Using qualitative methods in developing an instrument to identify barriers to self-care among persons with type 2 diabetes mellitus

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Abstract

Aims and objectives. To develop a questionnaire to address barriers and self-care behaviour among persons with type 2 diabetes mellitus.

Background. Several instruments are available in the literature to measure barriers to self-care in this population, but many of them present limitations in its psychometric validation process, and lack of theoretical background.

Design. Content validation study using multiple qualitative methods.

Methods. A systematic review was conducted, and two focus groups with fifteen participants (n=15) were analysed to identify key topics and categories concerning barriers and self-care behaviour. These categories were used to generate items that were subjected to expert scrutiny, using the Delphi technique. The resulting list of items was tested for readability and comprehension by nine diabetic patients (n=9), through cognitive interviews. The whole process was Conducted in accordance with the Theory of Planned Behaviour.

Results. The mean age (standard deviation) of participants in the focus groups and cognitive interviews was 66.05 (8.47) and 63.11 (6.13) years, respectively. 46.7% of the members of the focus groups and 44.4% of those interviewed were female, and the mean duration (standard deviation) of their diabetes was 6.53 (3.17) and 4.89 (3.84) years, respectively. After the qualitative analysis, 27 codes were obtained. Thereafter, items were generated in accordance with the dimensions of this theory: attitudes towards the behaviour (n= 23), social norms (n= 13), perceived behavioural control (n= 17) and behavioural intention (n= 15).

Conclusion. A rigorous process of content validation with multiple methods was implemented to obtain an instrument aimed at addressing barriers and self-care behaviour of patients with type 2 Diabetes Mellitus.

Relevance to clinical practice. An instrument theoretically rooted and supported on professional and patients' views is available to assess self-care behaviours in patients with type 2 Diabetes Mellitus. The evaluation of its reliability and construct validity will determine the instrument's value and practical application in the clinical context.

Keywords: content validity (MeSH), instrument development (MeSH), questionnaires (MeSH), self-care (MeSH), type 2 diabetes (MeSH), validation studies (MeSH)

Introduction

Type 2 diabetes mellitus (DM II) is currently one of the chronic diseases making the greatest impact on healthrelated quality of life, and the data being generated in this respect are alarming. The International Diabetes Federation (IDF) has estimated that 366 million people suffer DM II worldwide and that by 2030 the figure will be close to 552 million (Whiting et al. 2011). Major efforts are being made by clinicians, researchers and health systems to promote self-care among this population, as an essential element of successful health care (Serrano-Gil & Jacob 2010).

Background

At present in international research in this field, there is no consensus on the concept of self-care. One recently proposed definition for persons with chronic diseases describes 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). Other closely related concepts also play key roles in the description of strategies to promote self-care. These include self-efficacy, defined as a mediator of relationship between knowledge or abilities and activity performance, or as a moderator of the effectiveness of an intervention (Richard & Shea 2011), and empowerment, which is also considered a key element in enabling patients to take decisions independently and in co-responsibility (Ramsay Wan et al. 2012). There is a close relationship between the development of Effective self-care behaviour by DM II patients and their perceived quality of life, and so emphasis should be placed not only on treatment recommendations but also on the personalisation of care by means of a patient-centred approach, to help prevent complications (Inzucchi et al. 2012).

With a view to improving clinical outcomes and the quality of life of persons with DM II, many programmes have been designed in the field of diabetes education

by which interventions are adapted to the perceived needs of patients (Elissen et al. 2012, Radhakrishnan 2012). In this respect, one approach that helps clinicians and researchers better understand patients' viewpoints is the use of questionnaires to provide directly reported information, i.e. Patient Reported Outcomes (PROs) (Fehnel et al. 2013). Various questionnaires have been published to evaluate the self-care needs of DM II patients, but they present weaknesses such as an inadequate procedure of psychometric validation (to ensure internal/external consistency, the validity of criteria/ constructs/content, sensitivity to change, etc.) and the absence of a theoretical model on which to solidly develop the items that will comprise the measurement instrument (Caro-Bautista et al. 2014).

The aim of the present study is to develop a new instrument to identify barriers and self-care behaviour in persons with DM II, taking a multidimensional approach and based on a solid theoretical framework. For this purpose, the content is validated by rigorous methods to determine the extent to which an instrument represents the most relevant and important aspects of a concept in the context of a given measurement application (Magasi et al. 2012). This is an essential step, and in the case of PROs the rigour of the approach is increased by the inclusion of qualitative methods in its construction and design, incorporating the Outlook and the perceptions of the patients themselves throughout the process. Moreover, this enhances the understandability and end user acceptability of the instrument (Lasch et al. 2010).

Methods

Study design

The study to design the instrument was carried out by a combination of methods, with the collaboration of patients with DM II [focus groups (FGs) – and cognitive interviews] and healthcare personnel and researchers (Delphi technique), together with a review of the literature, taking as a reference the model for the development of questionnaires proposed by Brod and colleagues (Brod et al. 2009) (Fig. 1).

Theoretical framework

The Theory of Planned Behaviour (TPB) (Ajzen 1985) underpinned the development of this instrument at each step of the process. This conceptual model is intended to predict a specific behaviour (in the present study, the adherence behaviour of patients with DM II) in terms of four constructs: behavioural intention, beliefs, perceived behavioural control and self-evaluation (positive or negative) and social and peer pressure (subjective norm). This theoretical model has been updated several times and for this study, we took as a reference the version proposed by Conner and Sparks (1996) (Fig. 2). Both in developing the script to be presented to the FGs and in generating the initial questionnaire items, these constructs were considered such that each dimension addressed could be analysed in terms of the TPB. The questions were worded taking as a reference the manual developed in project 'Research-Based Education and Quality Improvement' (ReBEQI) on health services Research in the European Union (Francis et al. 2004).

