fear of weight gain, high blood glucose levels as well as fear of hypoglycaemia affects patient’s dietary habits.

### Table 3. Distribution of responses for the Audit of Diabetes Dependent Quality of life (ADDQoL-19) Bulgarian version by impact and importance rating together with Average Weighted Impact (AWI).

| Specific life domain                  | NA response n = 411 (%) | Impact rating n = 209 | Importance rating n = 209 | AWI n = 209 |
|--------------------------------------|-------------------------|-----------------------|---------------------------|-------------|
|                                      | Rank*                   | Mean SD               | Mean SD                   | Mean SD     |
| Leisure activities                   | –                       | 17                    | –1.32 ± 0.82              | 1.70 ± 0.67 | –2.47 ± 2.02 |
| Working life                         | 116 (28.22)             | 4                     | –1.54 ± 0.92              | 2.13 ± 0.75 | –3.49 ± 2.58 |
| Local or long distance journeys      | –                       | 16                    | –1.33 ± 0.99              | 1.64 ± 0.74 | –2.49 ± 2.34 |
| Holidays                             | 99 (24.09)              | 8                     | –1.47 ± 0.95              | 1.90 ± 0.70 | –3.07 ± 2.43 |
| Physically can do                   | 3                      | –1.63 ± 0.77           | 2.16 ± 0.73               | –3.66 ± 2.33 |
| Family life                          | 18 (4.38)               | 2                     | –1.54 ± 0.89              | 2.45 ± 0.64 | –3.91 ± 2.65 |
| Friendships and social life          | –                       | 11                    | –1.33 ± 0.95              | 2.05 ± 0.68 | –2.95 ± 2.55 |
| Close personal relationship          | 61 (14.84)              | 5                     | –1.42 ± 0.98              | 2.25 ± 0.69 | –3.37 ± 2.72 |
| Sex life                             | 91 (22.14)              | 6                     | –1.42 ± 0.97              | 1.98 ± 0.82 | –3.13 ± 2.66 |
| Physical appearance                  | –                       | 7                     | –1.51 ± 0.85              | 1.90 ± 0.74 | –3.12 ± 2.34 |
| Self-confidence                      | –                       | 10                    | –1.42 ± 0.95              | 1.93 ± 0.68 | –3.02 ± 2.48 |
| Motivation                           | –                       | 15                    | –1.23 ± 0.95              | 1.75 ± 0.74 | –2.53 ± 2.30 |
| People’s reaction                    | –                       | 18                    | –0.93 ± 0.97              | 1.75 ± 0.74 | –1.91 ± 2.36 |
| Feelings about the future            | –                       | 13                    | –1.33 ± 0.93              | 1.91 ± 0.67 | –2.82 ± 2.43 |
| Financial situation                  | –                       | 14                    | –1.31 ± 0.94              | 2.02 ± 0.55 | –2.81 ± 2.39 |
| Living conditions                    | –                       | 12                    | –1.32 ± 0.91              | 2.04 ± 0.52 | –2.83 ± 2.27 |
| Depend on others                     | –                       | 12                    | –1.25 ± 0.98              | 2.10 ± 0.72 | –2.83 ± 2.62 |
| Freedom to eat                       | 1                      | 1                     | –1.79 ± 0.87              | 2.05 ± 0.67 | –3.97 ± 2.60 |
| Freedom to drink                     | –                       | 9                     | –1.52 ± 0.93              | 1.67 ± 0.90 | –3.03 ± 2.73 |

Impact rating (conditions without DM): 3, very much better; 2, much better; 1, a little better; 0, the same; –1, worse.

Importance rating: 0, not at all important; 1, somewhat important; 2, important; 3, very important.

Weighted impact score = impact rating (−3 to +1) × importance rating (0–3) = −9 (maximum negative impact of DM) to +3 (maximum positive impact of DM).

*1 being the greatest impact; items with the same mean weighted impact scores have the same rank.
As shown in a multi-centre study, there is a relationship between diabetes-specific QoL and dietary behaviour [46]. This implies that a disease management programme that suggests preventive interventions to promote eating flexibility according to the treatment, will improve QoL for most people with T2DM [20,21].

