Patient-reported outcome measures for assessing health-related quality of life in people with type 2 diabetes: A systematic review

Marlous Langendoen-Gort1,3 · Lenka Groeneveld2,3 · Cecilia A. C. Prinsen2,4 · Joline W. Beulens2,3,5 · Petra J. M. Elders1,3,5 · Ilana Halperin6 · Geetha Mukerji6,7 · Caroline B. Terwee2,4 · Femke Rutters2,3,5

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Abstract

Patient-Reported Outcome Measures (PROMs) are important tools to assess outcomes relevant to patients, with Health-Related Quality Of Life (HRQOL) as an important construct to be measured. Many different HRQOL PROMs are used in the type 2 diabetes field, however a complete overview of these PROMs is currently lacking. We therefore aimed to systematically describe and classify the content of all PROMs that have specifically been developed or validated to measure (aspects of) HRQOL in people with type 2 diabetes. A literature search was performed in PubMed and EMBASE until 31 December 2021. Studies on the development or validation of a PROM measuring HRQOL, or aspects of HRQOL, in people with type 2 diabetes were included. Title and abstract and full-text screening were conducted by two independent researchers and data extraction was performed independently by one of the researchers. Data were extracted on language in which the PROM was developed, target population, construct(s) being measured, names of (sub)scales and number of items per (sub)scale. In addition, all PROMs and subscales were classified according to specific aspects of HRQOL based on the Wilson & Cleary model (symptom status, functional status, general health perceptions) to aid researchers in PROM selection. In total 220 studies were identified that developed or validated PROMs that measure (aspects of) HRQOL in people with type 2 diabetes. Of the 116 unique HRQOL PROMs, 91 (of the subscales) measured symptom status, 60 measured functional status and 26 measured general health perceptions. In addition, 16 of the PROMs (subsccales) measured global quality of life. 61 of the 116 PROMs (subscales) also include characteristics of the individual (e.g. aspects of personality, coping) or environment (e.g. social or financial support) and patient-reported experience measures (PREMs, e.g. measure of a patient’s perception of their personal experience of the healthcare they have received, e.g. treatment satisfaction), which are not part of the HRQOL construct. Only 9 of the 116 PROMs measure all aspects of HRQOL based on the Wilson & Cleary model. Finally, 8 of the 116 PROMs stating to measure HRQOL, measured no HRQOL construct. In conclusion, a large number of PROMs are available for people with type 2 diabetes, which intend to measure (aspects of) HRQOL. These PROMs measure a large variety of (sub)constructs, which are not all HRQOL constructs, with a small amount of PROMs not measuring HRQOL at all. There is a need for consensus on which aspects of HRQOL should be measured in people with type 2 diabetes and which PROMs to use in research and daily practice. PROSPERO: CRD42017071012. COMET database: http://www.comet-initiative.org/studies/details/956.

Research in context

What is already known about this subject?
- Patient-Reported Outcome Measures (PROMs) are important tools to assess outcomes relevant to patients, with Health-Related Quality Of Life (HRQOL) as an important construct to be measured.
- Many different HRQOL PROMs are used in the type 2 diabetes field, however a complete overview of these PROMs is currently lacking.

What is the key question?
- Can we systematically describe and classify the content of all PROMs that have specifically been developed or validated to measure (aspects of) HRQOL in people with type 2 diabetes?

What are the new findings?
- Of the 116 unique HRQOL PROMs, 91 (of the subscales) measured symptom status, 60 measured functional status and 26 measured general health perceptions.
- About half of the PROMs (subsccales) also include characteristics of the individual or the environment or patient-reported experience measures (PREMs), which are not part of the HRQOL construct.
- About 5% of the PROMs only measured global quality of life and/or PREMs and thus no HRQOL construct.

Extended author information available on the last page of the article
Introduction

Due to the high global prevalence of type 2 diabetes (~400 million) combined with the chronic nature of the disease, it is important to measure outcomes that matter most to patients [1, 2]. This can be done by measuring patient-reported outcomes (PROs). PROs are health outcomes directly reported by patients about how they feel or function in relation to a health condition. In clinical research and care an important PRO to measure is (aspects of) health-related quality of life (HRQOL), including symptom status, functional status and general health perceptions [3]. The terms HRQOL and Quality of Life (QOL) are often used interchangeably. However many authors state that (overall) QOL is a broader concept, referring to how happy or satisfied a person is with his/her life as a whole [4–6]. Clinicians and researchers in the medical field generally prefer to measure only those aspects of QOL related to health (often referred to as HRQOL) instead of QOL, because the non-medical aspects of QOL are outside the scope of health care interventions. Not only in care, but also clinical trials, the measurement of HRQOL is becoming increasingly important.