Study population

The study population of patients consisted of subjects with DM II, with a confirmed diagnosis in their health record, irrespective of the duration of evolution of the disease and of the treatment prescribed (lifestyle modification, oral antidiabetics or insulin), registered with the Málaga-Valle del Guadalhorce (Spain) primary health care district. Sampling was intentional, both for the FGs and for the cognitive interviews, seeking parity in gender and treatment (insulin vs. noninsulin dependent, IDDM vs. NIDDM). Exclusion criteria were sensory disability (such as blindness), moderate-severe mental disability, and difficulty in reading comprehension (for subjects included in the cognitive interviews). In addition, patients with DM I were excluded.

The experts involved in the consensus meetings were professionals with over 10 years' experience treating or studying DM II, in primary care, in hospital care or as a teacher/ researcher.

Data collection

Literature review

The first step was to conduct a systematic review of the literature, looking for instruments that examine barriers and self-care behaviour among DM II patients

(1990‑2012). Searches were carried out in six databases: Pubmed, CINAHL, PsycINFO, ProQuolid, BiblioPRO and Google SCHOLAR. The quality of the studies was assessed by two authors independently using Terwee0s proposed criteria: psychometrics properties, dimensionality, theoretical ground and population used for validation through each included instrument (Terwee et al. 2007). Among many of the published studies analysed, significant weaknesses were identified in the psychometric validation process. The methodology used and the results of this literature review have been presented elsewhere (Caro-Bautista et al. 2014).

Focus groups

Two FGs were created with fifteen participants (n= 15) between June and July of 2012 with patients from eight areas of the city of Málaga with different demographic characteristics, to obtain diversity in the patients' sociocultural outlook. The team supervising the FGs consisted of three nurses (two male and one female), with experience in qualitative research and in conducting group interviews, all of whom had a Master's degree and experience in health service management. The researchers had no prior relationship with the group participants, who were recruited by clinicians unrelated to the study.

A semi-structured script was prepared, based on TPB constructs (Ajzen 1985) and on the questionnaires included in the literature review until April 2012. The script addressed five dimensions of self-care: nutrition, exercise, medication, blood glucose self-analysis and precautions in risk situations (Appendix S1). A more flexible approach was taken for the interview, however, allowing the opportunity to consider specific self-care situations that concerned the participants (for example, family responsibilities). Questions of a personal nature were left until the end of the interview, so that its development would not be affected and to ensure the participation of all members of the group. Both group interviews were audio-taped and transcribed verbatim, and encoded on the basis of topics that arose and subsequent qualitative analysis using ATLAS.ti 7 software (Friese 2012).

Each group had a moderator who facilitated an orderly approach to the dimensions to be addressed, and an observer recorded aspects of the context

and development of the interview. Consolidated Criteria for Reporting Qualitative Research (COREQ) recommendations were followed to describe how the FGs functioned, detailing the characteristics of the research team, the study design and the collection/ reporting of the findings (Tong et al. 2007).

Sampling in the FGs was performed in accordance with the principle of saturation. Thus, when the second group had met, a saturation matrix was created, which revealed that the categories and codes never diverged by more tan 8% in the two interviews, a similar figure to that obtained in previous, similar studies (Guest et al. 2006). The interviewees were not given transcripts or feedback on the results obtained (Table 1).

Delphi technique

To reach a consensus on which of the questions selected were representative, from the standpoint of the professionals consulted, a Delphi process was undertaken using an online application (LimeSurvey) between February and March 2013, with the participation of 13 experts in DM II (nurse practitioners and diabetes educators, primary care physicians, endocrinologists and a psychologist). They were asked to state their views on the appropriateness of the inclusion or otherwise of each questionnaire item, using a Likert scale of 1‑9 (where 1 is the lowest level of relevance and 9, the highest).

Cognitive interviews

The legibility of the instrument was assessed using the Fernández-Huerta index. Furthermore, to determine the comprehensibility of the instrument and to reach a consensus from the patients' standpoint, cognitive interviews (CIs) were conducted (April-May 2013) by nine diabetic patients (n = 9), based on the recommendations of Brod and colleagues. The patients were asked draft survey questions, and additional verbal information was obtained about the survey responses, which was used to evaluate the quality of the response and to help determine whether the question was generating the information that its author intended (Beatty & Willis 2007). A 'verbal probing' technique was used as a qualitative approach. This involved, first, giving the interviewee a questionnaire to complete, and then conducting the interview, based on a pre-established script, on how easy or difficult it was for the subject to understand and complete

(Appendix S2). The interviews were Structured in blocks of three, so that a statement or answer choice would be modified, or a further item incorporated, if two out of three respondents in each block agreed in this respect. All interviews were conducted in person by a member of the team, immediately after the questionnaire had been completed. The respondents were also asked to provide, on a Likert scale (1-7), their overall assessment of the questionnaire, the instructions, the response options and the degree of agreement between what they had answered and how they actually lived with DM.

Data analysis

The data obtained from the FGs were analysed using content analysis, following Taylor and Bogdan (Taylor & Bogdan 1998). The recordings were transcribed verbatim and an initial reading of the data was then performed to identify significant issues. Inductive coding of the transcript was then carried out in two phases: a first coding process where significant paragraphs, sentences and statements were assigned different codes that treated to assign a summative, salient, essence-capturing and/or evocative attribute of the selected fragment of patients' speech. Following, a second coding process was carried out to refine the portions coded, extending, modifying or even reconfiguring the codes themselves developed thus far. Subsequently, the unencoded material was reviewed to detect possible fragments of significant speech; any such fragments that were observed were then assigned the appropriate codes. The final codes were then clustered and organised into categories by their similarity or communality, with the ATLAS.ti software. Finally, the reflexivity of the researchers was evaluated; their possible influence on the research context was determined by reviewing the interviewers' notes and those of any other persons present during the interview. To prevent any influence arising from a treatment relationship, there was no clinical relationship between researchers and patients.

The analysis of the expert consensus phase was Conducted as proposed by the RAND Corporation (Fitch et al. 2001), based on percentiles and the interquartile range as a measure of agreement/disagreement. Questions with a median value >8 were directly accepted provided the interquartile rank was <3; questions with a median value <5 were removed, and those with a median value of 5-8 were

subjected to a second phase. In this second round, the remaining questions were grouped by domains and the participants were asked to rank them from highest to lowest priority. The first two questions from each domain were then selected, and thus proportionality was maintained between the questions finally selected and those proposed at the outset. In consequence, no area was under-represented.

