Development and Psychometric Validation of an Instrument to Identify Barriers to Self-Care Among Spanish Patients With Type 2 Diabetes on the Basis of Theory of Planned Behavior

Jorge Caro-Bautista, RN, PhD,[1,2*] Milagrosa Espinar-Toledo, RN, MPH,[3] Francisca Villa-Estrada, RN, PhD,[2,4] Inmaculada Lupiáñez-Pérez, RN, PhD,[2,5] Shakira Kaknani-Uttumchandani, RN, PhD,[2,6] Silvia García-Mayor, RN, PhD,[2,6] Felipe Salas-Samper, RN,[7] José Miguel Morales-Asencio, RN, PhD,[2,6]

[1]Health Care Centre "El Limonar," District of Primary Health Care of Málaga, Andalusian Public Health System, Málaga, Spain; [2]Instituto de Investigación Biomédica de Málaga-IBIMA, Málaga, Spain; [3]Health Care Centre "Rincón de la Victoria," District of Primary Health Care of Málaga, Andalusian Public Health System, Málaga, Spain; [4]Health Care Centre "Miraflores de los Ángeles," District of Primary Health Care of Málaga, Andalusian Public Health System, Málaga, Spain; [5]Health Care Centre "Carlinda," District of Primary Health Care of Málaga, Andalusian Public Health System, Málaga, Spain; [6]Department of Nursing and Podiatry, Universidad de Málaga, Málaga, Spain; [7]Health Care Centre "La Carihuela," District of Primary Health Care of Costa del Sol, Andalusian Public Health System, Málaga, Spain

* Address correspondence to: Jorge Caro-Bautista, RN, PhD, Health Care Centre "El Limonar," District of Primary Health Care of Málaga, Andalusian Public Health System, República Argentina St, Málaga 29016, Spain. Email: jorge.caro.sspa@juntadeandalucia.es

ABSTRACT

Background: Several instruments are available to evaluate barriers to self-care in people with type 2 diabetes, but with significant psychometric weaknesses and poor theoretical background.

Objectives: To develop and psychometrically validate a questionnaire to identify barriers to self-care in this population on the basis of the theory of planned behavior.

Methods: The study was carried out in 15 primary healthcare centers belonging to the Public Health Care System in Andalusia (Spain). After content validity was confirmed, an initial pilot study was undertaken (n = 54) and the model was evaluated in 2 samples of 205 subjects each to test its configural and metric invariance by confirmatory factor analysis. Internal consistency, test-retest reliability, criterion validity, and interpretability were carried out following COSMIN standards.

Results: A 4-factor instrument (intention, subjective norms, perceived control, and attitudes) with 15 items was obtained with a good fit: goodness-of-fit index = 0.92, comparative fit index = 0.93, and root mean square error of approximation = 0.043 (90% confidence interval 0.034-0.052). Cronbach a was 0.78, and test-retest reliability was adequate (intraclass correlation coefficient 0.73; P< .0001). The instrument revealed an adequate criterion validity depending on the treatment complexity and level of metabolic control. Thus, participants with poor self-care scores were more likely to suffer from diabetes-related complications (odds ratio 1.91; 95% confidence interval 1.15-3.1).

Conclusions: A theory-driven instrument is suitable for its use with Spanish people with type 2 diabetes to assess their selfcare needs and make tailored recommendations for lifestyle modifications on the basis of their behavioral determinants.

Keywords: instrument development, psychometric validation, self-care, theory of planned behavior, type 2 diabetes mellitus.

Introduction

Type 2 diabetes mellitus (T2DM) is one of the most common chronic diseases and is among those causing the greatest impact on patients' quality of life; furthermore, it is associated with numerous comorbidities and it demands large amounts of resources from public health services. According to the International Diabetes Federation, the disease is evolving toward a genuinely pandemic scenario, with a prevalence of 382 million people in 2013, a figure that could rise to 592 million by 2035, with lower middle-income countries likely to experience the sharpest increase in the coming years.[1] In Spain, according to the Di@bet.es Study, the prevalence in 2010 was 13.8% (95% confidence interval [CI] 12.8%-14.7%), with 6% cases of unknown diabetes.[2] In continental Europe, these data were surpassed only in Germany, Portugal, Serbia, and Turkey.1 In the United States, the Hispanic population presented the greatest increase in diabetes prevalence in the period 1997 to 2012, rising to 11.4% (95% CI 10.2%-12.7%) but not reaching that of the African-American population, with 12.6% (95% CI 11.6%-13.6%).[3]

As in many other chronic conditions, self-care is a key issue in the maintenance and control of symptoms, complications, and quality of life.[4] The concept of self-care with respect to diabetes presents several features common to most chronic diseases such as the need of social and emotional support,[5] or the presence of physical limitations, the lack of knowledge, and the impact of clinical complications and treatment-related problems.[6]

The great challenge for patients and providers is to sustain long-term self-care practices.[7] To achieve this goal, some authors have proposed that care for individual needs should be adapted using patient-reported outcomes before any intervention.[8] These instruments have proved to be an effective means of measuring health outcomes, provided that their development includes inputs from both patients and clinicians, and that they are designed and validated for the target population.[9]

In the last decade, there has been a significant increase in the number of instruments intended to evaluate behavior and/or barriers regarding self-care, self-efficacy, and empowerment in the T2DM population.[10] Nevertheless, many of these instruments have some pitfalls in their psychometric validation process,[11] regarding content validity (scarce use of qualitative techniques, or poorly described) in some cases,[12-14] and failing to meet construct validity (eg, hypotheses regarding constructs not defined in advance)[15] or criterion validity (low-moderate correlation with criterion standard, such as glycated hemoglobin A1c [HbA1c] or further related measures).[16,17]

In addition, the absence of a theoretical model on which to base their structure limits their construct validity, precludes the explanatory power that some theoretical models offer in the field of chronic care, and constrains the acceptability of the interventions that are carried out as a result of this interpretation.[18]

Nevertheless, many questionnaires evaluate diabetes self-care construct from a single-dimensional approach, such as medication, [19] foot care,[20] or physical activity,[21] which is not a limitation, but does not allow a multidimensional approach to diabetes care.