One of the most often used conceptual models of HRQOL was developed by Wilson and Cleary [4]. The model contains five levels of outcomes, namely biological and psychological variables, symptom status (including disease specific symptoms, physical symptoms and mental symptoms), functional status (including physical function, psychological function and social/role function), general health perceptions and overall quality of life (including overall quality of life, well-being and life satisfaction). In this review, we define HRQOL as symptoms, functional status and general health perceptions.

To date, many different PRO measurement instruments (PROMs) are available that measure HRQOL in people with type 2 diabetes, identified by previous reviews [7–16]. However, these reviews included studies in both people with type 1 and 2 diabetes, which represent different pathologies and large differences in age, and therefore different PROs may be relevant or the validity and reliability of PROMs may be different in people with type 1 versus type 2 diabetes [7, 8, 11]. Other reviews only included patients with amputations [14], only PROMs measuring one aspect of HRQOL, e.g. depressive symptoms [11] or were conducted over 10 years ago [9, 12]. A recent review by Wee et al. 2021 aimed to identify all PROMs used for people with diabetes [15]. However, Wee et al. did not classify (sub)scales of PROMs according to which specific aspects of HRQOL, based on the Wilson & Cleary model, they measure. This classification is important because instrument selection should be based on the relevant aspects of HRQOL to measure, not on available PROMs, which are mostly multi-dimensional instruments that measure many different things. Therefore, the content and quality of PROMs should be evaluated for each PROM separately. Furthermore, often questionnaires that are being referred to as HRQOL PROMs include (sub)scales that measure non-HRQOL aspects, such as characteristics of the individual, overall quality of life, or even patient-reported experience measures (PREMs), which are not part of the HRQOL construct according to the Wilson and Cleary model. This has not been made clear in previous reviews. Because of these research gaps, we aimed to systematically describe and classify the content of all PROMs that have specifically been developed or validated to measure (aspects of) HRQOL in people with type 2 diabetes.

Methods

This systematic review has been conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement [17] and the COSMIN guideline for conducting systematic reviews [18]. The protocol was registered in the PROSPERO database on 2 July 2017 (registration number CRD42017071012).

2.1 Literature search

The databases PubMed and EMBASE were searched from date of inception until May 2019 and then updated until 31st of December 2021. This literature search has been performed by researcher CBT in cooperation with a medical librarian from the Amsterdam UMC, Amsterdam, the Netherlands. The search strategy was built up around three blocks of search terms, namely type 2 diabetes, measurement properties (i.e. different search terms for reliability, validity, responsiveness and interpretability) and PROMs (i.e. different search terms...
for report, questionnaire and survey). For the type 2 diabetes dimension search terms were used to identify studies that focused on people with type 2 diabetes. For finding studies on measurement properties a highly sensitive validated search filter was used [19] and a comprehensive PROM filter, developed by the Patient Reported Outcomes Measurement Group, University of Oxford and available through the COSMIN website, was used to search for PROMs [20]. An overview of the search strategy can be found in Appendix 1.

All identified studies were uploaded in Covidence [21], which is an online platform that supports researchers in conducting systematic reviews by enabling them to upload all of the identified studies, studies on title and abstract and full-text article. In case of any disagreements between two of the researchers a third researcher was consulted to reach consensus. From the identified studies reference lists of the included articles were checked by one of the researchers (MLG or FR) to search for additional eligible studies, after which pairs of researchers reviewed the studies found through reference search. The screening and selection process was conducted based on pre-defined eligibility criteria.

A study was included when it met all five of the following inclusion criteria: (I) the authors aimed to develop a PROM, evaluate the measurement properties or evaluate the interpretability (e.g. floor and ceiling effects) of a PROM, (II) it concerned a PROM that aims (according to the authors of the included papers) to measure at least (aspects of) symptom status, functional status, general health perceptions or HRQOL based on the model of Wilson and Cleary [4], (III) the PROM is filled in by the patient in self-report, interview or diary form or is completed on behalf of the patient (proxy), (IV) > 50% of the study population consisted of people with type 2 diabetes, as reported in the article or when it could be assumed based on age and type of diabetes medication, or studies that reported measurement properties specifically for a subgroup of people with type 2 diabetes, and (V) the article is available in full-text. There were no restrictions on language in which the article was written.

