

Systematic review of the psychometric properties and theoretical grounding of instruments evaluating self-care in people with type 2 Diabetes Mellitus

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Abstract

Aim. To determine the psychometric properties and theoretical grounding of instruments that evaluate self-care behaviour or barriers in people with type 2 diabetes.

Background. There are many instruments designed to evaluate self-care behaviour or barriers in this population, but knowledge about their psychometric validation processes is lacking.

Design. Systematic review.

Data sources. We conducted a search for psychometric or validation studies published between January 1990–December 2012. We carried out searches in Pubmed, CINAHL, PsycINFO, ProQuolid, BibliPRO and Google SCHOLAR to identify instruments that evaluated self-care behaviours or barriers to diabetes self-care.

Review methods. We conducted a systematic review with the following inclusion criteria: Psychometric or clinimetric validation studies that included patients with type 2 diabetes (exclusively or partially) and which analysed self-care behaviour or barriers to self-care and proxies like self-efficacy or empowerment, from a multidimensional approach. Language: Spanish or English. Two authors independently assessed the quality of the studies and extracted data using Terwee's proposed criteria: psychometrics properties, dimensionality, theoretical ground and population used for validation through each included instrument.

Results. Sixteen instruments achieved the inclusion criteria for the review. We detected important methodological flaws in many of the selected instruments. Only the Selfmanagement Profile for Type 2 Diabetes and Problem Areas in Diabetes Scale met half of Terwee's quality criteria.

Conclusion. There are no instruments for identifying self-care behaviours or barriers elaborated with a strong validation process. Further research should be carried out to provide patients, clinicians and researchers with valid and reliable instruments that are methodologically solid and theoretically grounded.

Keywords: nursing assessment, patient education, psychometrics, self-care, Systematic review, type 2 diabetes

Introduction

Diabetes Mellitus (DM) is currently one of the most prevalent chronic diseases, with rising figures that reflect a pandemic scenario. In a recent report, the International Diabetes Federation (IDF) estimated that 366 million people worldwide have DM and by 2030, that number will be near 552 million (Whiting et al. 2011).

The frequency of type 2 diabetes mellitus (T2DM) is increasing worldwide. T2DM is a leading cause of suffering due to complications, including cardiovascular disorders, blindness, end-stage renal failure or amputations (Inzucchi et al. 2012). Lifestyle and self-care strategies are key components for preventing complications because they determine the evolution and complications of DM and they both require comprehensive educational interventions. A wide consensus exists about the areas that have to be tackled (Walsh et al. 2011, Funnell et al. 2012, International Standards for Diabetes Education 2012). Multiple Educational and health-promotion programmes have been deployed around the world in an effort to provide patients with adequate skills for their self-care and empowerment (Deakin et al. 2006, Trento et al. 2010, Miguel et al. 2011, Khunti et al. 2012). The role of nurses in these educational programmes has been described as a facilitator. This role involves: (1) shared authority and group ownership; (2) conception of diabetes as a highly complex disease interconnected with all aspects of one's life; (3) focus on quality of life; and (4) recognition of perfectionism as neither possible nor desirable in self-management (Costello 2013).

One of the main challenges for educational programmes is the selection of interventions with long-term effects, because most of the programmes obtain positive results in a short or middle-term (Deakin et al. 2008, Duke et al. 2009, Loveman et al. 2008).

Despite the efforts of healthcare systems and professionals to involve patients in their self-care and the availability of theoretical knowledge applicable in educational programmes, there is a knowledge, attitude and practice gap in how lifestyles of people with T2DM should be managed (Serrano-Gil & Jacob 2010). As a result, the literatura emphasizes the relevant role of promoting self-care and

empowerment in patients who need changes in their lifestyle to control the disease (Lauder 2001).

Although many definitions of self-care exist, no consensual definition has been reached, being actually considered a complex concept that requires a multidimensional approach. Moreover, many different social and disciplinary factors have influenced the current concept, so that it is embedded in diverse theoretical perspectives and paradigms (Wilkinson & Whitehead 2009). A recent conceptual analysis has proposed self-care as an activity initiated, consciously and following learning, which is appropriate to the situation and focused on a goal (Mailhot et al. 2013).

In this review, we have drawn on the model presented by Richard and Shea (2011), as a broad concept subsuming self-management, self-monitoring and symptom management when performed by self. Thus, auto-efficacy is presented like a mediator of relationship between knowledge or abilities and activity performance, or like a moderator of the effectiveness of an intervention. Furthermore, we have incorporated into the model the concept of empowerment as a key element for taking responsibility for self-care behaviours (Ramsay et al. 2012) and the presence of barriers which hinder autonomous decision-making and autonomous execution of the agreed on treatment plan (Naik et al. 2009).

Self-monitoring in T2DM is composed of three attributes, which are influenced by culture: (1) awareness of; (2) interpretation of; and (3) response to a patient's particular manifestations of T2DM (Song & Lipman 2008).

In this regard, the logical path seems to be to connect clinical objectives with patients' perceptions about their healthcare needs. Thus, one of the most frequently used strategies has been the development of patient-reported outcomes (PROs). These are reports on the status of a patient's health condition that come directly from the patient, without interpretation by a clinician, which can be evaluated with absolute measures or as a change in a previous measure (Lohr & Zebrack 2009). PROs are designed to evaluate how the patients live their illness and treatments (Lasch et al. 2010).

In DM, many instruments have been created for measuring barriers to self-care behaviours or compliance with treatment and more recently, qualitative methods

have been used to explore these issues (Nagelkerk et al. 2006, Vermeire et al. 2007). Numerous protocols and experimental studies in the international literature have incorporated a previous appraisal of diabetic patients' needs in their design (Versnel et al. 2011, Teal et al. 2012). The aim is clear: an approach based on removing barriers and emphasis on empowerment (Zoffmann & Kirkevold 2012) to improve health outcomes through shared decision-making (Drewelow et al. 2012). However, there is no consensus about which is the ideal approach for this goal (Sigurdardottir et al. 2009).

The presence of a wide number of instruments makes it difficult for clinicians and researchers to select the most adequate tool. Some reviews have been performed to evaluate these instruments, but they have been focused exclusively on those that measure the health-related quality of life (HRQL) (Sánchez Lora et al. 2010) or very concrete issues of DM self-care, or partial dimensions of this process (psychological adjustment, knowledge, satisfaction...) (Eigenmann et al. 2009). Moreover, several authors state the need for a different approach beyond how to manage each type of DM (Redmond et al. 2006, Peterson et al. 2007, Ko et al. 2012).

The review

Aim

To determine the psychometric properties and theoretical grounding of instruments that evaluate self-care behaviour or barriers in people with type 2 diabetes to facilitate clinicians' and researchers' selection of the best instrument for patients' follow-up or evaluating the effectiveness of Educational and counselling interventions.

Design

A systematic psychometric review using the analytical framework of Terwee et al. for health status questionnaires (Terwee et al. 2007) was undertaken to retrieve published studies about instruments for evaluating self-care behaviours or barriers to diabetes self-care in T2DM. The review question, objectives and general approach to searching for and retrieval of evidence were based on

general recommendations for conducting systematic reviews in the Cochrane Handbook (Higgins & Green 2009).