Ethics

The study was approved by the Málaga Northeast Ethics Committee, working within the Andalusian Health Service, on 24 July 2012. All participants were given a leaflet detailing the characteristics of the project (research team, study goals, duration, confidentiality in the data processing, etc.) and all signed the corresponding informed consent form. All data were treated anonymously.

Results

Study sample

The mean age (SD) of the participants in the FGs and Cis was 66.05 years (8.47) and 63.11 years (6.13), respectively, with a fairly equal gender distribution (46.7 and 44.4%, respectively, were female). The median clinical history of DM for patients participating in the FGs and CIs was 6.53 years (3.17) and 4.89 years (3.84) respectively, and 87.6% of the FG members and 77.8% of the CI participants stated they received family support for self-care. HbA1c (SD) was 7.22% (0.84), obtained on average 95.15 (49.36) days previously for the FGs. The corresponding figures for the CIs were 6.84% (0.68) and 65.33 (49.77) days previously. Table 2 provides full details of the characteristics of comorbidity and pharmacological treatment of the patients included in this study. In the CIs, the mean time employed in completing the questionnaire was 23 minutes (6.02).

The professionals who composed the panel of experts had a mean age (SD) of 48.38 years (5.2) and an average professional experience of 25.92 years (5.12). 53.9% were female (n = 7). The majority were nurse practitioners (61.5%, n = 8) and physicians (30.8%, n = 4), associated with primary health care (76.9%, n =10) (Table 3).

Results of focus groups

The participants (n= 18) were selected intentionally (fase to face), seeking an even distribution by gender and type of treatment (IDDM vs. NIDDM), and were socio-economically diverse. Two participants did not attend the FG and one attended the wrong venue.

Following the inductive coding of the data and the review of the nonencoded material, the data were clustered into five categories (behaviour modification, knowledge deficit, relations with professionals, social pressure and perceived threats and benefits), with a total of 27 codes and 241 references.

To evaluate whether the information obtained was sufficient, the frequency of occurrence of the codes in the two FGs was determined, and found to range from 7.71% divergence for social pressure and 1_59% for perceived threats and benefits (Table 4). The first FG had addressed 92.6% of the codes included (25/27) and only 7.4% (2/27) were newly appearing codes identified in the second FG (barriers-relations with providers and barriers-anxiety).

A full description was obtained of how the topics and categories identified by the FGs were related to the TPB described in Fig. 3.

Results expert consensus

After the literature review and the FGs, two team members drew up a preliminary list of 118 items; after the elimination of duplicate items, this list was finally reduced to 86. When these two members were unable to agree, the question was resolved by a third member of the team.

Two rounds were needed for the experts to reach a consensus on which items should be included in the questionnaire, of the 86 questions identified from the literatura review and the FGs. In the first round, a total of 51 questions obtained a median value ≥ 8 and an interquartile range <3 and were accepted by the panellists, and none were discarded in this phase (median <5). In the second round, the panellists were asked to rank the remaining questions in each domain by level of importance. Although the initial criterion was to select the two highest-rated questions, in order not to oversize certain areas relative to the initial number of items, and taking into account the questions accepted in the first round, in four of the dimensions (physical activity, medication, self-monitoring and smoking) only one item was accepted. By contrast, in the coping dimension, one question

was clearly the most highly valued and there was a triple tie for second place. The research team reviewed this situation, and in view of the diversity of topics addressed and of the theoretical constructs in each case, it was decided to include all three. In the second phase, 15 questions were accepted and 20 rejected. Finally, 66 items were incorporated in the definitive version of the questionnaire (Table 5).

Results of cognitive interviews

The legibility scores obtained ranged from 75/100 (fairly easy), which was produced by the data block on 'how to deal with special situations and complications' to 97/100 (very easy) to the block on 'nutrition'.

Nine CIs were conducted, structured into three blocks; in the first of these, the questionnaire was completed, after which the interview was held, using a 'verbal probing' methodology. After each block of interviews, appropriate modifications were made to the questionnaire for it to be tested with the following group. After the contributions provided in the first block, the wording of item 21 was extended (to include the presence of other diseases as a barrier to physical activity), questions 40 and 66 were modified to make them affirmative, and two items were added regarding the approach to diabetic retinopathy. After the second block, question 48 was modified to include a conditional verb form, and in the instructions the patients were informed that a response of '4' should be made when it was not understood what was being asked or when they had no pre-existing opinion. In the third block, there was no consensus among the respondents, and the research team did not consider it appropriate to make any further modifications. The instructions, the response scales and the degree of agreement between what the respondents stated and how they actually lived with their DM all produced a median value (range) of 6 (5‑7), and in general the questionnaire was awarded a score of 7 (4‑7) (Table 6).

As the final outcome of the above process, 23 items were obtained for the construct 'attitudes regarding behaviour,' 13 for 'social norms', 17 for 'perceived behavioural control' and 15 for 'behavioural intention'. In addition, certain components, such as 'physical activity and pain' and 'complexity of the treatment regimen' were identified as barriers to behaviour by patients with DM. Finally, to

make the ‘EBADE questionnaire’ (Evaluation of Barriers to Self-Care in DM, in Spanish) more operative, the questions were grouped intoareas of self-care that were readily identifiable by the patients (such as food or medication) while completing the questionnaire. Figure 4 shows the flow of items selected/eliminated in each of the phases of the qualitative process.

Discussion

The aim of this study is to design and validate the content of an instrument to detect barriers to self-care by diabetic patients. The study is based on multiple methods, including the patients’ own views on the question. In consequence, we obtained a tool with 68 items, based on a solid theoretical model, and the patients made a significant contribution to the entire process.

Content validity is a fundamental psychometric property, ensuring that the study goal is properly represented in the questions contained within the questionnaire. For some authors, this property is the most valuable of all for validating the instrument, as a superficial approach in this respect could introduce bias into all other measurements (Terwee et al. 2007, Caro-Bautista et al. 2014).