Highest importance rating was reported for ‘family life’ and ‘personal relationship’. A similar observation has been reported by authors from Asia [47]. In a Bulgarian context, this may be interpreted in terms of Bulgarians having traditions that highly esteem strong family and personal relationships.

Analysis of patterns of response showed that several areas (‘working life’, ‘holidays’ and ‘sex life’) constitute the majority of the ‘not applicable’ data. This is understandable, since the majority of respondents were retired or unemployed and working life was not the major concern for them. ‘Missing’ answers to the question ‘sex life’ may be explained by the fact that most Bulgarians would avoid openly discussing topics related to sex with their doctor.

We recognize some limitations in our study. The major limitation is the cross-sectional design of the study that cannot determine the causal nature of the associations. Second, our respondents, who were recruited from secondary care settings, may differ in sociodemographic characteristics from the general population with this disease. Third, the study setting in a single geographical region, although the second largest in Bulgaria, may not be representative for patients with diabetes mellitus throughout Bulgaria. Nevertheless, we have shown that ADDQoL is useful in this subgroup. Further investigation should be spread to other outpatient practices or endocrinology clinics in other regions.

Conclusions
T2DM has a significant impact on QoL and its assessment is an important tool in the management of this disease. The negative values reflect the general negative impact of diabetes mellitus over all 19 examined aspects of QoL of our patients, the ones most affected being: ‘freedom to eat’, ‘family life’ and ‘physically can do’. These findings are of importance to health professionals and policy makers to identify and implement appropriate interventions for achieving better disease management and ultimately to increase the quality of life of patients with type 2 diabetes mellitus.

Acknowledgments
We gratefully acknowledge the outpatient diabetic centres, the health professionals and the diabetic patients for their willingness to participate in the study. Permission to use the ADDQoL questionnaire was granted by Professor Clare Bradley, Health Psychology Research, Royal Holloway University of London, Surrey, UK. The authors would like to express their appreciation of Prof. Clare Bradley and Ms. Rosalind Poultright for their advice and revision to an initial draft of this article. ADDQoL19 in its original version in English and the validated translation into Bulgarian can be obtained from the copyright holder, Professor Clare Bradley, via her website: http://www.healthpsychologyresearch.com.

Disclosure statement
The authors declare that they have no competing interests.

Funding
This paper was published under grant number BG05M2OP001-2.009-0025, “Doctoral training at MU-Plovdiv for Competence, Creativity, Originality, Realization and Academism in Science and Technology - 2 (DOCTORANT - 2)”, funded under the Operational Programme "Science and Education for Smart Growth", co-funded by the Structural and Investment Funds of the EU.

Research involving human participants
This study was approved by the Ethics Committee of Medical University – Plovdiv. Informed consent was obtained from all patients included in the study.

ORCID
Boryana Angelova Levterova http://orcid.org/0000-0002-0215-6119
Maria Orbetzova http://orcid.org/0000-0001-9918-0707
Georgi Levterov http://orcid.org/0000-0001-6163-2763

References
[1] International Diabetes Federation. IDF diabetes Atlas. 8th ed. International Diabetes Federation: Brussels (Belgium); 2017. http://www.diabetesatlas.org.
[2] Borisova A-M, Zaharieva S, Tankova T. Preporaki za dobra klinichna praktika pri zaharen diabet [Recommendations for good clinical practice in diabetes]. Bulgarian Society of Endocrinology: Sofia (Bulgaria); 2016 (Bulgarian).
[3] Tankova T, Chakarova N, Atanassova I, et al. Evaluation of the Finnish Diabetes Risk Score as a screening tool for impaired fasting glucose, impaired glucose tolerance and undetected diabetes. Diabetes Res Clin Pract. 2011;92:46–52.
[4] Borissova A-M, Shinkov A, Kovatcheva R, et al. Changes in the prevalence of diabetes mellitus in Bulgaria (2006–2012). Clin Med Insights Endocrinol Diabetes. 2015;8:41–45.

[5] Borissova A-M, Shinkov A, Vlahov J, et al. Razprostranenie na zaharnia diabet i prediabet v Bulgaria dnes [Prevalence of diabetes mellitus and prediabetes in Bulgaria today]. Endocrinologia. 2012;12:182–192 (Bulgarian).