Search methods

We conducted searches in English and Spanish in six databases: Pubmed; CINAHL; BiblioPRO; Google Scholar; Pro-Qolid; and PsycINFO, from January 1990-December 2012. Search terms, filters and operators used are detailed in a supplementary file (see Appendix S1). For Pubmed, the search strategy was carried out according to Terwee' s strategy (Terwee et al. 2009): construct search (in this study about self-care behaviours or barriers); population search (DM), instrument search (questionnaires, scales...); measurement properties filters and exclusion filters. For the other databases, as there is no validated strategy available, we used a shorter version of Terwee's strategy.

Inclusion criteria

- Types of participants: People with T2DM (with or without insulin therapy). Studies were selected if they were intended specifically for people with T2DM or, at least 50% of the sample comprised people with this type of diabetes. It was considered important to include any questionnaire validated in a sample of people with T2DM, regardless of whether it was specific for this population.
- Type of studies: Psychometric or clinimetric validation studies in English or Spanish language.
- Type of outcomes: Self-care behaviours or barriers to self-care. Self-care was defined, according to the model presented by Richard and Shea (2011), as a broad concept subsuming self-management, self-monitoring and symptom management when performed by self. In this conceptual framework, we have considered several proxies like self-efficacy or empowerment.

Exclusion criteria

- Types of participants: Studies planned specifically for people with type 1 diabetes (T1DM) or exclusively for insulin-dependent patients. When papers did not address the type of diabetes, they were excluded. This decisión was based

on the differences on factors and beliefs which regulate self-care behaviours in T2DM compared with T1DM (Plotnikoff et al. 2010, Broadbent et al. 2011).

- Type of studies: papers which main aim was not to develop and validate an instrument or those validated in other languages than English or Spanish. Pilot studies were also excluded. Instruments published in books or theses not subjected to peer review were excluded.

- Type of outcomes: Those studies that evaluated selfcare, but not particularly in T2DM, were also excluded. Additionally, instruments that exclusively evaluated other aspects of diabetes, like HRQL, satisfaction, etc. were not included. We did not take into account instruments that explored only partial dimensions of living with diabetes, like depression, glycaemic self-control, physical activity, etc.

Search outcome

We identified 1,333 potential studies in the first stage from which 273 were duplicated among different databases. The remaining 1,060 were screened starting with an appraisal of titles, abstracts and key words; 22 of them were not published in peer-reviewed journals and 799 were not validation studies. A total of 1,015 studies were discarded as they did not meet the inclusion criteria.

We examined 45 full-text articles and finally, 16 met all the inclusion criteria. The flow of the process of selected studies was based in the PRISMA statement for Systematic reviews (Liberati et al. 2009) (Figure 1).

A complete description of the excluded instruments is available as a supplementary file (Appendix S2). There were 42 studies excluded because they were replications of existing validated instruments, although some of them were used to complete the description of selected psychometric properties (see Appendix S3).

Quality appraisal

Due to the nature of papers, no quality appraisal of studies was undertaken.

Psychometric appraisal

Two blinded reviewers evaluated the entirety of records. Any discrepancies in the process were resolved by discusión between the two evaluators, assisted by the Intervention of a third expert. Reviewers were experts in Systematic Reviews,

Psychometrics and Clinimetry, Evidence Based Health Care and Community Nurses.

For the appraisal of selected studies, we used the criteria determined by Terwee et al. for health status questionnaires (Terwee et al. 2007), with the addition of the assessment of its theoretical background.

Content validity: extent to which the concepts of interest are comprehensively represented by the items in the questionnaire. For the positive rating of this property, authors had to provide a clear description of the following aspects: measure aim, target population, concepts that the questionnaire is intended to measure, item selection and item reduction, interpretability of items, involvement of target population, and either researcher or experts. If a clear description is lacking or only target population has been involved or design or Method applied is doubtful, content validity is rated as indeterminate. If target population is not involved, a poor rating is given.

Internal consistency: extent to which items in a questionnaire scale are correlated, thus measuring the same concept. The most common method used is Cronbach's alpha and it should be calculated for each dimension separately. Positive evaluation is given if its value is between 0.70-0.95. If Cronbach's alpha has a value >0.95 (indicates redundancy) or <0.70 (indicates lack of correlation), it is rated as poor (despite adequate design and method). An indeterminate rating is given if there is a design and method doubtful or no factor analysis is applied.

Criterion validity: extent to which scores on a particular instrument relate to a gold standard. A positive rating is given if the used standard is a reference gold and if values of correlation between the instrument and the standard are over 0.70. If this correlation is under 0.70, it is rated as poor and as indeterminate if there are no convincing arguments that gold standard is really 'gold'.

Construct validity: compilation of bodies of empirical evidence that test predefined hypotheses. Terwee and colleagues give a positive rating if at least 75% of the results are in correspondence with these hypotheses (convergent-discriminant validity). We have additionally considered factor analysis or equivalent methods as one of the resources used despite it being not mentioned in the Terwee's original paper, because of their relevance to test the construct validity. Based on

Terwee's criteria, a poor rating is given if the correspondence with the predefined hypotheses is lower than 75%. If hypotheses have a design doubtful, an indeterminate rating is given.

Reproducibility (Agreement): extent to which the scores on repeated measures are close to each other (absolute measurement error). A positive rating is given if the minimal important change (MIC) is less than the smallest detectable change (SDC) or if MIC outside the limits of agreement (LOA) or if authors give convincing arguments that agreement is acceptable. If MIC is higher than or equal to SDC or MIC is equal or inside LOA, a negative rating is given. If it is considered that instrument has an important methodological weakness, this property is rated like indeterminate.

Reproducibility (Reliability): extent to which patients can be distinguished from each other, despite measurement errors. It is usually measured with an Intraclass Correlation Coefficient (ICC) or weighted kappa and values higher than 0.7 are considered good. Test-retest reliability: degree to which repeated measurements in stable persons provide similar answers. Correlation values greater to 0.70 are considered acceptable. If this correlation is <0.70, it is rated as poor and as indeterminate if there is a doubtful design.

Responsiveness: detection of the effect of treatment, or the correlation of changes in the instrument with changes in other measures (Terwee et al. 2003). As there are no standard criteria about how to evaluate this aspect, we decided only to evaluate its presence/absence in the original study.

Floor/Ceiling effects: they are considered to be present when more than 15% of respondents obtain the lowest or highest possible score, affecting content validity and reliability. A positive rating is given if no floor/ceiling effects are present in a sample size of at least 50 patients (Streiner & Norman 2011). If floor/ceiling effects are present, it (>15%) is considered as poor and as indeterminate, if a doubtful design or method is presented.

Interpretability: degree to which one can assign qualitative meaning to quantitative scores. When the mean and standard deviation (SD) scores are presented of at least four relevant subgroups of patients and MIC is defined, a positive rating is given. This property is evaluated as indeterminate if there are

less than four subgroups or no MIC defined. In the Terwee's original paper, the poor rating is not defined.

Additionally, we assessed the presence or absence of theoretical ground for the development of the questionnaire. This issue has been considered essential because any hypothesis should be contrasted guided by a theory for avoiding the risk of bias (Terwee et al. 2003).