A study was excluded when any of the following exclusion criteria were met: the PROM (I) was only used as a determinant or outcome measure or was used as a comparison instrument in a validation study of another instrument, (II) solely measured characteristics of the individual or behaviors (e.g. aspects of personality, self-efficacy, coping and eating behavior), characteristics of the environment (e.g. social support and financial support), patient-reported experience measures (PREM, i.e. a measure of a patient's perception of their personal experience of the healthcare they have received, e.g. treatment satisfaction) or overall quality of life (QOL) (e.g. well-being or satisfaction with life in general), or (III) was primarily developed for screening, diagnostic or prognostic purposes. PROMs that make a combination of (aspects of) HRQOL as well as other constructs were included if the main aim was to measure (aspects of) HRQOL.

### 3 Study selection

Pairs of two researchers (JWB, PJME, AAH, IH, MLG, GM, CACP, FR, CBT and MW) independently reviewed the identified studies based on title and abstract and full-text article. In case of any disagreements between two of the researchers a third researcher was consulted to reach consensus. From the identified studies reference lists of the included articles were checked by one of the researchers (MLG or FR) to search for additional eligible studies, after which pairs of researchers reviewed the studies found through reference search. The screening and selection process was conducted based on pre-defined eligibility criteria.

In case of any uncertainties a second researcher (CBT) was consulted. The characteristics of the PROM, including official name, language in which the PROM was developed, target population for which the PROM was developed (including type 1 or type 2 diabetes), construct(s) being measured, name of (sub)scales as well as number of items were extracted using a study-specific and pilot-tested PROM characteristics table. If necessary, relevant comments were also recorded. With regard to the (sub)scales, we extracted the number of items per subscale and the original names when possible. However, some studies did not clearly mention the number of items per subscale or the names of the subscales and then we noted the total number of items and for the names we either used a name that matched the authors’ description of the subscales or when the authors added or eliminated only a few items (not changing the scales), we used the subscale name of the original instrument.

All PROM (sub)scales were classified according to the constructs of HRQOL measured, based on the Wilson & Cleary model [4]. This classification was based on reviewing the names of the (sub)scales and not the content of the PROMs. Some (sub)scales did not measure aspects of HRQOL, but were classified as measures of overall quality of life (including well-being and life satisfaction), characteristics of the individual/environment or PREM. If information on PROM characteristics could not be found in the paper, additional resources such as other articles, Google (e.g. manuals or websites) or the PROQOLID database [22] were consulted.

### 4 Results

Figure 1 represents the flowchart of the screening and selection process.
4.1 Characteristics of the PROMs

A total of 116 unique HRQOL PROMs were identified, of which 82 (70.7%) were specifically developed for people with (type 1 and 2) diabetes (Table 1). Other PROMs were validated in people with type 2 diabetes, but were originally developed for 21 different target populations, the main one being the general population, namely 20/116 (17.2%). The PROMs were developed in 32 different languages, most often in English (N = 68), Dutch (N = 9), Japanese (N = 7) and Spanish (N = 7). 7/116 (6.0%) PROM were developed in more than one language at the same time, such as the World Health Organisation Quality of Life (WHOQOL-100) [23] and the World Health Organisation Quality of Life (WHOQOL)-BREF [24, 25]. For all 116 PROMs, the number of (sub-)scales varied from 1 to 21.

We identified numerous different versions of the same PROM, for example 17 different versions were identified for the Diabetes Quality of Life questionnaire (DQOL). For many PROMs, these versions arose from translations, which during the validation process were modified by removing items or adding new items. By modifying, this makes it a new PROM, because it cannot be assumed that measurement properties are the same for different versions. When PROMs were only translated, with the same amount of subscales and items per subscales, we tallied this PROM as one of the same version and added the reference to that row of the PROM in Table 1. Finally, two studies consisted of non-standard PROMs, which were a decision tree [26] and a visual interactive PROM [27].