The purpose of this study was to develop and implement a psychometric validation of a new instrument to identify barriers to self-care in the T2DM population on the basis of the theory of planned behavior (TPB) from a multidimensional approach.

Methods

Questionnaire Development Process

This questionnaire was developed in 2 phases: first, content validation, followed by an empirical psychometric validation, in accordance with the model proposed by Brod et al.[22] The content validity phase was guided by the International Society for Pharmacoeconomics and Outcomes Research recommendations in terms of eliciting key concepts for a new instrument[23] and the assessment of patient understanding.[24]

The instrument was subsequently evaluated in an initial pilot study, after which empirical validation was performed to determine its psychometric properties. The COSMIN checklist and its extension were used for assessing the final measurement properties of the instrument and the methodology for content validity, respectively.[25,26]

Theoretical framework

The TPB[27] was selected as the theoretical framework for this study. The TPB postulates 4 constructs that model behavior: attitudes toward behavior (behavioral beliefs), subjective norms (normative beliefs), perceived control of behavior (beliefs about factors that facilitate or hinder behavior), and behavioral intention. The TPB was used throughout the development of our questionnaire, from the scripts used in the qualitative phase till the final generation of the questions.

Several models have been proposed to describe the procedure for creating questionnaires on the basis of the TPB. In the present case, we used the manual developed by the Research-Based Education and Quality Improvement project, which also provides recommendations for avoiding possible bias.[28]

Content validation Phase

Systematic review

First, a systematic review of the literature was conducted, searching for questionnaires that identified self-care behavior and/or barriers in people with T2DM from a multidimensional approach. The search strategy applied to each of 6 databases used (PubMed, CINAHL, ProQuolid, PsycINFO, BiblioPRO, and Google Scholar), the theoretical models used, and the psychometric evaluation of the 16 instruments included in the review have been described in a previous publication.[11]

Qualitative methods

After this literature review, content validation was completed by combining various qualitative methods, including the participation of 15 persons with T2DM in 2 focus groups. To reach consensus, 2 rounds were undertaken with the participation of 13 experts in T2DM (nurse practitioners and diabetes educators, primary care physicians, endocrinologists, and a psychologist). The patients had the last word in this stage, expressed in 9 cognitive interviews. The entire qualitative analysis of the material obtained in the interviews, the characteristics of the population, as well as the selection/reduction of questionnaire items have been described in detail previously.[29]

As a result of this phase, 68 items were generated that covered self-care aspects such as nutrition, physical activity, treatment, self-analysis of capillary blood glucose, tobacco use, foot care, response to health complications, relations with Healthcare personnel, and access to information. The responses were expressed on a 7-point Likert scale, with explanatory labels both at the minimum and maximum values, on which higher values corresponded to better self-care behavior and hence fewer barriers. The questionnaire was designed to be self-administered, at the primary healthcare setting, under conditions of daily clinical practice.

Psychometric Validation Phase

Pilot study

The possible difficulties of comprehensibility or Interpretation of the items included in the questionnaire were explored in a pilot study with the same inclusion criteria of the later phase. Internal consistency was assessed by Cronbach α coefficient and by itemtotal correlation. In addition, the readability of the items finally included was evaluated by the Flesch-Szigriszt index, an instrument that has been validated for use in a Spanish-speaking population.[30]

Population and data collection

The reference population for the psychometric validation phase was composed of people with T2DM who were able to read and write and, regardless of the type of antidiabetic treatment prescribed, were being recruited consecutively in primary healthcare centers. Diabetic patients with less time of evolution and fewer comorbidities have shown greater disposition for the adoption of healthy lifestyles.[31] For this reason, it was decided to include patients younger than 70 years.

Persons with severe mental illness (checked in clinical records) or who were visually impaired, which would have prevented them from replying, as well as those with type 1 diabetes were excluded from the study. We also excluded cases in which questions remained unanswered.[32]

Patients attended to in primary healthcare centers who met the inclusion criteria were offered a chance to participate, being recruited consecutively if they gave their consent. A multicenter sample was obtained by 35 clinical nurses between March 2014 and October 2015 from 15 primary healthcare clinics with different sociodemographic characteristics, located in the Málaga-Valle del Guadalhorce and the Costa del Sol Healthcare districts (Spain). Each participant was provided with an information sheet detailing the purpose and characteristics of the research and was asked to sign the informed consent form. Although the literatura recommends retesting between 2 and 14 days,[33] it was decided to expand this time frame to 28 days to avoid discomfort to patients. Also, on the basis of previous accounts of behavior change among people living with chronic illnesses, the likelihood of lifestyle change between the 2 surveys would have been low.[34] Both (participants and professionals) were unaware of the scores obtained on the first administration. Moreover, an additional followup of the population was carried out till March 2018 to evaluate the onset of any diabetes complication. The instrument was named EBADE (Evaluación de Barreras de Autocuidados en Diabetes mEllitus tipo 2 [Assessment of Barriers to Self-Care in Type 2 Diabetes Mellitus]).

The study was approved by the Málaga Northeast Ethics Committee, working within the Andalusian Health Service, on July 24, 2012.

The sample size was estimated using the MacCallum- Browne-Sugawara approach[35]; to test the null hypothesis that the root mean square error of approximation (RMSEA) (R0 = 0.05) is less than or equal to population RMSEA (R = 0.08) (H_0: R ≤ R0), with a type I error rate (α) (RMSEA), and a power goal of 0.80, with a range from 51 to 224 df, where df = $[(p-m)^2 - (p + m)]/2$, with p being the number of items and m the number of factors (on the basis of different models from a lower bound of 4 factors and 15 items to an upper bound of 4 factors and 29 items), a minimum sample size of 211 was required for the lower level of degree of freedom. These calculations were carried out using STATISTICA 12 (Dell Software, Tulsa, OK).