Every issue was rated as positive (values over the accepted standard), negative (values under the accepted standards) and indeterminate (concerns about methods or measures) or absent (no information available), except for responsiveness and theoretical ground, which were rated only as present/absent.

Data abstraction

Data extracted from eligible studies included: year of publication; psychometric properties; number of dimensions and items; type of measurement scale; theoretical ground of the instrument; and population used for the validation process.

Data synthesis

Sixteen studies met all the inclusion criteria and were included for the final analysis (Table 1). The characteristics of these studies are summarized in Table 2. No metaanalysis was carried out because of the heterogeneity of dimensions and outcomes included in each study.

Results

We initially identified 1,333 potential studies from which 1,015 were excluded after an appraisal of titles, abstracts and key words; and 273 were removed because they were duplicated among different databases. The remaining 45 were full-text examined and finally, 16 met all the inclusion criteria. Of papers included, seven instruments (44%) had nurses in their research teams, which gives an idea of relevance of the topic for these professionals (assessment self-care behaviour or barriers in people with T2DM).

Dimensions and structure

Dimensions

Instruments were very heterogeneous in number of items, scales of measurement and dimensions. The range of dimensions went from one, as in the Problem Areas in Diabetes Scale (PAID) (Polonsky et al. 1995, Welch et al. 1997, 2003), the Diabetes Management Self-efficacy Scale (DMSES, UK version) (Sturt et al. 2010) or the Patient-perceived Difficulty in Diabetes Treatment Scale (PDDT) (Tamir et al. 2012), up to 14, as in the Diabetes Care Profile (Fitzgerald et al. 1996).

The areas included fluctuated from classical self-care dimensions like diet, physical activity, glucose self-analysis, management of drugs, smoking, to others with a more psychosocial orientation: coping; social support; or relationships with healthcare providers.

Structure

Concerning their extension, there were short forms of some instruments (with fewer than 15 items) that make them very easy to use: The Diabetes Self-care Barriers in Older Adults (DSCB-OA, 12 items) (Tu & Barchard 1993), The Summary of Diabetes Self-Care Activities Measure (SDSCA, 11 items) (Toobert & Glasgow 1994, Toobert et al. 2000), DMSES (15 items) or PDDT (12 items).

On the other hand, some instruments have a comprehensive structure with a large number of items, which might hinder its applicability: The Environmental Barriers to Diabetes-Regimen Adherence (EBAS, 60 items) (Irvine et al. 1990), DCP (> 100 items), the Diabetes Obstacles Questionnaire

(DOQ, 77 items) (Hearnshaw et al. 2007), the Diabetes Self-management Assessment Report Tool (Spanish version) (D-SMART, 49 items) (Fain 2007) or the Personal Diabetes Questionnaire (PDQ, 67 items) (Stetson et al. 2011).

The most frequently used scale for measurement is the 5-point Likert scale, with some exceptions like DMSES, SDSCA, D-SMART, PDQ or Self-management Profile for Type 2 Diabetes (SMP-T2D) (Peyrot et al. 2012). Other instrument like DSCB-OA or The Diabetes Distress Scale (DDS) (Polonsky et al. 1995) did not specify a measurement scale.

Theoretical grounding

Only eight instruments did not have an explicit theoretical grounding for their design. Bandura's Social Learning Theory (Bandura 1977) has been the most used (in three instruments), with self-efficacy as one of the main constructs in EBAS, DMSES and Diabetes Self-efficacy Scale (DSES) (Rapley et al. 2003). The Transtheoretical Model of Health Behaviour Change (Prochaska & Velicer 1997) was used by the PDQ and the Empowerment Model by The Diabetes Empowerment Scale (Anderson et al. 2000). The Health Belief Model (Rosenstock 1974) was used by DCP and by The Diabetes Health Beliefs (Brown et al. 2002), while D-SMART was based on a combination of theories (the HOBBIT Model).

Target population

This review has included a population of 7,877 diabetic patients, of which 4,102 were female (52_1%). The mean age of patients was 57_3 years and the mean time since diagnosis was 10_4 years (n = 6,862); DMSES, D-SMART, SMP-T2D and Diabetes Health Profile (Meadows et al. 1996, 2000) did not detail this information.

The type of DM and the presence of insulin therapy could classify patients included in the studies, although both aspects were not clearly stated in some papers. Most patients were T2DM (n = 4,905, 84_8%); DSES, PAID, PDDT and one study of SDSCA did not specify the type of DM. Seven studies included exclusively T1DM patients (DESC-OA, DMSES, DHP, Diabetes Health Beliefs, DOQ, D-SMART and SMP-T2D). If we consider the type of treatment, almost half of patients included were insulin-independent (n = 3,041, 47.0%); DMSES, DOQ, D-SMART and one study of SDSCA did not report this information.

Psychometric properties

Terwee's criteria for appraising health status questionnaires, which are summarized in Table 3, guided the analysis of this issue.

Validity

Regarding content validity, the most common methods used are qualitative techniques (in-depth interviews, focus groups...) and expert consensus through the Delphi technique, although not all the studies reported full details about this

process (DCP, DSES and PDQ). Some studies applied legibility techniques for face validity, as the Flesh- Kincaid Index (DMSES, DDS, PDQ and SMP-T2D).

We evaluated criterion validity by comparing the instrument scores against glycosylated haemoglobin values in 6 studies. PAID was the questionnaire that obtained the best correlation coefficients, but with no statistical significance (depending on the type of treatment, in males, the correlation was from $r = 0.15$ to $r = 0.65$ and in females, from $r = 0.003$ to $r = 0.66$).

When other instruments were used to evaluate criterion validity, there was a large variation in the type of comparator selected. Moderate correlation was reported in several scales including EBAS, DCP, PAID, DMSES, DES, SDSCA, Diabetes Health Beliefs, DDS, SMP-T2D and DOQ. The rest of the instruments obtained correlations under 0.30 (DSES, PDQ and PDDT) or did not assess this property (DSCB-OA, DHP-18 and D-SMART).

For construct validity, only three instruments got a positive rating (PAID, PDDT and SMP-T2D). An indeterminate rating was given to seven, mainly due to a design or methods indetermination (e.g. hypotheses were not defined). The remaining six, were negative (DCP, DHP-18 and DSES) or not information was available (SDSCA, D-SMART and PDQ). There were two clear approaches: seven of them used discriminant analysis depending on different types of DM or treatment and six studies carried out factorial analysis. In those studies that carried out exploratory factorial analysis, the total variance explained was between 44.0% (Diabetes Health Beliefs) and 60_7% (DSES).

Internal consistency and reliability

Internal consistency was evaluated by Cronbach's alpha, either for the global scale or for each sub-scale. Fifteen of sixteen instruments addressed this property (except PDDT) and eight of them achieved Terwee's criteria (Cronbach's alpha >0.70 and <0.95). The values obtained were between 0.56-0.65 in several sub-scales of the DCP, PDQ or Diabetes Health Beliefs, or globally 0_69 in the DSCB-OA, to 0.93 in the DDS, 0.94 in the EBAS, 0.95 in the PAID and 0.96 in the DES.