4.2 Levels of HRQOL measured with the PROMs

Table 2 and Supplemental Table 1 provide an overview of the specific levels of HRQOL that the included PROMs measure based on the Wilson and Cleary model [4]. Of the 116 unique HRQOL PROMs, 91 of their subscales measured symptom status, 60 measured functional status and 26 measured general health perceptions. With regard to symptom status, 22/91 measured diabetes-related symptoms, which included problems with vision, hearing, speaking, neuropathy, hypoglycemia, hyperglycemia, motor agitation and vasomotor function disturbance as well as cardiovascular disease. When examining the PROMs, there is overlap between the diabetes-related symptoms subscales and the general symptom status scales referring to physical symptoms and mental symptoms, such as pain or depressive feelings. For example, the Patient-reported outcomes in Thai patients with type 2 diabetes mellitus (PRO-DM-Thai) states to measure diabetes-related symptoms, but these include sleep problems, sexual problems and pain, which could be considered generic symptoms [28].

Within the symptom status level, 31/91 of the PROMs (sub) scales measured physical symptoms, including pain, energy/fatigue and sleep as well as 69/91 measured mental symptoms, including distress, anxiety/worry and depression. With regard to the functional status level, 40/60 of the PROMs measured physical function, including activities of daily living and sexual function, 28/60 measured psychological function and 38/60 measured social/role function. There is a lot of
| Reference                  | PROMs                                                                 | Development language | Development target population | Construct(s) being measured                               | Names of (sub)scales                                                                 | Number of items per (sub)scale | Comments              |
|---------------------------|-----------------------------------------------------------------------|----------------------|-------------------------------|----------------------------------------------------------|-------------------------------------------------------------------------------------|------------------------------|-----------------------|
| Akinci et al. [57]        | 15D standardized measure of health-related quality of life Finnish (15D Finnish) | Finnish             | General population            | Generic health-related quality of life                   | 1. Breathing 2. Mental function 3. Speech 4. Vision 5. Mobility 6. Usual activities 7. Vitality 8. Hearing 9. Eating 10. Elimination 11. Sleeping 12. Distress 13. Discomfort and its symptoms 14. Sexual activity 15. Depression | 1 item per subscale          | Not applicable         |
| Bradley et al. [58]       | Audit of Diabetes Dependent Quality of Life (ADDQOL)-13               | English             | Diabetes patients             | Quality of life                                          | 1. General quality of life 2. Diabetes-specific quality of life 3. Domains impacted by diabetes | 1.1 item 2.1 item 3.13 items | Not applicable         |
| Demirci et al. [59]       | Audit of Diabetes Dependent Quality of Life (ADDQOL)-16               | Spanish             | Diabetes patients             | Diabetes-specific quality of life                        | 1. General quality of life 2. Diabetes-specific quality of life 3. Domains impacted by diabetes | 1.1 item 2.1 item 3.16 items | Not applicable         |
| Lemon et al. [60]         | Audit of Diabetes Dependent Quality of life (ADDQOL)-16               | Spanish             | Diabetes patients             | Diabetes-specific quality of life                        | 1. General quality of life 2. Diabetes-specific quality of life 3. Domains impacted by diabetes | 1.1 item 2.1 item 3.16 items | Not applicable         |
| Speight et al. [61]       | Audit of Diabetes Dependent Quality of Life (ADDQOL) -17-senior       | English             | Diabetes patients             | Quality of life                                          | 1. General quality of life 2. Diabetes-specific quality of life 3. Domains impacted by diabetes | 1.1 item 2.1 item 3.17 items | Not applicable         |
| Costa et al. [62]         | Audit of Diabetes Dependent Quality of Life (ADDQOL) -18              | Portuguese          | Diabetes patients             | Quality of life                                          | 1. General quality of life 2. Diabetes-specific quality of life 3. Domains impacted by diabetes | 1.1 item 2.1 item 3.18 items | Not applicable         |
| Daher et al. [63]         | Audit of Diabetes Dependent Quality of Life (ADDQOL) -18              | Portuguese          | Diabetes patients             | Quality of life                                          | 1. General quality of life 2. Diabetes-specific quality of life 3. Domains impacted by diabetes | 1.1 item 2.1 item 3.18 items | Not applicable         |
| Kamarul Imran [64]        | Audit of Diabetes Dependent Quality of Life (ADDQOL) -18              | Portuguese          | Diabetes patients             | Quality of life                                          | 1. General quality of life 2. Diabetes-specific quality of life 3. Domains impacted by diabetes | 1.1 item 2.1 item 3.18 items | Not applicable         |
| Speight et al. [61]       | Audit of Diabetes Dependent Quality of Life (ADDQOL) -17-senior       | English             | Diabetes patients             | Quality of life                                          | 1. General quality of life 2. Diabetes-specific quality of life 3. Domains impacted by diabetes | 1.1 item 2.1 item 3.19 items | Not applicable         |
| Elasy et al. [76]         | A health status instrument developed for South-African women           | English             | Women with type 2 diabetes    | Health-related quality of life                          | 1. Mental well-being 2. Social well-being | 24 items in total | Not applicable         |