Statistical analysis

In the psychometric analysis of this stage, internal consistency was assessed by Cronbach a coefficient, with values of 0.70 to 0.95 being considered acceptable,[36] and by item-total correlation (<0.30 was taken as indicative of poor correlation). Test-retest reliability was assessed using the intraclass correlation coefficient and taking values more than 0.70 as acceptable.[36] In addition, the ceiling or floor effects were evaluated according to the frequency distribution of the items and are present if more tan 15% of respondents achieved the highest or the lowest posible score, respectively.[37]

Confirmatory factor analysis (CFA) was applied to corroborate the theoretical structure derived from the 4 components of the TPB, using the following parameters as indices of good fit: χ^2/df (CMIN/df) less than 3, RMSEA less than 0.08 (preferably ,0.06), with the respective 90% CI, comparative fit index (CFI) of more than 0.90, and goodness-of-fit index (GFI) of more than 0.90.[38]

The sample was divided into 2 subsamples, by a random sampling procedure, to confirm the theoretical constructs of TPB by means of CFA. Covariances between factors and the unexplained covariance described as residual errors or those in the standardized matrix of residual covariances were calculated.

Configural invariance and metric invariance were tested by comparing the goodness of fit for the model in both samples. Configural invariance was evaluated by comparing the pattern of fixed and free parameters between both samples, without constraints. Metric invariance was tested by comparing factor loadings, intercepts, and variances with and without constraints, contrasting the GFIs, and comparing the difference between the χ^2 values and their respective degrees of freedom. In addition, multigroup critical ratio for differences was calculated. Furthermore, the multinormality of the model was analyzed by reviewing the kurtosis and coefficient of asymmetry of each item and by calculating the Mardia coefficient.

The criterion validity was determined according to the instrument's capacity to distinguish, on one hand, between self-care barriers in patients with T2DM treated with insulin therapy (with or without oral antidiabetic treatment) or only with oral antidiabetic drugs, and, on the other hand, between levels of metabolic control (HbA1c ≤7% vs >7%). Mann-Whitney U and Wilcoxon tests were conducted in each case. In addition, the probability of suffering diabetes complications was determined evaluating the odds ratio (OR) of complications such as retinopathy, nephropathy, diabetic foot, hypoglycemia, ketoacidosis, neuropathy, or cardiovascular events (acute myocardial infarction, angina stroke, and peripheral arterial insufficiency) in those subjects who attained higher than or lower than the median and the first quartile in the EBADE total score.

All analyses were performed using SPSS version 23.0 (IBM, Armonk, NY) and AMOS 22.0.

Results

Sample Characteristics

The 33 men and 21 women recruited to pilot the questionnaire had a mean age of 59.28 6 8.02 years; of these, 48.1% had only primary education and 33.4% were employed. On average, each patient had had the disease for 6.34 6 4.16 years and presented a mean HbA1c value of 7.26% ± 1.59%.

Thereafter, of the 524 persons invited to take part in the empirical psychometric validation study, 39 refused, for reasons such as lack of time or interest. Thus, an initial sample population of 485 patients was obtained; of these, 4.95% (n = 24) did not respond to 1 or more items and 51 participants failed to meet the inclusión criteria and were excluded. Thus, the final study population was composed of 410 persons with T2DM (Fig. 1).

The average age was 59.69 ± 7.56 years for subsample 1 and 59.34 ± 8.72 years for subsample 2, with the same rate of women for both samples (40% vs 39.5%). Only 30.4% and 28.6%, respectively, were in active employment at the time of the study, and a high proportion (43.4% and 43.3%) were retired. On average, each participant had had diabetes for 7.02 ± 6.04 years for subsample 1 versus 7.18 ± 6.48 years for subsample 2, and presented a mean HbA1c value of 6.95% ± 1.30% and 7.46% ± 1.62% ($P < .001$). Both subsamples had similar characteristics in terms of comorbidities, with the only significant differences concerning retinopathy (P =.014) and smoking habit (P = .014). Subsample 2 had significantly more patients with T2DM treated with insulin therapy (n = 89, 43.4%; P <.001) (Table 1). From the initial sample, 392 people were followed till March 2018 with a mean follow-up of 40.2 months (range 29-48). From this sample, 32 developed retinopathy, 20 nephropathy, and 18 diabetic foot (a complete description is available in Supplemental Materials S1 found at https://doi.org/10.1016/j.jval.2019.04.1921).

Psychometric Analysis: Item Reduction

Of the initial 68 items, 20 were eliminated in the pilot study, for reasons such as very low item-total correlation (<0.20) or readability concerns. In subsequent phases and with the final sample, various elements were eliminated (those with an itemtotal correlation <0.30 or which reduced the consistency or those being focused on overly specific subgroups [smokers, patients with diabetic retinopathy, or patients treated with insulin therapy]). After this psychometric analysis, a total of 29 items remained with an a value of 0.852.

Construct Validity

The model was tested in the first sample (n = 205) and invariance was evaluated in the second sample (n = 205). The initial 29-item model was reduced progressively after analyzing residual errors in the standardized matrix of residual covariances. Successive versions were tested after item deletion by this Statistical reason, until finding a parsimonious structure of 15 items, with adequate fitness indices. CFA showed good fit values (CMIN/df = 1.75; GFI = 0.92; CFI = 0.93; RMSEA = 0.043 [90% CI 0.034-0.052]) when both samples were compared (Fig. 2). Metric invariance was tested by comparing the χ^2 between unconstrained (χ^2 = 259.9; df = 148) and fully constrained (χ^2 = 279.2; df = 163) models, with a nonsignificant difference that corroborated the metric invariance (19.3; df = 15). These final scores have a range from 15 to 105.

Internal Consistency and Reliability

The final instrument obtained showed good internal consistency, with item-total correlations ranging from 0.326 to 0.549, and with a final Cronbach α of 0.78. A total of 214 persons with T2DM (48.85% of the study population) completed the test-retest (no missing data reported) after a mean period of 43.86 ± 29.9 days.

This subpopulation had no differences in terms of sociodemographic characteristics or comorbidities with basal sample; only HbA1c was lower (20.41%; P<.0001). The correlation obtained was satisfactory (intraclass correlation coefficient 0.73; 95% CI 0.65-0.80; P<.0001).