Reproducibility was evaluated by two different properties, reliability and agreement. Test-retest reliability was reported in eight instruments with values higher than 0.70 for all of them except for SDSCA $r = 0.40$. D-SMART only described test-retest reliability for three of seven dimensions (for this reason, it was considered like indeterminate) and DSCB-OA used an interrater reliability, which was not rigorous enough. The time interval for repeating the test ranged between 1-week (DMP-T2D) and 3-4 months (SDSCA). On the other hand, no instrument addressed the agreement criteria.

Other properties

The floor/ceiling effect was only assessed in three instruments: DHP-18, with values of 0.8-29.4% and 0-1.2% respectively, SMP-T2D with 2.5% and 33% and DOQ, which eliminated items with >90% of responses in a category, but reported no specific dates.

Responsiveness was only evaluated in three studies: PAID, ($t = 8.5$, $P < 0.001$; $t = 2.1$, $P < 0.06$) with an effect size from 0.32 to 0.64, SMP-T2D and an improvement in 50% after medication change and SDSCA [responsiveness index = $-0.09 - (0.43)$]. Six instruments presented subgroups of patients assessing the interpretability; none of them got a positive rating.

Translations and adaptations to other languages were searched for all the instruments (Table 2). The PAID is the most extended, with adaptations to Dutch, Portuguese, Icelandic, Chinese, Swedish, Turkish, Norwegian, Iranian and Greek. Other instruments that have been validated in several languages are DMSES (Dutch, Turkish, Chinese, Spanish and Australian, US and UK English) and SDSCA (Korean, Spanish, Turkish, Greek and Portuguese). Additionally, there are two short versions for the Problem Areas in Diabetes Scale (PAID-5 and PAID-1) and for the Diabetes Empowerment Scale (DES-SF).

Final assessment

Globally, the PAID and the SMP-T2D were the instruments with more items evaluated positively (five out of 10): Good content and construct validity, reliability (internal consistency and test-retest) and evaluation of responsiveness. The four missing features were criterion validity, agreement, floor-ceiling effect and lack of

theoretical ground. Actually, PAID is the more translated instrument and it has two short forms (PAID-5 and PAID-1).

Other instrument (DMSES) was of a moderate quality (four out of 10 criteria). This questionnaire obtained a positive rating in content validity, internal consistency and reliability, with a good theoretical basis (Self-efficacy Theory). However, floor/ceiling effect, agreement, interpretability or responsiveness were not checked and a negative rating was given for criterion validity.

Discussion

This review evaluated the instruments reported for a comprehensive assessment of self-care behaviours or barriers in type 2 diabetic patients (T2DP), with a detailed appraisal of their characteristics (psychometric properties, theoretical ground, dimensions, etc.). Moreover of 9 Terwee's criteria for evaluating health status questionnaires, we have taken into account the presence of a theoretical ground. The instruments' quality was low to moderate, with partial descriptions on methods for content validity or patient participation, the use of gold standards for criterion validity, such as glycosylated haemoglobin, which has demonstrated to be a poor reference for this purpose and a succession of modest correlation values against other instruments. Sample size in many studies was insufficient for evaluating construct validity, as 31% of the studies (EBAS, DSCB-OA, DCP, DOQ and D-SMART) had fewer than 10 subjects per item (Knapp & Campbell-Heider 1989).

From the perspective of applicability, questionnaires with more than 40-50 items could be too long to use in a clinical context, because of time constraints. Thus, EBAS (60 items), DCP (>100 items), PDQ (67 items) and DOQ (77 items) would have this limitation. Nevertheless, it is not easy to decide the balance between parsimony and precision: data reduction and model simplification have been reported to be a weakness in some behavioural models, but problems with multicollinearity and clinical applicability can emerge if an appropriate item reduction is not carried out (Rhodes et al. 2004, Pesudovs et al. 2007).

Despite factorial analysis having been carried out in six studies, a Kaiser-Meyer-Olkin test prior to the analysis only was performed in one study (DOQ).

Furthermore, no confirmatory factorial analysis has been reported. Internal consistency and test-retest reliability were two of the parameters that achieved good values. The scarce inquiry about floor/ceiling effect (only in the DHP-18, DOQ and SMP-T2D) and responsiveness (only in the PAID, SDSCA and SMP-T2D) is remarkable. These flaws in constructing validity could lead to the omission of important dimensions of self-care behaviours in DM and, consequently, the understanding of latent elements of self-care that could help improve the way that patients and practitioners manage the disease. Construct validation is an on-going process of learning more and more about the construct, making new predictions and testing them (Bandura 1991). If construct validation is not carried out with solid methods, the theoretical progress in how to support patients in the development of self-management skills will be unsuccessful.

The frequent lack of a theoretical framework for the development of the questionnaire (EBAS, DSCB-OA, PAID, DHP-18, SDSCA, DDS, DOQ, PDDT and SMP-T2D) means that content validity is limited methodologically. In those studies where a theory is used, as the Social Learning Theory or the Health Belief Model, there is no deep argumentation about the item selection according to the model. This review included instruments validated in both type 1 diabetic patients (T1DP) and T2DP or in T2DP exclusively, and those studies where only the type of treatment for DM was differentiated, but only a few studies included a proportional rate of insulinized and non-insulinized patients (DSES, DDS and PDQ).

Nevertheless, the ability of the selected instruments to discriminate: (1) between the self-care skills of T1 and T2DP; or (2) between insulinized and non-insulinized patients is not clear. The PAID seems to be the best instrument in showing distinctive results with higher scores in T1DP. Several reviews in the literature address different, but related aspects to this study. One review (Eigenmann et al. 2009) included instruments that measured other outcomes such as quality of life, depression and satisfaction in DM, but it was not focused on self-care explicitly. Schilling and colleagues (Schilling et al. 2002) wrote a review with the purpose of assessing self-management in people with diabetes, but focused exclusively on type 1 DM. Other reviews have identified questionnaires that measure specific

concepts in self-care, such as empowerment (Herbert et al. 2009), but without a comprehensive approach.

Subsequently, this review summarizes the available instruments for this dimension, which can be very useful for clinicians and researchers who work directly with DM patients. Barriers in DM self-care have been reported to be multifaceted and consistent with the Information-Motivation-Behavioural Skills Model (IMB): not only Information (diabetes knowledge), but also personal motivation (less fatalistic attitudes) and social motivation (more social support) are key determinants of patients' final behaviour and, consequently, of glycaemic control. Therefore, instruments should be comprehensive enough to target personal and social motivation to promote behaviour change (Osborn & Egede 2010).

Interactions with T2DP should not be only focused in reinforcing instructions, they should also serve as an opportunity to mutually agree on goals, so that healthcare professionals can understand the reality of diabetes for their patients and the patients can express their values and beliefs to the practitioners. The process of enabling patients to discuss methods on how to address their risk factors and supporting them in developing their own management plans can be improved with the use of valid and reliable instruments. This challenge should be a priority as improvements in glycaemic control in people who receive self-care management treatment with an educational approach have been reported (Minet et al. 2010).