The codes identified and the domains into which theywere grouped are consistent with the findings of previousstudies such as EUROBSTACLE (Vermeire et al. 2007) and with the meta-synthesis conducted by Stiffler and colleagues (Stiffler et al. 2014), for whom knowledge gaps, relationships with suppliers and the complexity of the treatment régimen all played a major role. Similarly, the saturation of topics was similar to the values reported in other studies (Guest et al. 2006, Martin et al. 2011), with a divergence of entries per code of no more than 8%, and so we believe the two FGs were sufficient to produce this saturation. Figure 3 illustrates the complexity in the description of conduct with respect to DM II, in accordance with the TPB. Accordingly, this study at all times adopts a multifactorial approach in addressing this behaviour, unlike other questionnaires observed in the literature review, which examined specific areas of DM self-care, such as medication or physical activity (Monahan et al. 2009, Van der Heijden et al. 2013).

One of the strengths of this validation process is precisely the use made of qualitative methods to obtain the patients' views. Organisations like The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) have reported that the lack of direct involvement by the reference population in the development of questionnaire content is one of the main threats to validity, that is, to the instrument actually reflecting the concept it purports to measure (Rothman et al. 2009). In this respect, we provide Information concerning the selection/reduction of questionnaire items, the script used in the group and individual interviews and the qualitative analysis carried out, as recommended by the Food and Drug Administration (FDA) (Fehnel et al. 2013).

The assessment made by the professionals involved is another essential element in determining which questions should be included in the questionnaire, because these persons' expectations of care often differ from the barriers identified by patients (Claydon-Platt et al. 2014, Raaijmakers et al. 2013). In the first round of Delphi, no items were eliminated, which in our opinion was the result of the conservative approach taken by the panellists, combined with a thorough prior examination of items in the literature review and by the FGs. In the second phase, a more stringent criterion for consensus was applied, and this produced a significant reduction in the number of questionnaire items, as was the case in previous studies when consensus techniques among medical personnel were adopted (Carratalá-Munuera et al. 2013).

A limitation of the present study is that feedback was not obtained from the FG participants after transcription and encoding. Nevertheless, the panel of experts carried out nine CIs, following the methodology described by Brod (Brod et al. 2009), and so information was obtained about the comprehensibility and relevance of the questions. Taking into account the contributions made by the questionnaire respondents, in addition to modifying various statements and adapting the instructions, it was decided to include two items concerning the barrier to self-care presented by the presence of diabetic retinopathy, despite the fact that in the previous phase the panellists had decided to eliminate a question in this regard. This divergence of opinión is a clear example of the above-mentioned differences of needs/expectations between professionals and patients. Hence, the importance of combining both methods.

Finally, to successfully address person-centred attention, for patients with chronic diseases, the PRO instruments used must be supported by reliable processes of validation, in which the patients are the real protagonists in the development of the questions that will compose the instrument, participating in every stage of the process (McGrath et al. 2010, Humphrey et al. 2013).

Conclusion

The results of this study provide abundant qualitative Information on the process by which the questionnaire described was developed. The aim of this questionnaire is to identify barriers and self-care behaviour for persons with DM II. It is based on a solid theoretical model, the TPB, and adopts the different standpoints required (literature, patients and professionals) for the instrument to present full content validity. However, the instrument has yet to be subjected to psychometric validation to assess its reliability and construct validity.

Relevance to clinical practice

The clinical applicability of this and similar models lies in its ability to identify the difficulties arising in self-care (Vigersky et al. 2013). These findings may help to understand factors that determine the adherence behaviour in persons among type 2 DM based on a person-centred attention.

Disclosure

The authors have confirmed that all authors meet the ICMJE criteria for authorship credit (www.icmje.org/ethi cal_1author.html), as follows: (1) substantial contributions to conception and design of, or acquisition of data or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content and (3) final approval of the version to be published.

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Conflict of interest

The authors declare that they have no conflict of interests.

Supporting Information

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

Appendix S1. Focus groups topics.

Appendix S2. Cognitive interviews guide.

References

Ajzen I (1985) From Intentions to Actions: A Theory of Planned Behavior. Springer, Berlin.

Beatty PC & Willis GB (2007) Research synthesis: the practice of cognitive interviewing. Public Opinion Quarterly 71, 287‐311.

Brod M, Tesler LE & Christensen TL (2009) Qualitative research and content validity: developing best practices based on science and experience. Quality of Life Research 18, 1263‐1278.

Caro-Bautista J, Martín-Santos FJ & Morales-Asencio JM (2014) Systematic review of the psychometric properties and theoretical grounding of instruments evaluating self-care in people with type 2 Diabetes Mellitus. Journal of Advanced Nursing 70, 1209‐1227.

Carratalá-Munuera MC, Gil-Guillen VF, Orozco-Beltran D, Navarro-Pérez J, Caballero-Martínez F, Alvarez-Guisasola F, García-Soidán J, Fluixá-Carrascosa C, Franch-Nadal J, Martín-Rioboó E, Carrillo-Fernández L & Artola-Menéndez S (2013) Barriers associated with poor control in Spanish diabetic patients. A consensus study. International Journal of Clinical Practice 67, 888‐894.

Claydon-Platt K, Manias E & Dunning T (2014) The barriers and facilitators people with diabetes from a nonEnglish speaking background experience when managing their medications: a qualitative study. Journal of Clinical Nursing. 23(15‐16), 2234‐2246.

Conner M & Sparks P (1996) The Theory of Planned Behaviour and Health Behaviour. In M. Conner & P. Norman (eds.) Predicting Health Behaviour: Research and Practice with Social Cognition Models, (pp. 121‐ 162). Buckingham, UK: Open University Press.

Elissen AMJ, Duimel-Peeters IGP, Spreeuwenberg C, Spreeuwenberg M & Vrijhoef HJM (2012) Toward Tailored disease management for type 2 diabetes. The American Journal of Managed Care 18, 619‐630.

Fehnel S, DeMuro C, McLeod L, Coon C & Gnanasakthy A (2013) US FDA patient-reported outcome guidance: great expectations and unintended

consequences. Expert review of Pharmacoeconomics & Outcomes Research 13, 441‐446.