Criterion Validity

Patients with T2DM treated with insulin therapy (with or without oral antidiabetic treatment) (n = 138) had a higher HbA1c value than did those treated with only oral antidiabetic drugs (n =272) (mean 8.05% ± 61.75% vs 6.78% ± 1.12%; P<.0001) and more time since diagnosis of DM (10.28 ± 7.6 years vs 5.33 ± 4.2 years; P<.0001). Population with an inadequate metabolic control (HbA1c>7%, n = 168) repeated the same pattern in terms of time since diagnosis with respect to an adequate control (HbA1c ≤ 7%, n = 227) (8.54 ± 7.5 vs 6.92 ± 4.5; P<.0001). Patients with T2DM treated with insulin therapy also had a higher rate of cardiovascular events (n = 46, 41.1%) than did those treated with oral drugs (n = 92, 30.9%; P = .050). There were no differences among subpopulations in the remaining sociodemographic characteristics or comorbidities.

The questionnaire was able to distinguish between insulintreated, median 93 (88-99); interquartile range (IQR) 11, and non–insulin-treated, median 96 (90-101); IQR 11 (Mann-Whitney U = 17 035.500; P = .005). The instrument also revealed significant differences according to whether the level of metabolic control was adequate, median 97 (90-101); IQR 11 or inadequate median 93 (88-99); IQR 11 (Mann-Whitney U = 15 604; P = .002) (Table 2).

In addition, the group with a lower median response (95 points) was more likely to suffer from diabetes-related complications than that with an upper median response (OR = 1.68; 95% CI 1.04-2.73). These probabilities were even greater taking the 25th percentile (89 points) as a cutoff point (OR 1.91; 95% CI 1.15-3.18). No association was found between the response profile of the questionnaire and the presence of cardiovascular complications.

Interpretability

The final distribution of the instrument was different to the normal one (P<.0001) with a median of 95 (Q_{25} = 89 and Q_{75} =100). A full description by item and subpopulations is widely detailed in Supplemental Materials S2 found at https://doi.org/10.1016/j.jval.2019.04.1921. The instrument retained multinormality, with a Mardia coefficient of 182.71, less than p(p + 2) (255), and a critical ratio of 57.91. The individual asymmetries of each itemwere acceptable, at less than 3 (except for item 27 [3.53] and item 24 [3.21]), and individual kurtosis values were also acceptable at less than 10, except for items 24, 27, and 20, which had values of 14.27, 22.03, and 12.84, respectively. The questionnaire did present a ceiling effect, with maximum scores (ie, 7 on the 7-point Likert scale) provided by 26% to 82.6% of the respondents, and there was no floor effect (ie, 1 on the Likert scale) (range 0.2%-8.8%). In addition, the questionnaire achieved Good readability results, reflected by Flesch-Szigriszt index scores ranging from 43.83 and 46.69 (somewhat difficult) for items 21 and 20, respectively, to 81.7 (very easy) for item 3; 13 of the 15 items included were considered to have a normal, easy, and very easy legibility (Table 3).

COSMIN Checklist

Six criteria were completed to assess the measurement properties of the questionnaire (internal consistency, reliability, content validity, structural validity, criterion validity, and interpretability) and the standards for good methodology quality were achieved. The detailed checklist is available in Supplemental Materials S3 found at https://doi.org/10.1016/j.jval.2019.04.1921 and the extension for content validity in Supplemental Materials S4 found at https://doi.org/10.1016/j.jval.2019.04.1921.

Discussion

The EBADE Questionnaire (see Supplemental Materials S5 found at https://doi.org/10.1016/j.jval.2019.04.1921) was subjected to a rigorous process of content validation to ensure the high representativeness of the "self-care" construct. During this phase, the persons to whom the questionnaire was addressed participated directly, through focus groups and cognitive interviews, as recommended by the International Society for Pharmacoeconomics and Outcomes Research.[39] In addition, the opinions of experts were taken into account, because the needs perceived by patients do not always coincide with caregivers'expectations,[40] and hence the importance of combining both views.

Although various methods can be used for the imputation of missing values, we decided to work with complete data, thus avoiding potential biases associated with these techniques.[32] No item showed a high nonresponse rate (<5% in all cases), which is attributable to an occasional oversight. The questionnaire was completed by the participants on a self-administered basis, at their respective health centers, under conditions of actual clinical practice. This condition lends added rigor to the process by preventing possible aid and partial or total completion of the questionnaire by relatives or friends.

Before carrying out the psychometric validation of the questionnaire, the instrument was methodologically improved by means of a pilot study, as recommended by experts in this area,[22] and by the subsequent reduction of items according to the psychometric results obtained. Statistical and conceptual aspects need to be taken into account for determining the most parsimonious solution.[41] Invariance analysis offers a robust evaluation to rule out whether the model obtained a good fit by chance. Thus, testing the hypothesis between 2 different random samples permits to confirm whether the goodness of fit remains invariable among different samples. Any questionnaire or psychometric instrument should measure identical constructs with the same structure across different groups. When measurement invariance can be demonstrated, it means that the participants across groups interpret the individual questions, as well as the underlying latent factor, in the same way.[42]

To our knowledge, only one previous report of a questionnaire has corroborated its structure by CFA in the field of diabetes self-care behaviors/barriers from a multifactorial perspective.[43,44] The model proposed by Schmitt et al for T2DM is in fact very similar to the one confirmed by EBADE (while grouping the factors in self-care dimensions), and thus a further contribution is made to understanding how such a construct may be obtained (in contrast to other studies in which construct validity has been obtained only by exploratory factor analysis).

EBADE presents good internal consistency, test-retest reliability, and ability to discriminate between different subpopulations of persons with T2DM. Patients with inadequate metabolic control (HbA1c>7%) or treated with insulin therapy obtain lower scores and hence are subject to greater barriers to self-care than those with adequate control or treated with oral drugs, as other authors have previously shown.45 In addition, EBADE has shown how people with more self-care barriers have been more likely to develop complications associated with diabetes. Recently another instrument (Self-Care of Diabetes Inventory) has found a direct and meaningful partnership between self-care behaviors and diabetes complications, reinforcing our findings.[46]

Furthermore, our model provides a reasonably Good representation of the main areas of self-care in this population,[47] which are integrated in the constructs of the TPB. One of the main contributions of the questionnaire will be the ability to evaluate self-care behaviors in diabetes through determinants of behavior on the basis of the constructs of the TPB, which offer a new perspective for decision making with tailored interventions for T2DM. There is no consensus in the literature about the weight that should be assigned to each theoretical construct in the final prediction of treatment compliance, as acknowledged by the original author in a subsequent development of the theory.[48] The TPB had been used previously to predict the intention to eat low-glycemic foods or to carry out physical activity in the T2DM population, with different mediators modulating the therapeutic behavior.[49-51] In our case, it seems that behavioral beliefs have had a greater weight as determinant, because this construct counts in EBADE with 7 of 15 items of the instrument.