Limitations

This study has some limitations. First, in some studies, the information about content validation is poorly described or refers to other studies that have proven to be difficult to locate, despite contacting with original authors. Additionally, the existence of multiple versions of some instruments in some cases muddled our ability to determine which one was used in the psychometric testing. Moreover, the information about the type of patients included cannot discern between the adequacy of the different instruments for T1 or T2DP.

Conclusion

This review reports useful information for clinicians and researchers about different instruments available for self-care behaviours in DM and it can be a resource that increases the knowledge about the limitations and strengths of current instruments. There is no single instrument that achieves all the validity and reliability requirements for identifying self-care behaviours or barriers. However, we believe like Terwee et al., that every psychometric property does not have the same value, considering probably content validity the most valuable.

This reality constitutes an important gap for clinical practice because the process for involving people into their self-care might benefit from the existence of adequate instruments for this aim. Lifestyles are not easy to be modified and the availability of instruments theoretically grounded could help nurses and people with diabetes not only to identify the main barriers to self-care, but also to design patient-centred strategies for introducing new healthy behaviours or reinforcing those positive ones self-developed by the patient. Consequently, further studies should be carried out to provide patients, clinicians and researchers with valid and reliable instruments that are methodologically solid and theoretically grounded.

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Conflict of interest

No conflict of interest has been declared by the authors.

Author contributions

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (http://www.icmje.org/ethical_1author.html)]:

- substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

Supporting Information Online

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Search strategy.

Appendix S2. Excluded instruments with reasons.

Appendix S3. Complementary studies on questionnaires included.

References

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Why is this research or review needed?

- Many structured education programmes address the empowerment of people with type 2 diabetes.
- It is necessary to bring patients' perceptions and the clinical objectives closer together to tailor educational interventions in diabetes.
- Several instruments focused on evaluating self-care behaviours or barriers to self-care in diabetes are available, but more knowledge is needed about their psychometric validation processes.

What are the key findings?

- Only two of 16 instruments reviewed obtained at least half of Terwee's quality criteria.
- The main gaps are related to criterion and construct validity, inter-observer agreement, floor and ceiling effect, responsiveness and interpretability of instruments.
- Diabetes self-care behaviour or barriers related to therapeutic regimen have been discriminated by very few instruments.

How should the findings be used to influence policy/practice/research/education?

- This review provides valuable information for decisionmaking on the selection of the most appropriate instrument to assess patients' self-care needs in diabetes care or research.
- Further studies should be carried out to provide patients, clinicians and researchers with valid and reliable instruments.
- These tools could be a useful resource in the provision of diabetic education programmes based on tailored interventions.

Figure 1 Flow chart of the process of selected studies.

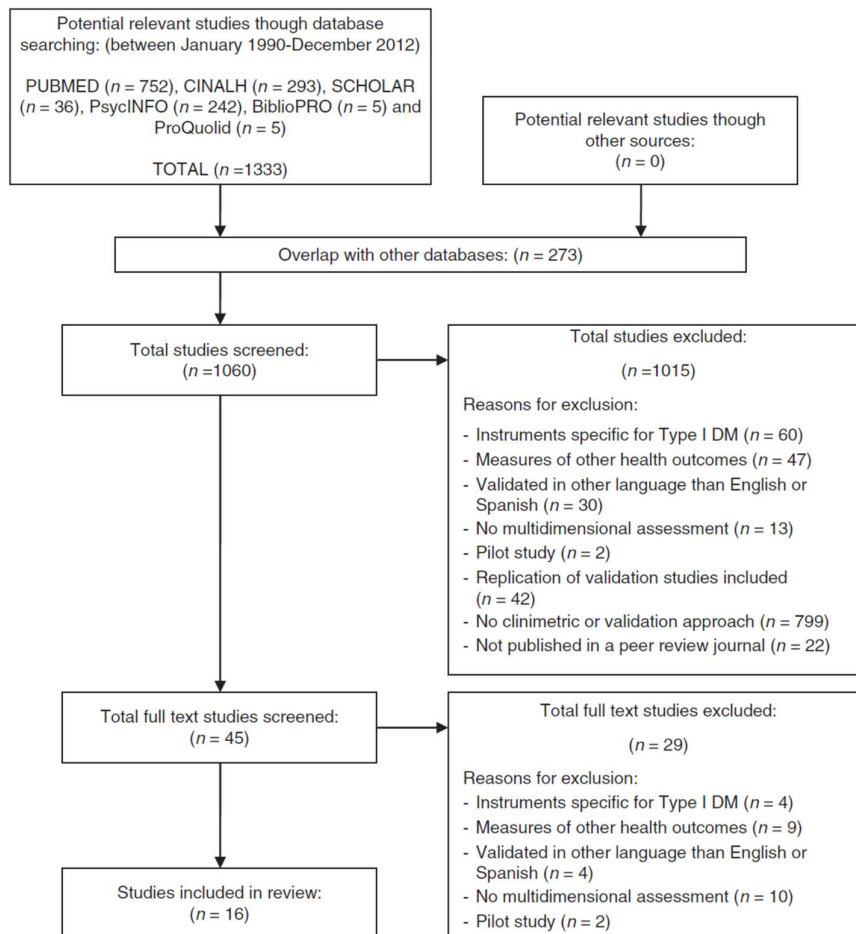


Table 1 Instruments included in the review.

Acronym	Full title
EBAS	Environmental Barriers to Diabetes-Regimen Adherence
DSCB-OA	Diabetes Self-care Barriers in Older Adults
DCP	Diabetes Care Profile
PAID	Problem Areas in Diabetes Scale
DMSES	Diabetes Management Self-Efficacy Scale
DHP-18	Diabetes Health Profile for DM type II
DES	Diabetes Empowerment Scale
SDSCA	Summary of Diabetes Self-care Activities
–	Diabetes-related Health Beliefs (Spanish)
DSES	Diabetes Self-Efficacy Scale
DDS	Diabetes Distress Scale
DOQ	Diabetes Obstacles Questionnaire
D-SMART	Diabetes Self-management Assessment Report Tool (Spanish version)
PDQ	Personal Diabetes Questionnaire
PDDT	Patient-perceived difficulty in diabetes treatment scale
SMP-T2D	Self-management Profile for Type 2 Diabetes

Table 2 Description of the included instruments.