| Reference                        | PROMs                                      | Development language | Development target population                                                                 | Construct(s) being measured                                                                 | Names of (sub)scales                                                                 | Number of items per (sub)scale | Comments                                                                                                                                 |
|---------------------------------|--------------------------------------------|----------------------|------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| Hayes et al. [77]               | Ability to Perform Physical Activities of Daily Living (APPADL) | English              | Type 2 diabetes patients and obesity                                                                 | Impact of weight on activities of daily living                                                 | Ability to perform daily physical activities                                              | 7 items in total              | The APPADL is the renamed version of the Impact of Weight on Activities of Daily Living questionnaire (IWADL).                           |
| Torres et al. [79]              | Attitudes to Diabetes (ATT)-19             | English              | Diabetes patients                                                                                   | Psychological adjustment to diabetes                                                            | Psychological adjustment to diabetes                                                      | 19 items in total             | Torres et al. [79] reports 19 items that include six factors. Welch et al. [80] reports a 19-item single subscale.                        |
| Dunn et al. [81]                | Attitude to Diabetes (ATT)-39              | English              | Diabetes patients                                                                                   | Psychological adjustment to diabetes                                                            | 1. Stress                                                                              | 39 items in total             | Not applicable                                                                                                                         |
| Ting et al. [82]                | Chinese Diabetes Distress Screening (CDDS)-15 | Chinese             | Diabetes patients                                                                                   | Diabetes distress                                                                               | 1. Emotional burden                                                                    | Not applicable                |                                                                                                                                          |
| Carter et al. [83]              | Centre for Epidemiological Studies Depression scale (CESD) | English              | General population                                                                                   | Depression                                                                                     | 1. Depressed affect                                                                    | Not applicable                |                                                                                                                                          |
| Price et al. [89]               | Cardiff Wound Impact Schedule (CWIS)       | English              | Diabetes patients                                                                                   | Quality of life in persons with chronic wounds                                                 | 1. Social life                                                                        | Not applicable                |                                                                                                                                          |
| Huang et al. [94]               | Chinese Cardiff Wound Impact Schedule (CCWIS) | Chinese             | Diabetes patients                                                                                   | Quality of life in persons with chronic wounds                                                 | 1. Social life                                                                        | Not applicable                |                                                                                                                                          |
| Boyer et al. [95]               | Diabetes-39 (D-39)                         | English              | Diabetes patients                                                                                   | Quality of life                                                                                 | 1. Energy and mobility                                                                 | Not applicable                |                                                                                                                                          |
| Reference            | PROMs                                                                 | Development language | Development target population | Construct(s) being measured                                      | Names of (sub)scales                                      | Number of items per (sub)scale | Comments                                           |
|---------------------|------------------------------------------------------------------------|----------------------|-------------------------------|------------------------------------------------------------------|--------------------------------------------------------|-------------------------------|---------------------------------------------------|