EBADE is an instrument that can be straightforwardly applied in primary care consultations and which helps clinicians assess main self-care barriers in people with T2DM: beliefs, social influences, skills, or social/professional roles.[52]

Nonetheless, EBADE does present some limitations. The questionnaire suffers from a ceiling effect, which we believe is caused by 2 circumstances: on one hand, the profile of the respondents who have mostly had the disease for more than 7 years during which they have received primary care and follow-up, and, on the other hand, the probable sustained exposure to aspects of diabetes care from multiple caregivers with whom a relationship has been sustained. These circumstances have already been reported byWang et al[53] in the development of the Diabetes-Related Distress Questionnaire.

Moreover, this study did not address certain properties, such as sensitivity to change, which will be covered in further studies. Another limitation is that questions related to important áreas such as tobacco use, self-monitoring of blood glucose, and retinopathy were not validated.

Conclusion

The assessment of patients' needs, before performing clinical interventions, is a key aspect in promoting self-care among this population. The EBADE Questionnaire is based on a robust theoretical framework that proposes a new perspective for decision making in the education and lifestyle modification of people with T2DM. This instrument has been validated in Spanish patients with T2DM; for its use in other populations, it would need to be culturally adapted.

Acknowledgments

We are grateful for the support provided by Francisco Javier Martín Santos (District of Primary Health Care of Málaga-Valle del Guadalhorce) and Eugenio Contreras Fernández (District of Primary Health Care of Costa del Sol) in the acquisition of the sample.

Source of Financial Support

This study was partially funded by the Andalusian Health Ministry (grant number: AC-0067-2013) and by the Carlos III Institute (grant number: PI14/01127) via the cofunded project with the European Regional Development Fund "Una manera de hacer Europa."

Supplemental Materials

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.jval.2019.04.1921.

REFERENCES

1. Guariguata L, Whiting DR, Hambleton I, et al. Global estimates of diabetes prevalence for 2013 and projections for 2035. Diabetes Res Clin Pract. 2014;103(2):137–149.

2. Soriguer F, Goday A, Bosch-Comas A, et al. Prevalence of diabetes mellitus and impaired glucose regulation in Spain: the Di@bet.es Study. Diabetologia. 2012;55(1):88–93.

3. Geiss LS, Wang J, Cheng YJ, et al. Prevalence and incidence trends for diagnosed diabetes among adults aged 20 to 79 years, United States, 1980-2012. JAMA. 2014;312(12):1218–1226.

4. Williams JS, Walker RJ, Smalls BL, Hill R, Egede LE. Patient-centered care, glycemic control, diabetes self-care, and quality of life in adults with type 2 diabetes. Diabetes Technol Ther. 2016;18(10):644–649.

5. Kim C-J, Schlenk EA, Kim DJ, et al. The role of social support on the relationship of depressive symptoms to medication adherence and self-care activities in adults with type 2 diabetes. J Adv Nurs. 2015;71(9):2164–2175.

6. Richard AA, Shea K. Delineation of self-care and associated concepts. J Nurs Scholarsh. 2011;43(3):255–264.

7. Loveman E, Frampton GK, Clegg A. The clinical effectiveness of diabetes Education models for type 2 diabetes: a systematic review. Health Technol Assess. 2008;12(9):1–136.

8. Sigurdardottir AK, Benediktsson R, Jonsdottir H. Instruments to tailor care of people with type 2 diabetes. J Adv Nurs. 2009;65(10):2118–2130.

9. Fehnel S, DeMuro C, McLeod L, Coon C, Gnanasakthy A. US FDA patientreported outcome guidance: great expectations and unintended consequences. Expert Rev Pharmacoecon Outcomes Res. 2013;13(4):441–446.

10. Lu Y, Xu J, Zhao W, Han H-R. Measuring self-care in persons with type 2 diabetes: a systematic review. Eval Health Prof. 2015;39(2):131–184.

11. Caro-Bautista J, Martín-Santos FJ, Morales-Asencio JM. Systematic review of the psychometric properties and theoretical grounding of instruments

evaluating self-care in people with type 2 diabetes mellitus. J Adv Nurs. 2014;70(6):1209–1227.

12. Fitzgerald JT, Davis WK, Connell CM, et al. Development and validation of the Diabetes Care Profile. Eval Health Prof. 1996;19(2):208–230.

13. Rapley P, Passmore A, Phillips M. Review of the psychometric properties of the Diabetes Self-Efficacy Scale: Australian longitudinal study. Nurs Health Sci. 2003;5(4):289–297.

14. Stetson B, Schlundt D, Rothschild C, et al. Development and validation of the Personal Diabetes Questionnaire (PDQ): a measure of diabetes self-care behaviors, perceptions and barriers. Diabetes Res Clin Pract. 2011;91(3):321–332.

15. Fain JA. Psychometric properties of the Spanish version of the Diabetes Self-Management Assessment Report Tool. Diabetes Educ. 2007;33(5):827–832.

16. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. Diabetes Care. 2000;23(7):943–950.

17. Tamir O, Wainstein J, Abadi-Korek I, Horowitz E, Shemer J. The patient perceived difficulty in diabetes treatment (PDDT) scale identifies barriers to care. Diabetes Metab Res Rev. 2012;28(3):246–251.

18. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. BMC Health Serv Res. 2017;17(1):88.

19. Sleath B, Carpenter DM, Blalock SJ, et al. Development of a new diabetes medication self-efficacy scale and its association with both reported problems in using diabetes medications and self-reported adherence. Patient Prefer Adherence. 2016;10:1003–1010.