Fitch K, Bernstein SJ, Aguilar MD, Burnand B & LaCalle JR (2001) The RAND/UCLA Appropriateness Method User's Manual (No. RAND/MR-1269- DG-XII/RE). RAND CORP, Santa Mónica.

Francis JJ, Eccles MP, Johnston M, Walker A, Grimshaw J, Foy R & Bonetti D (2004) Constructing Questionnaires Based on the Theory of Planned Behaviour. A Manual for Health Services Researchers. European Union Contract number QLG4-CT-2002-00657, Newcastle.

Friese S (2012) Qualitative Data Analysis with ATLAS.ti. Sage. Available at: http://www.atlasti.com/uploads/media/QuickTour_a7_es_02.pdf (accessed 6 March 2014).

Guest G, Bunce A & Johnson L (2006) How many interviews are enough? An experiment with data saturation and variability. Field Methods 18, 59‐82.

Humphrey L, Kulich K, Deschaseaux C, Blackburn S, Maguire L & Strömberg A (2013) The Caregiver Burden Questionnaire for Heart Failure (CBQ-HF): face and content validity. Health Quality of Life Outcomes 11, 84.

Inzucchi SE, Bergenstal RM, Buse JB, Diamant M, Ferrannini E, Nauck M, Peters AL, Tsapas A, Wender R & Matthews DR (2012) Management of hyperglycemia in type 2 diabetes: a patientcentered approach: position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care 35, 1364‐1379.

Lasch KE, Marquis P, Vigneux M, Abetz L, Arnould B, Bayliss M, Crawford B & Rosa K (2010) PRO development: rigorous qualitative research as the crucial foundation. Quality of Life Research 19, 1087‐1096.

Magasi S, Ryan G, Revicki D, Lenderking W, Hays RD, Brod M, Snyder C, Boers M & Cella D (2012) Content validity of patient-reported outcome measures: perspectives from a PROMIS meeting. Quality of Life Research 21, 739‐746.

Mailhot T, Cossette S & Alderson M (2013) An evolutionary analysis of the concept of self-care. Recherche en Soins Infirmiers 112, 94‐106.

Martin ML, Patrick DL, Gandra SR, Bennett AV, Leidy NK, Nissenson AR, Finkelstein FO, Lewis EF, Wu AW & Ware JE Jr (2011) Content validation of two SF-36 subscales for use in Type 2 diabetes and non-dialysis chronic kidney disease-related anemia. Quality of Life Research 20, 889‐901.

McGrath C, Rofail D, Gargon E & Abetz L (2010) Using qualitative methods to inform the trade-off between content validity and consistency in utility assessment: the example of type 2 diabetes and Alzheimer's disease. Health Quality of Life Outcomes. 8, 23.

Monahan PO, Lane KA, Hayes RP, McHorney CA & Marrero DG (2009) Reliability and validity of an instrument for assessing patients' perceptions about medications for diabetes: the PAM-D. Quality of Life Research 18, 941‐952.

Raaijmakers LG, Hamers FJ, Martens MK, Bagchus C, de Vries NK & Kremers SP (2013) Perceived facilitators and barriers in diabetes care: a qualitative study among health care professionals in the Netherlands. BioMed Central Family Practice 14, 1‐9.

Radhakrishnan K (2012) The efficacy of tailored interventions for self-management outcomes of type 2 diabetes, hypertension or heart disease: a Systematic review. Journal of Advanced Nursing 68, 496‐510.

Ramsay Wan C, Vo L & Barnes CS (2012) Conceptualizations of patient empowerment among individuals seeking treatment for diabetes mellitus in an urban, public-sector clinic. Patient Education and Counseling 87, 402‐404.

Richard AA & Shea K (2011) Delineation of self-care and associated concepts. Journal of Nursing Schorlarship 43, 255‐264.

Rothman M, Burke L, Erickson P, Leidy NK, Patrick DL & Petrie CD (2009) 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 12, 1075‐1083.

Serrano-Gil M & Jacob S (2010) Engaging and empowering patients to manage their type 2 diabetes, Part I: a knowledge, attitude, and practice gap? Advances in Therapy 27, 321‐333.

Stiffler D, Cullen D & Luna G (2014) Diabetes barriers and self-care management: the patient perspective. Clinical Nursing Research. doi:10547738135 07948. 23(6), 601‐26.

Taylor SJ & Bogdan R (1998) Introduction to Qualitative Research Methods: A Guidebook and Resource. Wiley, New York.

Terwee CB, Bot SDM, de Boer MR, van der Windt DAWM, Knol DL, Dekker J, Bouter LM & de Vet HCW (2007) Quality criteria were proposed for measurement properties of health status questionnaires. Journal of Clinical Epidemiology 60, 34‐42.

Tong A, Sainsbury P & Craig J (2007) Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International Journal of Quality in Health Care 19, 349‐357.

Van der Heijden MMP, Pouwer F & Pop VJM (2013) Psychometric properties of the Exercise Self-efficacy Scale in Dutch Primary care patients with Type 2 diabetes mellitus. International Journal of Behavioral Medicine, 21(2), 394‐401.

Vermeire E, Hearnshaw H, Rätsep A, Levasseur G, Petek D, van Dam H, van der Horst F, Vinter-Repalust N, Wens J & Dale J (2007) Obstacles to adherence in living with type-2 diabetes: an international qualitative study using meta-ethnography (EUROBSTACLE). Primary Care Diabetes 1,25‐33.

Vigersky RA, Fitzner K & Levinson J (2013) Barriers and potential solutions to providing optimal guideline-driven care to patients with diabetes in the us. Diabetes Care 36, 3843‐3849.

Whiting DR, Guariguata L, Weil C & Shaw J (2011) IDF diabetes atlas: global estimates of the prevalence of diabetes for 2011 and 2030. Diabetes Research and Clinical Practice 94, 311‐321.

What does this paper contribute to the wider global clinical community?