[6] Singh H, Bradley C. Quality of life in diabetes. Int J Diab Dev Ctries. 2006;26:7–10.

[7] Kaplan RM, Ries AL. Quality of life: concept and definition. COPD. 2007;4:263–271.

[8] Rubin RR, Peyrot M. Quality of life and diabetes. Diabetes Metab Res Rev. 1999;15:205–218.

[9] Snoek FJ. Quality of life: a closer look at measuring patients’ well-being. Diabetes Spectr. 2000;13:24–28.

[10] Cochrane J, Conn VS. Meta-analysis of quality of life outcomes following diabetes self-management training. Diabetes Educ. 2008;34:815–823.

[11] Fayers PM, Machin D. Quality of life: the assessment, analysis and interpretation of patient-reported outcomes. Wiley: West Sussex; 2007.

[12] Garratt AM, Schmidt L, Fitzpatrick R. Patient-assessed health outcome measures for diabetes: a structured review. Diabet Med. 2002;19:1–11.

[13] Speigh J, Reaney MD, Barnard KD. Not all roads lead to Rome—a review of quality of life measurement in adults with diabetes. Diabetic Med. 2009;26:315–327.

[14] Levetorova B, Dimitrova Z, Ovcharova N, et al. Instruments for disease-specific quality-of-life measurement in patients with type 2 diabetes mellitus—a systematic review. Folia Med (Plovdiv). 2013;55:83–92.

[15] Roborel de Climens A, Tunceli K, Arnould B, et al. Review of patient-reported outcome instruments measuring health-related quality of life and satisfaction in patients with type 2 diabetes treated with oral therapy. Curr Med Res Opin. 2015;31:643–665.

[16] El Achhab Y, Nejari C, Chikri M, et al. Disease-specific health-related quality of life instruments among adults diabetic: a systematic review. Diabetes Res Clin Pract. 2008;80:171–184.

[17] Bowling A. Measuring disease: a review of disease specific quality of life measurement scales. Open University Press: Buckingham, Philadelphia; 2001.

[18] Polonsky WH. Understanding and assessing diabetes-specific quality of life. Diabetes Spectr. 2000;13:36–41.

[19] Levetorova B, Foreva G, Dimitrova D, et al. Priloženieno na instrumenta za otsenka na kachestvoto na zhivot pri hronichni zabolyavania v bulgarskata meditsinska praktika [Use of instruments for assessment of the quality of life in chronic diseases in the Bulgarian medical practice]. Gen Med. 2014;16:12–18 (Bulgarian).

[20] Bradley C, Todd C, Gorton T, et al. The development of an individualized questionnaire measure of perceived impact of diabetes on quality of life: the ADDQoL. Qual Life Res. 1999;8:79–91.

[21] Bradley C, Speight J. Patient perceptions of diabetes and diabetes therapy: assessing quality of life. Diabetes Metab Res Rev. 2002;18:564–569.

[22] Speight J, Sinclair AJ, Browne JL, et al. Assessing the impact of diabetes on the quality of life of older adults living in a care home: validation of the ADDQoL senior. Diabetic Med. 2013;30:74–80.

[23] Levetorova B, Levetor G, Dragova E, et al. Bulgarian version of the Audit of Diabetes-Dependent Quality of Life (ADDQoL-19). Biotechnol Biotechnol Equip. 2017;31:581–587.

[24] Alberti KG, Zimmet PZ. Definition, diagnosis and classification of diabetes mellitus and its complications. Part 1: diagnosis and classification of diabetes mellitus. Provisional report of a WHO consultation. Diabet Med. 1998;15:539–553.

[25] Yordanova S, Petkova V, Petrova G, et al. Comparison of health-related quality-of-life measurement instruments in diabetic patients. Biotechnol Biotechnol Equip. 2014;28:769–774.

[26] Petkova VB, Petrova GI. Pilot project for education of patients with type 2 diabetes by pharmacists. Acta Diabetol. 2006;43:37–42.

[27] Plaveev O, Dimitrova Z, Ovcharova N, et al. Assessment of the decreased productivity of patients with diabetes type 2 in the Clinical Endocrinological Center Sofia, Bulgaria. Pharmacy Practice (Granada). 2006;4:204–207.