20. Navarro-Flores E, Morales-Asencio JM, Cervera-Marín JA, Labajos-Manzanares MT, Gijon-Nogueron G. Development, validation and psychometric analysis of the diabetic foot self-care questionnaire of the University of Malaga, Spain (DFSQ-UMA). J Tissue Viability. 2015;24(1):24–34.

21. Nakawatase Y, Taru C, Tsutou A, et al. Development of an evaluation scale for self-management behavior related to physical activity of type 2 diabetic patients. Diabetes Care. 2007;30(11):2843–2848.

22. Brod M, Tesler LE, Christensen TL. Qualitative research and content validity: developing best practices based on science and experience. Qual Life Res. 2009;18(9):1263–1278.

23. Patrick DL, Burke LB, Gwaltney CJ, et al. Content validity—establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO Good Research Practices Task Force Report, Part 1—Eliciting Concepts for a New PRO Instrument. Value Health. 2011;14(8):967–977.

24. Patrick DL, Burke LB, Gwaltney CJ, et al. Content validity—establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO Good Research Practices Task Force Report, Part 2—Assessing Respondent Understanding. Value Health. 2011;14(8):978–988.

25. Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. J Clin Epidemiol. 2010;63(7):737–745.

26. Terwee CB, Prinsen CAC, Chiarotto A, et al. COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study. Qual Life Res. 2018;27(5):1159–1170.

27. Ajzen I. The theory of planned behavior. Organ Behav Hum Decis Process. 1991;50(2):179–211.

28. Francis JJ, Eccles MP, Johnston M, et al. Constructing Questionnaires Based on the Theory of Planned Behaviour: A Manual for Health Service Researches. Newcastle upon Tyne, UK: Centre for Health Services Research, University of Newcastle; 2004:1–42.

29. Caro-Bautista J, Martín-Santos FJ, Villa-Estrada F, et al. Using qualitative methods in developing an instrument to identify barriers to self-care among persons with type 2 diabetes mellitus. J Clin Nurs. 2015;24(7-8):1024–1037.

30. Barrio-Cantalejo IM, Simón-Lorda P, Melguizo M, et al. Validación de la Escala INFLESZ para evaluar la legibilidad de los textos dirigidos a pacientes. An Sist Sanit Navar. 2008;31(2):135–152.

31. American Diabetes Association. Standards of Medical Care in Diabetes-2017 abridged for primary care providers. Clin Diabetes. 2017;35(1):5–26.

32. Finch WH. Imputation methods for missing categorical questionnaire data: a comparison of approaches. J Data Sci. 2010;8(3):361–378.

33. Streiner DL, Norman GR, Cairney J. Health Measurement Scales: A Practical Guide to Their Development and Use. Oxford, UK: Oxford University Press; 2015.

34. Backhaus J, Junghanns K, Broocks A, Riemann D, Hohagen F. Test–retest reliability and validity of the Pittsburgh Sleep Quality Index in primary insomnia. J Psychosomat Res. 2002;53(3):737–740.

35. MacCallum R, Lee T, Browne MW. The issue of isopower in power analysis for tests of structural equation models. Struct Equ Modeling. 2010;17(1):23–41.

36. Terwee CB, Bot SDM, de Boer MR, et al. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol. 2007;60(1):34–42.

37. McHorney CA, Tarlov AR. Individual-patient monitoring in clinical practice: are available health status surveys adequate? Qual Life Res. 1995;4(4):293–307.

38. Bollen KA, Long JS. Testing structural equation models. https://us.sagepub.com/en-us/nam/testing-structural-equation-models/book3893. Accessed October 14, 2017.

39. Rothman M, Burke L, Erickson P, et al. Use of existing patient-reported outcome (PRO) instruments and their modification: the ISPOR Good Research Practices for Evaluating and Documenting Content Validity for the Use of Existing Instruments and Their Modification PRO Task Force Report. Value Health. 2009;12(8):1075–1083.

40. Barnard KD, Holt RIG, Dyson PA, et al. Could the discrepancy in perceived emotional care received and provided be a barrier to active diabetes selfmanagement? Insights from the Second Diabetes Attitudes, Wishes and Needs (DAWN2) Study. Diabetes Care. 2016;39(2):e20–e21.

41. Rhodes RE, Plotnikoff RC, Spence JC. Creating parsimony at the expense of precision? Conceptual and applied issues of aggregating belief-based constructs in physical activity research. Health Educ Res. 2004;19(4):392–405.

42. Van de Schoot R, Lugtig P, Hox J. A checklist for testing measurement invariance. Eur J Dev Psychol. 2012;9(4):486–492.

43. Schmitt A, Gahr A, Hermanns N, et al. The Diabetes Self-Management Questionnaire (DSMQ): development and evaluation of an instrument to assess diabetes self-care activities associated with glycaemic control. Health Qual Life Outcomes. 2013;11(1):1.

44. Schmitt A, Reimer A, Hermanns N, et al. Assessing diabetes self management with the Diabetes Self-Management Questionnaire (DSMQ) can help analyse behavioural problems related to reduced glycaemic control. PLoS One. 2016;11(3):e0150774.

45. Delahanty LM, Grant RW, Wittenberg E, et al. Association of diabetes-related emotional distress with diabetes treatment in primary care patients with type 2 diabetes. Diabet Med. 2007;24(1):48–54.

46. Ausili D, Barbaranelli C, Rossi E, et al. Development and psychometric testing of a theory-based tool to measure self-care in diabetes patients: the Self-Care of Diabetes Inventory. BMC Endocr Disord. 2017;17(1):66.

47. Mayberry LS, Osborn CY. Family support, medication adherence, and glycemic control among adultswith type 2 diabetes. Diabetes Care. 2012;35(6):1239–1245.

48. Ajzen I. The theory of planned behaviour: reactions and reflections. Psychol Health. 2011;26(9):1113–1127.

49. Watanabe T, Berry TR, Willows ND, Bell RC. Assessing intentions to eat low glycemic index foods by adults with diabetes using a new questionnaire based on the theory of planned behaviour. Can J Diabetes. 2015;39(2):94–100.