- This research explored the content validity of a new questionnaire to identify barriers and behaviour to self-care among persons with type 2 Diabetes Mellitus (DM II), using múltiples qualitative methods with patients as well as clinicians. This tool was based on the Theory of Planned Behaviour (TPB) as theoretical framework.

- The instrument resulting had 68 items which were generated in accordance to the dimensions of the TPB: attitudes towards the behaviour (n = 23), social norms (n = 13), perceived behavioural control (n = 17) and behavioural intention (n = 15).

- The findings can be used to assess barriers and self-care behaviour among persons with type 2 DM and to know the main factors which can determine the adherence behaviour.

Table 1 Focus groups assessment based on COREQ

Domain and item number	Description of focus group development
Domain 1: Research team and reflexivity	
Personal characteristics	
1. Interviewer/facilitator	Leader: JCB; Co-leaders: FJMS and FVE
2. Credentials	JCB: RN, MSN, PhD candidate; FJMS: RN, PT, MPH, MSc and FVE: RN, BSc
3. Occupation	JCB and FVE: Nursing coordinator; FJMS: Director of Nursing
4. Gender	Two male, one female
5. Experience and training	Experience in conducting qualitative interviews and research. Degrees in Nursing and Sociology, Master Degree
Relationship with participants	
6. Relationship established	The researchers did not previously know any of the patients interviewed.
7. Participant knowledge of the interviewer	At the time of recruitment, the patients were given a leaflet explaining the purpose of the study, stating who would be responsible for it, how the data would be processed, etc. Before the start, they were invited to ask any questions they had about the procedure
8. Interviewer characteristics	At the beginning of the interview, it was explained what issues would be addressed and how the group interview would be conducted. A number of rules were set out to facilitate the participation of all group members. The discussion topics were shown on a blackboard at the beginning and were available for consultation at all times (nutrition, exercise, medication, self-analysis and resolution of special circumstances)
Domain 2: study design	
Theoretical framework	
9. Methodological orientation and theory	The questions guiding the interviews were based, as a theoretical model, on the Theory of Planned Behaviour and incorporated its theoretical constructs, namely behavioural beliefs, perceived behavioural control, subjective norms and behavioural intention
Participant selection	
10. Sampling	The patients were recruited intentionally, seeking parity of gender and type of treatment (NIDDM vs. IDDM), as well as an extrovert character, to facilitate participation
11. Method of approach	Face to face
12. Sample size	15
13. Nonparticipation	Three persons did not participate. Two did not arrive for the session, and one went to the wrong venue
14. Setting of data collection	Two primary health care clinics
15. Presence of non-participants	None; only the researchers and the interviewees were present
16. Description of sample	Sociodemographic and clinical characteristics are described in Table 1
Data collection	
17. Interview guide	The interview guide, with the questions, was provided to the interviewees
18. Repeat interviews	None of the interviews were repeated
19. Audio/visual recording	The interviews were audio-recorded and transcribed verbatim
20. Field notes	Notes were taken at the end of the group meetings, to make modifications for the second group, to improve the understandability of the script used. These notes were taken by the co-leader
21. Duration	First group: 83′21″; Second group: 102′41″
22. Data saturation	Data saturation was achieved by the repetition of codes
23. Transcripts returned	Transcripts were not given to the interviewees
Domain 3: analysis and findings	
Data analysis	
24. Number of data coders	One member of the research team (JMMA) encoded the groups. This coding was later discussed by the rest of the team
25. Description of the coding tree	A complete description of the set of codes developed during the analysis, with the respective references, was made. In turn, these codes were grouped into categories
26. Derivation of themes	The categories were developed from the data. There was no pre-analysis scheme (inductive coding)
27. Software	ATLAS.ti 7.0
28. Participant checking	No feedback was obtained from the interviewees on the results

Table 1 (continued).

Domain and item number	Description of focus group development
Reporting	
29. Quotations presented	Yes
30. Data and findings consistent	Yes, the results obtained and the data presented were consistent
31. Clarity of major themes	Yes, the main issues are adequately described by the categories identified
32. Clarity of minor themes	Yes, specific descriptions were made of each category related to the issues that arose

NIDDM, Non-insulin dependent diabetes mellitus; IDDM, Insulindependent diabetes mellitus.

Table 2 Patients' sociodemographic and clinical characteristics

	Focus groups (n = 15)	Cognitive interviews (n = 9)
Sociodemographic characteristics		
Mean age* (SD)	66·05 (8·47)	63·11 (6·13)
Female (%)	7 (46·7)	4 (44·4)
Occupation (%)		
Qualified handwork	1 (6·7)	–
Housework	5 (33·3)	2 (22·2)
Retirement	8 (53·3)	5 (55·6)
Unemployment	1 (6·7)	–
Administrative	–	1 (11·1)
Manager	–	1 (11·1)
Education (%)		
Without education	1 (6·7)	1 (11·1)
Primary school	9 (60)	–
Secondary/high school	2 (13·3)	5 (55·6)
University degree	3 (20)	3 (33·3)
Family support (%)	13 (87·6)	7 (77·8)
Time to answer questionnaire† (SD)	–	23 (6·02)
Comorbidities (%)		
Time since DM diagnosis* (SD)	6·53 (3·17)	4·89 (3·84)
Hypertension	12 (80)	6 (66·7)
Dislypidemia	7 (46·7)	3 (33·3)
Obesity (BMI > 30)	5 (33·3)	2 (22·2)
Cardiovascular history	3 (20)	1 (11·1)
Chronic kidney disease	2 (13·3)	–
Diabetic retinopathy	1 (6·7)	1 (11·1)
Oncologic process	2 (13·3)	2 (22·2)
Depression	2 (13·3)	3 (33·3)
Tobacco	2 (13·3)	3 (33·3)
Metabolic control (mean)		
HbA_1c (SD)	7·22% (0·84) (n = 13)	6·84% (0·68)
Time since determination‡ (SD)	95·15 (49·36)	65·33 (49·77)
Treatment (%)		
Hypoglycaemic Agents		
Metformin	12 (80)	9 (100)
Gliclazide	2 (13·3)	–
Glibemclamide	2 (13·3)	–
Sitagliptin	1 (6·7)	1 (11·1)
Vildagliptin	1 (6·7)	3 (33·3)
Insuline type		
Lispro/Aspart Protamine	4 (26·7)	–
Aspart	3 (20)	–
Glargine	2 (13·3)	1 (11·1)
NPH insuline	2 (13·3)	1 (11·1)
Diuretics	7 (46·7)	4 (44·4)
ARA II	7 (46·7)	3 (33·3)
Angiotensin converting enzyme inhibitors	4 (26·7)	1 (11·1)
Calcium antagonists	4 (26·7)	2 (22·2)
Blochers	3 (20)	1 (11·1)
Simvastatin	3 (20)	3 (33·3)
Atorvastatin	3 (20)	1 (11·1)
Rosuvastatin	1 (6·7)	–
Acetylsalicylic acid	9 (60)	1 (11·1)