| Leite et al. [100]  | Diabetes-39 scale (D-39) Short Form                                    | English              | Diabetes patients             | Health-related quality of life                                  | 1. Energy and mobility                                   | 1.5 items                      | Not applicable                                    |
|                     |                                                                        |                      |                               | 2. Diabetes control                                              | 2.5 items                                               |                               |                                                   |
|                     |                                                                        |                      |                               | 3. Anxiety and worry                                             | 3.4 items                                               |                               |                                                   |
|                     |                                                                        |                      |                               | 4. Social burden                                                 | 4.5 items                                               |                               |                                                   |
|                     |                                                                        |                      |                               | 5. Sexual functioning                                            | 5.3 items                                               |                               |                                                   |
| Anderson et al. [29]| Diabetes Care Profile (DCP)                                            | English              | Diabetes patients             | Diabetes-specific measure of self-care                          | 1. Control problems                                     | 1.18 items                     | Anderson et al. [29] validates a subsample of the scales |
| Fitzgerald et al. [30]|                                                                        |                      |                               | Diabetes-related quality of life                                | 2. Social and personal factors                           | 2.13 items                     |                                                   |
| Li et al. [101]     |                                                                        |                      |                               |                                                                  | 3. Positive attitude                                     | 3.5 items                      |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 4. Negative attitude                                     | 4.6 items                      |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 5. Self-care ability                                     | 5.4 items                      |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 6. Importance of care                                     | 6.4 items                      |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 7. Self-care adherence                                    | 7.4 items                      |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 8. Diet adherence                                         | 8.4 items                      |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 9. Medical barriers                                       | 9.8 items                      |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 10. Exercise barriers                                     | 10.5 items                     |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 11. Monitoring barriers                                   | 11.1 items                     |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 12. Understanding mgmt. practice                           | 12.10 items                    |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 13. Long-term care benefits                               | 13.5 items                     |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 14. Support attitudes                                     | 14.6 items                     |                                                   |
| Sousa et al. [102]  | Depressive Cognition Scale (DCS)                                       | English              | Older adults                  | Identifying depressive cognitions                               | Depression cognition                                     | 8 items in total                | Not applicable                                    |
| Zauszniewski et al. [103]|                                                                        |                      |                               |                                                                  |                                                        |                               |                                                   |
| Sato et al. [104]   | Diabetes Diet-Related Quality of Life (DDRQOL) Scale                   | Japanese             | Type 2 diabetes patients      | Diabetes diet-related quality of life                           | 1. Satisfaction with diet                                | 1.4 items                      | Not applicable                                    |