50. Boudreau F, Godin G. Participation in regular leisure-time physical activity among individuals with type 2 diabetes not meeting Canadian guidelines: the influence of intention, perceived behavioral control, and moral norm. Int J Behav Med. 2014;21(6):918–926.

51. Ferreira G, Pereira MG. Physical activity: the importance of the extended theory of planned behavior, in type 2 diabetes patients. J Health Psychol. 2016;22(10):1312–1321.

52. Rushforth B, McCrorie C, Glidewell L, Midgley E, Foy R. Barriers to Effective management of type 2 diabetes in primary care: qualitative systematic review. Br J Gen Pract. 2016;66(643):e114–e127.

53. Wang H-F, Yu N-C, Sheu WH-H, Yeh MC. The development of a questionnaire measure of diabetes-related distress in Chinese-speaking patients: the Diabetes Related Distress Questionnaire (DRDQ). Qual Life Res. 2016;25(3):721–729.

Table 1 Characteristics of T2DM population in sample.

Sociodemographic characteristics	Pilot study (N = 54)	Subsample 1 (N = 205)	Subsample 2 (N = 205)	*P* value
Age (y), mean ± SD	59.28 ± 8.0	59.69 ± 7.6	59.34 ± 8.7	.578*
Sex, female, n (%)	21 (39.8)	82 (40)	81 (39.5)	.920†
Occupation, n (%)	n = 49	n = 202	n = 203	.740†
Homemaker	8 (16.3)	31 (15.3)	33 (16.3)	
Retired	20 (40.8)	87 (43.1)	88 (43.3)	
Unemployed	8 (16.3)	23 (11.4)	24 (11.8)	
Executive	{	10 (5)	12 (5.9)	
Administrative	13 (26.5)	16 (8.0)	15 (7.4)	
Hardworking		15 (7.5)	16 (7.9)	
Self-employed		20 (9.9)	15 (7.4)	
Education, n (%)		n = 205	n = 205	.272†
None	1 (1.9)	9 (4.4)	8 (3.9)	
Primary	26 (48.1)	105 (51.2)	89 (43.6)	
High school	19 (35.2)	58 (28.3)	61 (29.8)	
University	8 (14.8)	33 (16.1)	47 (22.9)	
Family support, n (%)	44 (81.5)	164 (80.8), n = 203	153 (75.4), n = 203	.187†
	N = 54	N = 205	N = 205	
Time since diagnosis (y), mean ± SD	6.34 ± 4.2	7.02 ± 6.0	7.18 ± 6.5	.894*
Comorbidities, n (%)				
Hypertension	34 (63)	124 (60.5)	115 (55.6)	.317†
Dyslipidemia	32 (59.3)	88 (42.9)	70 (34.1)	.068†
Obesity (BMI > 30)	12 (22.2)	57 (27.8)	53 (25.9)	.656†
Cardiovascular records	11 (20.4)	53 (25.9)	59 (28.8)	.506†
Chronic renal disease	3 (5.6)	15 (7.3)	21 (10.2)	.295†
Cancer	2 (3.7)	10 (4.9)	17 (8.3)	.163†
Depression	7 (13)	33 (16.1)	20 (9.8)	.056†
Retinopathy	5 (9.3)	–	6 (2.9)	.014†
Tobacco, n (%)				.014†
Smoker	15 (27.8)	30 (14.6)	48 (23.4)	
Previous smoker	–	63 (31.2)	73 (35.6)	
	N = 54	N = 195	N = 200	
HbA_{1c}, mean ± SD	7.26% ± 1.6%	6.95% ± 1.3%	7.46% ± 1.6%	.001*
		N = 205	N = 204	
Hypoglycemic agents, n (%)				.264†
Metformin		178 (85.8)	157 (77)	
Sulfonylureas		44 (21.7)	31 (15.4)	
DPP-4 inhibitors		35 (17)	27 (13.4)	
Others		8 (4)	15 (7.5)	
Insulin therapy, n (%)	16 (29.6)	n = 49 (23.9)	n = 89 (43.4)	<.001†
Glargine		19 (9.3)	41 (20)	
Detemir		5 (2.5)	6 (3)	
NPH insulin		6 (3)	4 (2)	
Protamine mix		9 (4.5)	15 (7.5)	
Fast human insulin		3 (1.5)	14 (7)	
Aspart/Lispro		17 (8.5)	27 (13.5)	
Others		3 (1.5)	7 (3.5)	

Note. P value of subsample 1 vs subsample 2.
BMI indicates body mass index; DPP-4, dipeptidyl peptidase 4; HbA_{1c}, glycated hemoglobin A_{1c}; SD, standard deviation; T2DM, type 2 diabetes mellitus.
*Mann-Whitney Wilcoxon test.
†χ^2 test.

Table 2 Internal consistency, test-retest reliability, and criterion validity with constructs of TPB.

Factors	Items	Item-total correlation	α if item is deleted
Behavioral intention	10. Taking physical exercise even with pain ... 11. Although I do not feel like exercising, I do carry out it most of time ...	0.407 0.378	0.781 0.783
Subjective norms	6. Family helps me take physical exercise ... 25. Accessing to printed information ... 27. Receiving information makes ... 24. Opinion of professionals is important to me ...	0.326 0.399 0.403 0.513	0.778 0.772 0.772 0.768
Perceived control	3. Consuming a balanced diet in the future ... 29. Having clear-cut targets ...	0.474 0.414	0.765 0.771
Attitudes toward behavior	1. Knowing foods and control over diabetes ... 5. Physical exercise and control over diabetes ... 7. Taking regular physical exercise is important 12. Right medication better control ... 17. Foot self-care is important ... 20. Avoiding glucose alterations through diet ... 21. Avoiding high or low glucose levels is ...	0.396 0.549 0.426 0.417 0.339 0.513 0.464	0.772 0.768 0.775 0.774 0.778 0.765 0.768
Final internal consistency	**0.784**		
Test-retest reliability	Mean period: 43.86 ± 29.9 d ICC = 0.73 ($P < .0001$)		
Criterion validity	T2DM insulin therapy, median 93 (88-99); IQR 11 T2DM oral drugs, median 96 (90-101); IQR 11 U = 17 035.500 (P = .005)* $HbA_{1c} \leq 7\%$ median 97 (90-101); IQR 11 $HbA_{1c} > 7\%$ median 93 (88-99); IQR 11 U = 15 604 (P = .002)*		

HbA_{1c} indicates glycated hemoglobin A_{1c}; ICC, intraclass correlation coefficient; IQR, interquartile range; TPB, theory of planned behavior; T2DM, type 2 diabetes mellitus.
*Mann-Whitney Wilcoxon test.