BMI, Body Mass Index; NPH, Neutral Protamine Hagedorn; ARA II, Angiotensin II Receptor Antagonist.
*Years. †Minutes. ‡Days.

Table 3 Characteristics of the expert panel (n = 13)

Female (%)	7 (53·9)
Mean age* (SD)	48·38 (5·2)
Experience* (SD)	25·92 (5·12)
Profession (%)	
Physician	4 (30·8)
Nurse	8 (61·5)
Psychologist	1 (7·7)
Workplace (%)	
Primary health care	10 (76·9)
Hospital health care	2 (15·4)
Research	1 (7·7)

*Years.

Table 4 Summary of categories, codes and references

Categories	Codes	No. of references		Differences between groups
		FG 1 (%)	FG 2 (%)	TOTAL Δ %
Behaviour Modification	Barriers – Physical activity and pain	3 (2·86)	16 (12·60)	7·18
	Barriers – Complexity of treatment regimen	1 (0·95)	2 (1·57)	
	Compensating food noncompliance with physical activity	3 (2·86)	1 (0·79)	
	Compliance – Diet	11 (10·48)	16 (12·60)	
	Compliance – Medication	5 (4·76)	5 (3·94)	
	Compliance – Foot self-care	1 (0·95)	0 (0)	
	Compliance – Physical activity	8 (7·62)	4 (3·15)	
	Compliance – Smoking	1 (0·95)	1 (0·79)	
	Intention to change behaviour	4 (3·81)	5 (3·94)	
	Willing to self-care	3 (2·86)	7 (5·51)	
Knowledge deficit	Knowledge deficit	3 (2·86)	3 (2·36)	2·70
	Knowledge deficit – Glycaemic control and symptoms	4 (3·81)	4 (3·15)	
	Knowledge deficit – Recommended food	2 (1·90)	5 (3·94)	
Relations with professionals	Barriers – Relation with providers	0 (0)	3 (2·36)	3·77
	Education for self-care received	3 (2·86)	0 (0)	
	Professionals pro-activity	6 (5·71)	11 (8·66)	
	Social pressure – professionals*	14 (13·33)	5 (3·94)	
Social pressure	Barriers – Interference with social activity	8 (7·62)	5 (3·94)	7·71
	Barriers to self-care-family environment	2 (1·90)	5 (3·94)	
	Lack of control for food preparation	1 (0·95)	1 (0·79)	
	Social pressure- professionals*	14 (13·33)	5 (3·94)	
	Social pressure – family	9 (8·57)	11 (8·66)	
Threats and benefits perceived	Barriers-Anxiety	0 (0)	5 (3·94)	1·59
	Defensive coping	1 (0·95)	2 (1·57)	
	Perceived benefit – Symptom control	1 (0·95)	0 (0)	
	Perceived benefits – Food and symptoms	1 (0·95)	1 (0·79)	
	Perceived threat – Disease complications	1 (0·95)	5 (3·94)	
	Symptoms – Hypoglycaemia	9 (8·57)	4 (3·15)	

*Social pressure-professionals is repeated in two categories.

Table 5 Expert Consensus

Dimensions	Initial items	1st round		2nd round		Final items
		Accepted items*	Rejected items†	Accepted items‡	Rejected items§	
General	6	4	0	2	0	6
Nutrition	14	6	0	2	6	8
Physical activity	10	7	0	1	2	8
Medication	9	6	0	1	2	7
Self-monitoring	8	6	0	1	1	7
Smoking	5	3	0	1	1	4
Food care	4	3	0	0	1	3
Special situations and complications	8	6	0	1	1	7
Coping	9	3	0	4	2	7
Health care professionals and system relation	13	7	0	2	4	9
TOTAL	86	51	0	15	20	66

*Median ≥8 and interquartile range ≤3.
†Median <5.
‡First two items per dimension.
§Remaining items.

Table 6 Cognitive Interviews

	Items difficult to understand or respond to	Comment	Other observations	Modifications
1st group*				
1.	4, 66	4: No other diabetic patients known. 66: The negative statement created doubts	The patient wanted questions addressing the influence of other diseases on specific areas of self-care such as physical activity	Item 21: The statement was modified to include the presence of other diseases as a barrier to exercise.
2.	10, 37	10: The phrase 'large quantities' seemed very vague. 37: Unsure how to answer if no prior opinion had been formed on the issue in question	The patient self identified more with the questions addressing beliefs, and thought it would have been desirable to assess the access to accurate information about DM through new technologies	Items 40, 66: Both questions were re-expressed affirmatively. Item 51, 52. Two items were added to address beliefs and perceived self-care behaviour in relation to diabetic retinopathy
3.	14, 46, 66	14: The patient was slim and did not understand how not losing weight could hamper self-care. 46: The patient had never had hypoglycaemia. 66: The response scale was considered unclear	The patient considered it would have been desirable to address as a barrier the constraints to self-care arising from diabetic retinopathy	
2nd group*				
1.	4, 48		The patient considered it difficult to answer questions about situations that had not been experienced or about which no opinion had been formed	Item 48: The statement was modified to include a conditional form 'I take or would take food to raise glucose levels'.
2.	37	37: The patient had never considered whether there was an association between smoking and DM		The instructions were modified such that the patient was told that when the situation in question did not apply to his/her experience, an answer of '4' should be given, as a neutral value
3.	4	4: The patient knew other diabetics but was unaware of their level of self-care	The patient recommended changing the affirmative nature of the questions to an interrogative one, to improve their understandability	
3rd group*				
1.	11, 58	11: The patient confused number of food intakes with the total amount of food eaten. 58: The patient did not believe all DM patients seek self-care for the disease and therefore need not experience frustration in this respect	The patient mentioned the need for more written information to be provided in healthcare clinics, as addressed in the questionnaire	There was no general view among the interviewees concerning changes to the quantitative and qualitative assessments made, nor was any modification in this respect considered necessary by the research team
2.	–	–		
3.	–	–	The patient believed a response scale of 1–10 would have been more intuitive	
Instructions†				6 (5–7)
Response scales†				6 (5–7)
Congruence†				6 (5–7)
General†				7 (4–7)