Instrument and theoretical ground	Dimensions and structure	Population used for validation	Psychometric properties
Environmental Barriers to Diabetes-Regimen Adherence (EBAS) [Social Learning Theory]	4 dimensions: diet, exercise, glucose testing and medication 60 items Likert Scale with 5 items	T1DM (<i>n</i> = 37, 17, 29%) T2DM (<i>n</i> = 177, 82, 71%) IDDM (<i>n</i> = 133, 62, 15%) Age (mean): 48.7 years Female: 50.9%	- <i>Content validity</i> : 13 structured telephone interviews to type 1 and 2 DM + 6 diabetes healthcare providers. Face validity: 5 professionals reviewed the questionnaire - <i>Criterion validity (concurrent)</i> : BAS <i>r</i> = 0.63; DCP-BAS <i>r</i> = 0.51; DSCB: <i>r</i> = -0.33-0.52; HbA _{1c} <i>r</i> = 0.28 - <i>Construct validity (discriminant)</i> : two ways: 1° DSCB (regimen behaviour not measuring by EBAS) <i>r</i> = -0.18-(0.01). 2° Subscale EBAS with total score EBAS <i>r</i> = 0.73-0.86 - <i>Internal consistency</i> : Cronbach's alpha = 0.94 (0.84-0.91) - <i>Test-retest reliability</i> : <i>r</i> = 0.80 (0.59-0.74) 6 weeks No other validation methods described
Diabetes Self-care Barriers in Older Adults (DSCB-OA) [No specified]	3 dimensions: diet, exercise and blood glucose monitoring barriers 12 items Non-specified scale for measurement	T1DM (<i>n</i> = 82, 100%) IDDM (<i>n</i> = 65, 79, 2%) Age (mean): 68. years Female: 67%	- <i>Content validity</i> : literature review + panel of lay and professionals - <i>Construct validity</i> : factor analysis with varimax rotation, 3 factor solution (47.1% of total variance). - <i>Internal consistency</i> : Cronbach's alpha = 0.69 (0.60-0.86) - <i>Interrater reliability</i> : 95% (2 interviewers) No other validation methods described
Diabetes Care Profile (DCP) [Health Belief Model]	14 dimensions: control problems, social and personal factors, positive and negative attitude, self-care ability, importance of care, self-care adherence, diet adherence, medical exercise and monitoring barriers, understanding management practice, long-term benefits and support 103 items + demographic questions Likert Scale with 5 items (time for completion: 30-40 minutes approximately)	Study 1: Community T1DM (<i>n</i> = 49, 11%) T2DM (<i>n</i> = 391, 89%) IDDM (<i>n</i> = 198, 45%) Age (mean): 61 years Female: 55% Study 2: Medical Center T1DM (<i>n</i> = 116, 33%) T2DM (<i>n</i> = 236, 67%) IDDM (<i>n</i> = 236, 67%) Age (mean): 54 years Female: 60%	- <i>Content validity</i> : methods not well specified - <i>Criterion validity (concurrent)</i> : Study 1: HbA _{1c} <i>r</i> = -0.33-(0.21). Study 2: Social Provisions Scale <i>r</i> = -0.34-(0.51); CES-D <i>r</i> = -0.53-(0.48); Happiness and Satisfaction Scale: <i>r</i> = -0.27-(0.30) - <i>Construct validity (discriminant)</i> : differences between IDDM-NIDDM and NIDDM using or not using insulin. Study 1: 6 of 14 scales were significant differences. Study 2: 4 of 14 scales were significant differences - <i>Internal consistency</i> : Study 1: Cronbach's alpha = 0.60-0.95. Study 2: Cronbach's alpha = 0.66-0.94 - <i>Interpretability</i> was described mean and standard deviation of 3 groups (T1DM, T2DM insulin-dependent and T2DM non-insulin-dependent) Other validation methods: validated among Hispanic population and African Americans cultural assessment
Problem Areas in Diabetes Scale (PAID) [No specified]	1 dimension including: psychosocial aspects related with self-care, living with diabetes,	IDDM (<i>n</i> = 135, 52.7%) No specified type of DM Age (mean): 52 years Female: 55%	- <i>Content validity</i> : expert consensus and interviews with patients + pilot study in 25 IDDM (Polonsky <i>et al.</i> 1995) - <i>Criterion validity (concurrent)</i> : HbA _{1c} , <i>r</i> = 0.003-0.66 (NS); ATT39 + DCM <i>r</i> = -0.80-(0.72); HBM = -0.81-(0.10); DSSS <i>r</i> = -0.67-(0.09)

Table 2 (Continued).

Instrument and theoretical ground	Dimensions and structure	Population used for validation	Psychometric properties
	familiar support, Knowledge, beliefs, mood... 20 items Likert Scale with 5 items		- <i>Construct validity (discriminant)</i> : Between groups mean differences: T1DM vs. T1IDM Effect size (ES) = 0.4 ($P < 0.002$); T1DM vs. T1IDM using insulin ES = 0.32 ($P < 0.02$); T1DM vs. T1IDM not using insulin ES = 0.39 ($P < 0.05$) - <i>Internal consistency</i> : Cronbach's alpha = 0.95 - <i>Test-retest reliability</i> : $r = 0.83$ (Welch <i>et al.</i> 1997) - <i>Responsiveness</i> : $t = 8.5$ ($P < 0.001$) to 2.1 ($P < 0.06$). Effect Size = 0.32–0.64 (Welch <i>et al.</i> 2003) - <i>Interpretability</i> = 4 groups were presented (T1DM, T1IDM insulin-dependent, T1IDM tablet-treated and T1IDM diet-treated), but MIC was not defined. Other validation methods: Iranian, dutch, portuguese, icelandic, swedish, chinese, norwegian, turkish and greek-validated versions. Available two short-form versions (PAID)-5, (PAID)-1 and a specific version for parents (PAID-PR)
Diabetes Management Self-Efficacy Scale (DMSES) [Self-efficacy Theory]	1 dimensions including: blood glucose monitoring, healthy eating pattern, weight control, medication, physical exercise... 15 items 0–10 point scale	T1IDM ($n = 175$, 100%) No specified type of treatment Age (mean): 61 years Female: 37%	- <i>Content validity</i> : Consulting with the Warwick Diabetes Research and Education User Group + Flesch reading ease score = 82.9% or grade 2.6 (face validity). 30 T1IDM + group discussions with 3 cohorts of 20 patients each one. - <i>Criterion validity (concurrent)</i> : with PAID $r = -0.46$ - <i>Construct validity</i> : with HbA _{1c} , $r = -0.21$ - <i>Internal consistency</i> : Cronbach's alpha = 0.89; correlation between item scores and total score = 0.34–0.71 - <i>Test-retest reliability</i> : $r = 0.77$ ($n = 67$), 4 weeks Other validation methods: dutch, turkish, chinese, australian and US english and spanish-validated versions.
Diabetes Health Profile for DM type II (DHP-18) [No specified]	3 dimensions: psychological distress, barriers to activity and disinhibited eating. 18 items Likert Scale with 5 items	T1IDM ($n = 426$, 100%) IDDM ($n = 175$, 41.1%) Age (mean): 60.9 years Female: 44%	- <i>Content validity</i> : 25 in-depth interviews with T1DM, review of the literature and discussions with healthcare professionals + assessment of items endorsed (Meadows <i>et al.</i> 1996) - <i>Construct validity</i> : factor analysis with varimax rotation, 3 factor solution (45% of total variance). Discriminant (ANOVA): differences between IDDM-NIDDM for barriers to activity: $F = 24.24$, $P < 0.001$; for psychological distress: $F = 20.97$, $P < 0.001$ - <i>Internal consistency</i> : Cronbach's alpha (0.71–0.88) - <i>Floor/ceiling effect</i> : floor (0.8–29.4%); ceiling (0–1.2%) - <i>Interpretability</i> = was described mean and standard deviation of 3 groups (T1IDM insulin-dependent, T1IDM tablet-treated and T1IDM diet-treated), but MIC was not defined. Other validation methods: Danish version
Diabetes Empowerment Scale (DES) [Empowerment Model]	3 dimensions: managing the psychosocial aspects of diabetes, assessing dissatisfaction and	T1DM ($n = 93$, 25%) T1IDM ($n = 282$, 75%) IDDM ($n = 307$, 82%)	- <i>Content validity</i> : evaluated in previous studies (Anderson <i>et al.</i> 1995) - <i>Criterion validity</i> : with 3 subscales of DCP: positive attitude $r = 0.32$ –0.59; negative attitude $r = -0.59$ –(-0.38); diabetes understanding $r = 0.39$ –0.43; (HbA _{1c} , non specified)

Table 2 (Continued).