|                     |                                                                        |                      |                               |                                                                  | 2. Burden of diet therapy                                 | 2.8 items                      |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 3. Perceived merits of diet therapy                        | 3.5 items                      |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 4. General perception of diet                             | 4.1 item                       |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 5. Restriction of social functions                        | 5.2 items                      |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 6. Vitality                                                | 6.4 items                      |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 7. Mental health                                           | 7.5 items                      |                                                   |
| Sato et al. [105]   | Diabetes Diet-Related Quality of Life (DDRQOL)-R                       | Japanese             | Type 2 diabetes patients      | Diabetes diet-related quality of life                           | 1. Satisfaction with diet                                | 1.4 items                      | Not applicable                                    |
|                     |                                                                        |                      |                               |                                                                  | 2. Burden of diet therapy                                 | 2.8 items                      |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 3. Perceived merits of diet therapy                        | 3.5 items                      |                                                   |
| Sato et al. [105]   | Diabetes Diet-Related Quality of Life (DDRQOL)-R Short Form            | Japanese             | Type 2 diabetes patients      | Diabetes diet-related quality of life                           | 1. Satisfaction with diet                                | 1.3 items                      | Not applicable                                    |
|                     |                                                                        |                      |                               |                                                                  | 2. Burden of diet therapy                                 | 2.3 items                      |                                                   |
|                     |                                                                        |                      |                               |                                                                  | 3. Perceived merits of diet therapy                        | 3.3 items                      |                                                   |
| Fisher et al. [106] | Brief Diabetes Distress Screening (DDS)-2                              | English, Spanish     | Type 2 diabetes patients      | Diabetes distress                                              | Diabetes distress                                        | 2 items in total                | The DDS-2 was derived from the DDS-17 questionnaire |
| Reference | PROMs | Development language | Development target population | Construct(s) being measured | Names of (sub)scales | Number of items per (sub)scale | Comments |
|-----------|-------|-----------------------|------------------------------|----------------------------|----------------------|--------------------------------|----------|
| Chew et al. [107] | 17-item Diabetes Distress Scale (DDS-17) | English | Diabetes patients | Diabetes distress | 1. Emotional burden | 1.5 items | Not applicable |
| Chin et al. [108] | | | | 2. Physician-related distress | 2.4 items | |
| Curcio et al. [109] | | | | 3. Regimen-related distress | 3.5 items | |
| Farm et al. [110] | | | | 4. Interpersonal distress | 4.3 items | |
| Fenwick et al. [111] | | | | | | |
| Graue, 2012 [112] | | | | | | |
| Martinez-Vega et al. [113] | Diabetes Distress Scale (DDS)-Thai | Thai | Elderly diabetes patients | Diabetes distress | 1. Emotional and regimen-related burden | 1.10 items | |
| Mocan and Bāban [114] | | | | 2. Physician- and nurse-related distress | 2.4 items | |
| Polonsky et al. [115] | | | | 3. Diabetes-related interpersonal distress | 3.3 items | |
| Batais et al. [116] | Diabetes Distress Scale (DDS)-Saudi-Arabian | Saudi-Arabian | Type 2 Diabetes patients | Diabetes distress | 1. Emotional burden | 1.5 items | Not applicable |
| | | | | 2. Physician-related distress | 2.4 items | |
| | | | | 3. Regimen-related distress | 3.5 items | |
| | | | | 4. Interpersonal distress | 4.3 items | |
| Kokoszka et al. [119] | Depression in Diabetes Self-Rating Scale | Polish | Diabetes patients | Depressive symptoms | Depressive symptoms | 6 items in total | Not applicable |
| Poole et al. [120] | Dreiser's Functional Hand Index (DFI) | French | Osteoarthritis | Hand function | Difficulties of ten different daily activities to execute | 10 items in total | The DFI is also called the functional index for hand osteoarthritis (FIHOA) |
| Abetz et al. [31] | Diabetes Foot Ulcer Scale (DFS) | English | Diabetes patients | Impact of foot ulcers and their treatment on quality of life | 1. Leisure | 1.5 items | Not applicable |
| | | | | 2. Physical health | 2.6 items | |
| | | | | 3. Daily activities | 3.6 items | |
| | | | | 4. Emotions | 4.17 items | |
| | | | | 5. Non-compliance | 5.2 items | |
| | | | | 6. Family | 6.5 items | |
| | | | | 7. Friends | 7.5 items | |
| | | | | 8. Positive attitude | 8.5 items | |
| | | | | 9. Treatment | 9.4 items | |
| | | | | 10. Satisfaction | 10.1 items | |
| | | | | 11. Financial | 11.2 items | |
| Bann et al. [121] | Diabetes Foot Ulcer Scale (DFS-SF) | English | Diabetes patients | Impact of diabetic foot ulcers on patients' quality of life | 1. Leisure | 1.5 items | |
| Hui et al. [122] | | | | 2. Physical health | 2.5 items | |
| Macioch et al. [123] | | | | 3. Worried about ulcers | 3.4 items | |
| Martinez-Gonzalez et al. [124] | | | | 4. Dependence/daily life | 4.5 items | |
| Kontodimopoulos et al. [125] | | | | 5. Negative emotions | 5.6 items | |
| | | | | 6. Bothered by ulcer care | 6.4 items | |