[28] Tankova T, Dakovska G, Koev D. Education and quality of life in diabetic patients. Patient Educ Couns. 2004;53:285–290.

[29] Levetorova B, Levetor G, Dragova E. Quality of life in patients with type 2 diabetes mellitus in Bulgaria: a cross-sectional study. EJPM. 2016;4:7–12.

[30] Bradley C, editor. Handbook of psychology and diabetes: a guide to psychological measurement in diabetes research and practice. 5th ed. Routledge: Abingdon (UK); 1994.

[31] Bradley C, Gamsu DS. Guidelines for encouraging psychological well-being: report of a Working Group of the World Health Organization Regional Office for Europe and International Diabetes Federation European Region St Vincent Declaration Action Programme for Diabetes. Diabet Med. 1994;11:510–516.

[32] National Statistical Institute Database. http://www.nsi.bg/census2011/PDOC52/Census2011final_en.pdf.

[33] Tang TS, Yusuf FL, Polonsky WH, et al. Assessing quality of life in diabetes: II–Deconstructing measures into a simple framework. Diabetes Res Clin Pract. 2017;126:286–302.

[34] Gibbons E, Fitzpatrick R. A structured review of patient-reported outcome measures for people with diabetes: an update 2009. http://phi.uhcet.ox.ac.uk/pdf/Diabetes_2009FINAL.pdf.

[35] Zhang XH, Tan K, Tan HH, et al. Are English and Chinese versions of the audit of diabetes-dependent quality of life equivalence? An exploratory study based on the universalist approach. Value Health Reg Iss. 2012;1:75–81.

[36] Standards of Medical Care in Diabetes—2018: summary of revisions. Diabetes Care. 2018;41:S1–S2.

[37] Ozder A, Sekeroglu M, Eker HH. Quality of life and satisfaction with treatment in subjects with type 2 diabetes: results from primary health care in Turkey. Int J Clin Exp Med. 2014;7:5715–5722.
[38] Demirci H, Cinar Y, Bayram N, et al. Quality of life in type II diabetic patients in primary health care. Dan Med J. 2012;59:A4468

[39] Papazafiropoulou AK, Bakomitrou F, Trikallinou A, et al. Diabetes-dependent quality of life (ADDQOL) and affecting factors in patients with diabetes mellitus type 2 in Greece. BMC Res Notes. 2015;8:786 [cited 2018 May 28] DOI:10.1186/s13104-015-1782-8

[40] Wang HF, Yeh MC. The quality of life of adults with type 2 diabetes in a hospital care clinic in Taiwan. Qual Life Res. 2013;22:577–584.

[41] Sundaram M, Kavookjian J, Patrick JH, et al. Quality of life, health status and clinical outcomes in Type 2 diabetes patients. Qual Life Res. 2007;16:165–177.

[42] Holmanová E, Zíaková K. Audit diabetes-dependent quality of life questionnaire: usefulness in diabetes self-management education in the Slovak population. J Clin Nurs. 2009;18:1276–1286.

[43] Pichon-Riviere A, Irazola V, Beratarrechea A, et al. Quality of life in type 2 diabetes mellitus patients requiring insulin treatment in Buenos Aires, Argentina: a cross-sectional study. Int J Health Policy Manag. 2015;4:475–480.

[44] Avramopoulos I, Moulos A, Nikas N. Glycaemic control, treatment satisfaction and quality of life in type 2 diabetes patients in Greece: The PANORAMA study Greek results. WJD. 2015;6:208–216.

[45] Kuznetsov L, Griffin SJ, Davies MJ, et al. Diabetes-specific quality of life but not health status is independently associated with glycaemic control among patients with type 2 diabetes: a cross-sectional analysis of the Addition-Europe trial cohort. Diabetes Res Clin Pract. 2014;104:281–287.

[46] UK Prospective Diabetes Study Group. Quality of life in type 2 diabetic patients is affected by complications but not by intensive policies to improve blood glucose or blood pressure control (UKPDS 37). Diabetes Care. 1999;22:1125–1136.

[47] Kong D, Ding Y, Zuo X, et al. Adaptation of the Audit of Diabetes-Dependent Quality of Life questionnaire to people with diabetes in China. Diabetes Res Clin Pract. 2011; 94:45–52.