*Each group consisted of three interviews.
†Median and range.

Figure 1 The PRO development process.

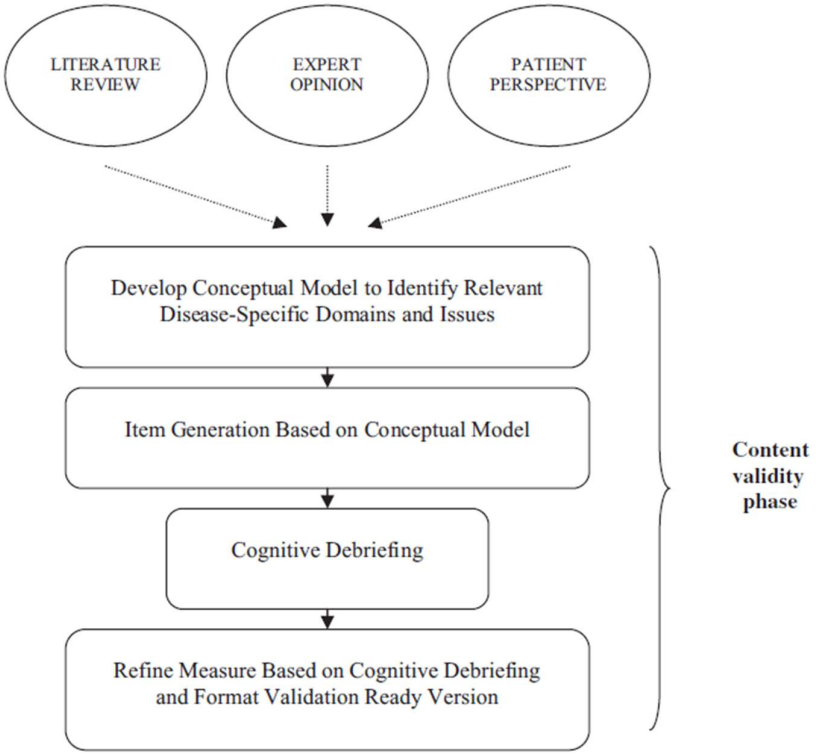

Figure 2 Theory of Planned Behaviour model adapted from Conner and Sparks.

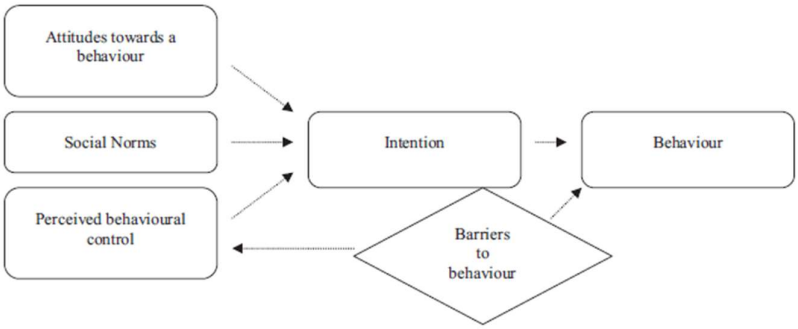

Figure 3 Relation between themes and categories with Theory of Planned Behaviour in Type II DM.

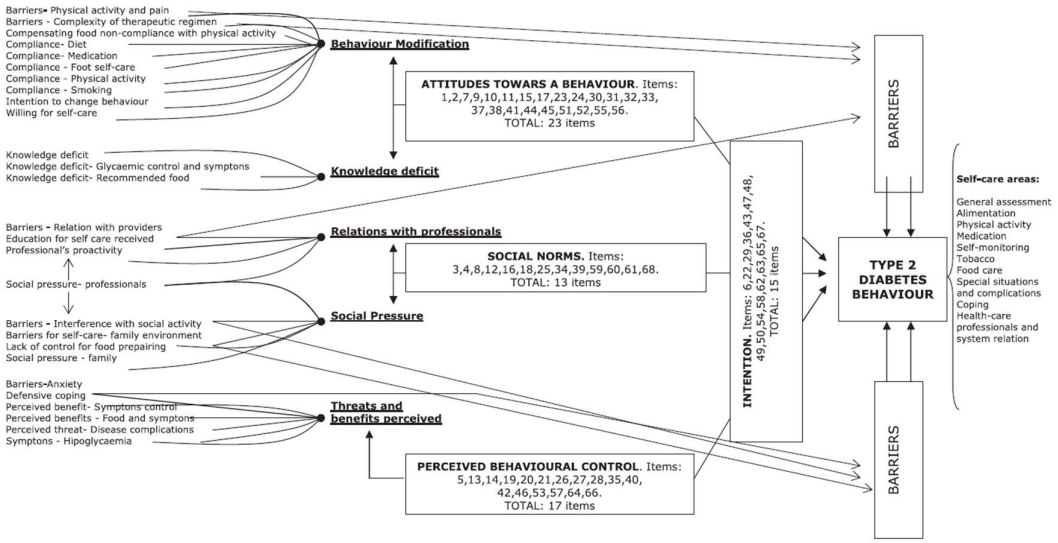

Figure 4 Flowchart of instrument development and item reduction.