Instrument and theoretical ground	Dimensions and structure	Population used for validation	Psychometric properties
	readiness to change and setting and achieving diabetes goals. 28 items Likert Scale with 5 items	Age (mean): 50.4 years Female: 55%	- <i>Construct validity</i> : factor analysis with varimax rotation, 3 factor solution (56% of total variance) - <i>Internal consistency</i> : alpha Cronbach = 0.96 - <i>Test-retest reliability</i> : $r = 0.79$, 6 weeks. Other validation methods: Iranian, icelandic, swedish and chinese-validated versions. Available two short-form versions (DES-SF) and the chinese version short form.
Summary of Diabetes Self-Care Activities Measure (SDSCA) [No specified]	5 dimensions: general diet, specific diet, exercise, medication taking and blood-glucose testing. Additional dimensions: foot care and smoking. 11 items + 14 additional Several scales for measurement	T1DM ($n = 137$, 12.3%) T2DM ($n = 975$, 87.7%) IDDM ($n = 408$, 36.7%) Review of 7 studies ($n = 1988$). Study 1 ($n = 876$) no specified type of DM Age (mean): 61.6 years Female: 53.8% ($n = 1069$)	- <i>Content validity</i> : evaluated in previous studies(Toobert & Glasgow 1994) - <i>Criterion validity</i> : use of several scales related with food records and exercise. r (range) = -0.54 – (0.58) , - <i>Internal consistency</i> : inter-item correlation r (mean) = 0.47, except for specific diet ($r = 0.07$ – 0.23) - <i>Test-retest reliability</i> : r (mean) = 0.40, range (-0.05 to 0.78), 3–4 months. - <i>Responsiveness</i> : responsiveness index = -0.09 – (0.43) Other validation methods: spanish, korean, turkish, greek and portuguese-validated versions
Diabetes Health Beliefs (spanish-speaking) [Health Belief Model]	4 dimensions: barriers, social support for diet, impact of job on therapy and benefits of therapy. 25 items Likert Scale with 5 items	T1DM ($n = 326$, 100%) IDDM ($n = 85$, 26%) Age (mean): 53.2 years Female: 65%	- <i>Content validity</i> : literature review and pilot study with 70 spanish-speaking diabetic patients - <i>Criterion validity</i> : item-total correlation between original instrument (Given <i>et al.</i> 1983) and final instrument. $r = 0.26$ – 0.74 - <i>Construct validity</i> : factor analysis with varimax rotation, 4 factor solution (44% of total variance) - <i>Internal consistency</i> : Cronbach's alpha (0.56–0.90) No other validation methods described
Diabetes Self-Efficacy Scale (DSES) [Self-efficacy Theory]	5 dimensions: diabetic routines, confidence in ability to self-treat, certainty belief, efficacy belief about diet and belief about ability to exercise 18 items Likert Scale with 5 items	NIDDM ($n = 122$, 54%) IDDM ($n = 104$, 46%) No specified type of DM Age (mean): 51.6 years Female: 46.9%	- <i>Content validity</i> : methods not well specified - <i>Criterion validity</i> : with GSE $r = (0.12$ – $0.29)$, $(0.06$ – $0.31)$, $(0.20$ – $0.35)$ (0, 3 and 9 months respectively) - <i>Construct validity</i> : factor analysis with varimax rotation, 5 factor solution (60.7% of total variance); range (0.58–0.83). Hypothesis testing (efficacy beliefs will increase over the time): was only partially supported (3 of 5 dimensions) - <i>Internal consistency</i> : Cronbach's alpha = 0.82–0.84–0.84 (0, 3 and 9 months respectively) No other validation methods described
Diabetes Distress Scale (DDS) [No specified]	4 dimensions: emotional burden, physician-related distress, regimen-related distress and diabetes-related interpersonal distress.	T1DM ($n = 111$, 16.7%) T2DM ($n = 572$, 83.3%) IDDM ($n = 344$, 50.4%) (four diverse sites) Age (mean): 56.3 years Female: 47.8%	- <i>Content validity</i> : review scales previously development (like PAID) asking patients and professionals. Pilot study with item resultants. Flesch-Kincaid index: 7.3 - <i>Criterion validity</i> : with CESD $r = 0.34$ – 0.56 ; HbA _{1c} $r = 0.01$; Total cholesterol $r = 0.20$ - <i>Construct validity</i> : factor analysis with varimax rotation, 4 factor solution; range (0.581–0.877). Item-total correlation $r = 0.82$

Table 2 (Continued).

Instrument and theoretical ground	Dimensions and structure	Population used for validation	Psychometric properties
	17 items Non-specified scale for measurement		- <i>Internal consistency</i> : Cronbach's alpha = 0.93 - <i>Interpretability</i> = was described mean and standard deviation of 3 groups (IDDM, NIIDM tablet-treated and NIDDM diet-treated), but MIC was not defined. No other validation methods described
Diabetes Obstacles Questionnaire (DOQ) [No specified]	8 dimensions: medication, self-monitoring, knowledge and beliefs, diagnosis, relationships with healthcare professionals, lifestyles changes, coping and advice and support. 77 items Likert Scale with 5 items	T1DM (<i>n</i> = 176, 100%) No specified type of treatment Age (mean): 62.2 years Female: 50%	- <i>Content validity</i> : Focus Group (EUROBSTACLE) (Vermeire <i>et al.</i> 2007) + literature review + panel by 21 members of the Warwick Diabetes Care Research User Group - <i>Criterion validity</i> : PAID <i>r</i> = 0.383–0.706 (dimensions); - <i>Construct validity</i> : KMO test = 0.712–0.903. Correlation between HbA _{1c} and 4 dimensions DOQ, <i>r</i> = 0.184–0.34; Correlation between ADDQoL and 3 dimensions DOQ, <i>r</i> = 0.169–0.271. - <i>Internal consistency</i> : Cronbach's alpha = 0.766–0.937 - <i>Floor/ceiling effect</i> : Eliminated 18 items (with >90% of responses in one category of each item), but not reported dates. Other validation methods: Dutch-validated version
Diabetes Self-Management Assessment Report Tool (D-SMART, spanish version) [HOBBIT Model]	7 dimensions: exercise/physical activity, eating, medication, blood glucose monitoring, problem-solving, barriers and living with diabetes (distress and support). 49 items Several scales for measurement	T1DM (<i>n</i> = 174, 100%) not specified type of treatment Age (mean): 52 years Female: 59%	- <i>Content validity</i> : 4 Focus Group with T1DM, pilot testing with 8 represented patients of focus group and consensus of research team. - <i>Internal consistency</i> : Cronbach's alpha = 0.80, 0.76, 0.65 (barriers, distress and support respectively). No specified internal consistency for other dimensions. - <i>Test-retest reliability</i> : <i>r</i> = 0.89, 0.85, 0.83 (barriers, distress and support respectively) 2 weeks. No specified test-retest reliability for other dimensions. No other validation methods described
Personal Diabetes Questionnaire (PDQ) [Transtheoretical Model of Health Behavior Change]	4 dimensions: diet-nutrition, drug management, glycaemic self-monitoring and physical activity. 67 items (time for completion: less than 30 minutes) Several scales for measurement	T1DM (<i>n</i> = 194, 26%) T1DM (<i>n</i> = 552, 74%) IDDM (<i>n</i> = 382, 51.20%) Age (mean): 51.3 years Female: 54%	- <i>Content validity</i> : patient interviews + items obtained from previous studies + multidisciplinary assessment (methods no specified). Legibility analysis through Flesh-Kincaid Index (63/100) - <i>Criterion validity</i> : HbA _{1c} T1DM <i>r</i> = 0.207. T1DM (ID) <i>r</i> = 0.362. T1DM (NID) <i>r</i> = 0.161. All PDQ dimensions were no significant with BMI. - <i>Internal consistency</i> : Cronbach's alpha = 0.65–0.834 - <i>Interpretability</i> = 3 groups were presented (T1DM, T1DM insulin-dependent, T1DM not insulin-dependent), but MIC was not defined. No other validation methods described