Table 3 Distribution, multinormality, floor/ceiling effect, and legibility.

Factors	Items	Mean ± SD	Asymmetry	Kurtosis	Critical ratio	Floor effect (%)	Ceiling effect (%)	Legibility*	
Behavioral intention	10. Taking physical exercise even with pain …	4.81 ± 1.93	−0.67	0.52	−1.53	8.8	26	55.0	Normal
	11. Although I do not feel like exercising, I do carry out it most of time …	5.02 ± 1.85	−0.70	−0.47	−1.36	6.7	29.2	71.9	Fairly easy
Subjective norms	6. Family helps me take physical exercise …	6.26 ± 1.18	−1.84	3.29	9.61	1.2	60.3	78.3	Fairly easy
	25. Accessing to printed information …	6.04 ± 1.26	−1.73	3.73	10.9	1.6	49	73.8	Fairly easy
	27. Receiving information makes …	6.59 ± 0.8	−3.53	22.03	64.39	0.5	70.8	81.1	Very easy
	24. Opinion of professionals is important to me …	6.65 ± 0.73	−3.22	14.28	41.72	0.2	74.9	79.6	Fairly easy
Perceived control	3. Consuming a balanced diet in the future …	6.01 ± 1.16	−1.68	4.09	11.94	0.9	44.1	81.7	Very easy
	29. Having clear-cut targets …	6.40 ± 0.96	−1.64	2.66	7.76	0.7	60.8	65.1	Fairly easy
Attitudes toward behavior	1. Knowing foods and control over diabetes …	6.35 ± 0.97	−1.39	1.51	4.42	1.2	58.7	75.7	Fairly easy
	5. Physical exercise and control over diabetes …	6.70 ± 0.65	−2.71	8.77	25.63	0.2	78.4	70.0	Fairly easy
	7. Taking regular physical exercise is important	6.74 ± 0.58	−2.88	8.48	24.77	1.2	79.8	59.0	Normal
	12. Right medication better control …	6.73 ± 0.62	−2.33	5.28	15.44	0.5	78.9	69.8	Fairly easy
	17. Foot self-care is important …	6.70 ± 0.74	−2.7	6.71	19.61	0.7	82.6	75.1	Fairly easy
	20. Avoiding glucose alterations through diet …	6.56 ± 0.84	−2.83	12.85	37.55	0.5	68.2	46.69	Somewhat difficult
	21. Avoiding high or low glucose levels is …	6.56 ± 0.88	−2.29	5.18	15.15	0.5	72.2	43.83	Somewhat difficult
	Multivariate			182.72		57.921			

SD indicates standard deviation.
*Flesch-Szigriszt index: very difficult: <40; somewhat difficult: 40-55; normal: 55-65; fairly easy: 65-80; and very easy: >80.

Figure 1 Flowchart of population sample.

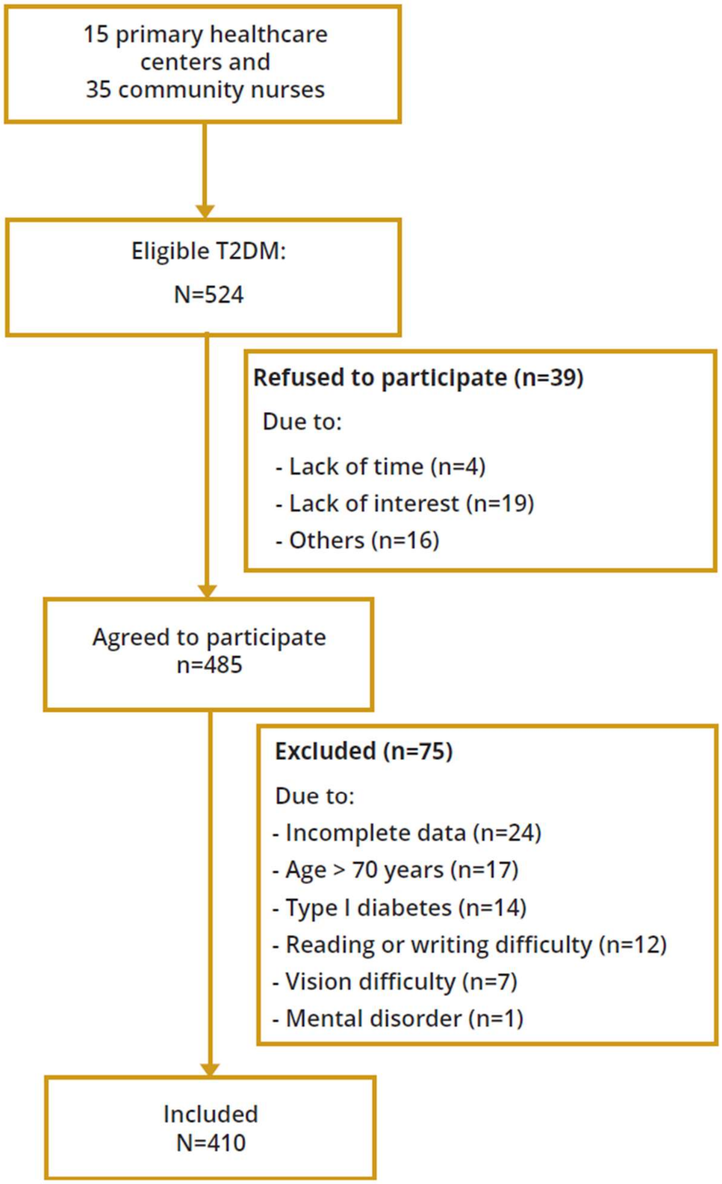

Figure 2 Confirmatory factor analysis with 4 constructs of theory of planned behavior.