Table 2 (Continued).

Instrument and theoretical ground	Dimensions and structure	Population used for validation	Psychometric properties
Patient-perceived difficulty in diabetes treatment scale (PDDT) [No specified]	1 dimension including: self-care, drug management, glycaemic self-monitoring, diet, relation with health providers and costs. 12 items Likert Scale with 5 items	IDDM ($n = 384$, 38.9%) NIDD ($n = 604$, 61.1%) No specified type of DM Age (mean): 60 years Female: 50.8%	- <i>Content validity</i> : literature review + 4 focus group with 24 TIIDM patients + cognitive interview with 34 TIIDM + expert panel (in epidemiology and diabetes care) + pilot study with a sample of 83 diabetic patients. - <i>Criterion validity</i> : HbA _{1c} , $r = 0.19$, range: 0.12–0.20; Holistic QoL, $r = 0.25$, range: 0.11–0.36; Diabetes-specific QoL, $r = 0.60$, range: 0.31–0.46. - <i>Construct validity (discriminant)</i> : hypotheses contrasted (there were significant differences between scores groups by type of treatment for 11/12 items (91%)) - <i>Interpretability</i> = 3 groups were presented (IDDM, NIIDM only tablet-treated and NIDDM diet-treated), but MIC was not defined. No other validation methods described
Self-management Profile for Type 2 Diabetes (SMP-T2D) [No specified]	5 dimensions: blood glucose monitoring, medication taking, healthy eating, being physically active and coping) and two constructs (weight management and confidence to manage) 18 items (time for completion: 3–5 minutes) Several scales for measurement	Study 1: TIIDM ($n = 147$, 100%) (all sample was NIDDM) Age (mean): 54.6 years Female: 40.1% Study 2: TIIDM ($n = 93$, 100%) (all sample was NIDDM) Age (mean): 50.8 years Female: 34.4%	- <i>Content validity</i> : literature review + interview with 49 TIIDP + expert panel (in epidemiology and diabetes care) + pilot study with a sample of 83 diabetic patients. Flesch–Kincaid index: 7.0 + cognitive interviews with 34 TIIDP. - <i>Criterion validity</i> : all correlations <0.70 (HbA _{1c} : –0.43 to 0.21; DTSQs: –0.44 to 0.12; IWQOL: –0.05 to 0.44; EQ-5D: –0.22 to 0.34; WHO-5: 0.08–0.46) - <i>Construct validity</i> : all hypotheses described were confirmed (ease and behaviour measures had strong associations) with a 81% of concordance (statistical significance). - <i>Internal consistency</i> : Cronbach’s alpha = 0.80 (0.71–0.87) - <i>Test–retest reliability</i> : $r = 0.83$ (study 1), 1 week. - <i>Responsiveness</i> : follow-up 24 week after medication change 50% of measures showed improvement (study 2) - <i>Floor/ceiling effect</i> : floor (median for both studies) = 2.5%; ceiling (median) = 33.0% No other validation methods described

TIDM, Type I diabetes mellitus; TIIDM, Type II diabetes mellitus; IDDM, Insulin-dependent diabetes mellitus; NIDDM, Non-insulin-dependent diabetes mellitus; BAS, Barriers to diabetes adherence scale; DCP-BAS, Diabetes Care Profile barriers to self-care; DSCB, Diabetes self-care behaviour; CES-D, Center for Epidemiologic Studies Depression Scale; ATT39, Attitudinal coping styles; DCM, Diabetes Coping Measure; HBM, Health Belief Model; MIC, Minimal important change; DSSS, Diabetes Social Support Scale; BA, Barriers to activity; PD, Psychological distress; GSE, General Self-efficacy Scale; CESD, Center for Epidemiological Studies Depression Scale; KMO, Kaiser-Meyer-Olkin; ADDQoL, Audit of Diabetes Dependent Quality of Life; QoL, Quality of Life; TIIDP, Type II diabetic patients; WHO-5, World Health Organization-Five Well-Being Index; EQ-5D, EuroQoL-Five Dimensions; DTSQs, Diabetes Treatment Satisfaction Questionnaire-Status Version; IWQOL, Impact of Weight o Quality of Life-Lite.

Table 3 Summary of psychometric properties.

	Content validity	Internal consistency	Criterion Validity	Construct Validity	Reproducibility: Agreement	Reproducibility: Reliability	Responsiveness	Floor/Ceiling effect	Interpretability	Theoretical ground	Final assessment
EBAS	?	+	-	?	0	+	0	0	0	+	
DSCB-OA	?	-	0	?	0	?	0	0	0	0	
DCP	?	-	-	-	0	0	0	0	?	+	
PAID	+	+	-	+	0	+	+	0	?	0	√
DMSES	+	+	-	?	0	+	0	0	0	+	
DHP-18	+	+	0	-	0	0	0	-	?	0	
DES	+	-	-	?	0	+	0	0	0	+	
SDSCA	+	?	-	0	0	-	+	0	0	0	
Diabetes Health Beliefs (spanish-speaking)	+	-	-	?	0	0	0	0	0	+	
DSES	?	+	-	-	0	0	0	0	0	+	
DDS	+	+	-	?	0	0	0	0	?	0	
DOQ	+	+	-	?	0	0	0	?	0	0	
D-SMART (spanish version)	+	?	?	0	0	?	0	0	0	+	
PDQ	+	-	-	0	0	0	0	0	?	+	
PDDT	+	0	-	+	0	0	0	0	?	0	
SMP-T2D	+	+	-	+	0	+	+	-	0	0	√

+ Positive rating; ?, Indeterminate rating; -, Negative rating; 0, No information available.