Macioch et al. [123] uses a different number of items per subscale after translation and adaption of the Polish version.
| Reference          | PROMs                                 | Development language | Development target population | Construct(s) being measured                                                                 | Names of (sub)scales                      | Number of items per (sub)scale | Comments                                                                 |
|--------------------|---------------------------------------|-----------------------|-------------------------------|------------------------------------------------------------------------------------------------|------------------------------------------|-------------------------------|-------------------------------------------------------------------------|
| Meadows et al. [126] | Diabetes Health Profile (DHP)-18      | English               | Diabetes patients             | Psychological and behavioural impact that diabetes can have on a person’s daily live due to diabetes | 1. Psychological distress  
2. Barriers to activity  
3. Disinhibited eating | 1.6 items  
2.7 items  
3.5 items | Mulhern et al. [128] developed a Diabetes Health Profile-3  
Dimension and Diabetes Health Profile-5  
Dimension based on the DHP-18  
Tan et al. [129] validates a subscale of the DHP-18 |
| Mulhern et al. [127] |                                        |                       |                               |                                                                                                   |                                          |                               |                                                                         |
| Tan et al. [129]    |                                        |                       |                               |                                                                                                   |                                          |                               |                                                                         |
| Benazizi et al. [130]|                                        |                       |                               |                                                                                                   |                                          |                               |                                                                         |
| Godijn et al. [131] | Diabetes Health Profile (DHP)-31      | Dutch                 | Diabetes patients             | Psychological and behavioural impact that diabetes can have on a person’s daily live due to diabetes | 1. Psychological distress  
2. Barriers to activity  
3. Disinhibited eating | 1.14 items  
2.12 items  
3.5 items | Godijn et al. [131] deleted an item for the analysis |
| Holmes-Truscott et al. [32] | DAWN2 Impact of Diabetes Profile (DIDP)-6 | English               | Diabetes patients             | Perceived impact of diabetes on quality of life                                                   | 1. Physical health  
2. Financial situation  
3. Relationships  
4. Leisure activities  
5. Work or studies  
6. Emotional well-being | 1 item per subscale | Not applicable |
| Holmes-Truscott et al. [32] | DAWN2 Impact of Diabetes Profile (DIDP)-7 | English               | Diabetes patients             | Perceived impact of diabetes on quality of life                                                   | 1. Physical health  
2. Financial situation  
3. Relationships  
4. Leisure activities  
5. Work or studies  
6. Emotional well-being  
7. Dietary freedom | 1 item per subscale | Not applicable |
| Hammond et al. [132] | Diabetes Impact Measurement Scales (DIMS) | English               | Diabetes patients             | Health status                                                                                   | 1. Symptoms  
2. Well-being  
3. Diabetes-related morale  
4. Social role fulfillment | 1.17 items  
2.11 items  
3.11 items  
4.5 items | Not applicable |
| Li et al. [133]     |                                        |                       |                               |                                                                                                   |                                          |                               |                                                                         |
| Lin et al. [134]    | Diabetes-Specific Quality of Life Questionnaire (DMQoL) | Mandarin             | Diabetes patients             | Health-related quality of life                                                                  | Health-related quality of life           | 10 items in total | Not applicable |
| Saffari et al. [135]|                                        |                       |                               |                                                                                                   |                                          |                               |                                                                         |
| Reference          | PROMs                                                                 | Development language | Development target population | Construct(s) being measured | Names of (sub)scales                                      | Number of items per (sub)scale | Comments         |
|-------------------|-----------------------------------------------------------------------|----------------------|-------------------------------|-----------------------------|----------------------------------------------------------|------------------------------|------------------|
| Shen et al. [35]  | Diabetes Quality of Life Clinical Trial Questionnaire (DQLCTQ)         | English              | Diabetes patients             | Quality of life of diabetes patients in clinical trials | Generic: 1. General health 2. Comparative health 3. Physical functioning 4. Global role functioning 5. Social functioning 6. General social functioning 7. Energy/fatigue 8. Health distress 9. Mental health | 1.1 item                      | Not applicable   |
|                   |                                                                       |                      |                               |                             | Diabetes-specific DQOL: 1. Satisfaction 2. Impact 3. Social worry 4. Diabetes worry Worry | 2.27 items                    |                  |
|                   |                                                                       |                      |                               |                             | Newly developed: 1. Treatment satisfaction 2. Treatment flexibility 3. Social stigma 4. Frequency of symptoms 5. Bothersomeness of symptoms 6. Self-efficacy | 1.18 items                    |                  |
|                   |                                                                       |                      |                               |                             | Demographics: 1.1 item 2.1 item 3.6 items 4.2 items 5.1 item 6.1 item 7.5 items 8.6 items 9.5 items | 1.8 items                    |                  |
|                   |                                                                       |                      |                               |                             |                                                  |                              |                  |
| Shen et al. [35]  | Diabetes Quality of Life Clinical Trial Questionnaire-Revised (DQLCTQ-Rev) | English              | Diabetes patients             | Quality of life of diabetes patients in clinical trials | 1. Physical function 2. Energy/fatigue 3. Health distress 4. Mental health 5. Satisfaction 6. Treatment satisfaction 7. Treatment flexibility 8. Frequency of symptoms | 57 items in total             | Not applicable   |
|                   |                                                                       |                      |                               |                             |                                                  |                              |                  |
| Goh et al. [33]   | Asian Diabetes Quality of Life (DQOL)-Chinese-18                        | Mandarin             | Diabetes patients             | Diabetes-specific quality of life | 1. Financial concerns 2. Relationship 3. Memory 4. Diet and activities 5. Energy levels | 18 items in total             | Not applicable   |
|                   |                                                                       |                      |                               |                             |                                                  |                              |                  |
| Goh et al. [33]   | Asian Diabetes Quality of Life (DQOL)-English-21                       | English              | Diabetes patients             | Diabetes-specific quality of life | 1. Financial 2. Energy levels 3. Memory and cognition 4. Relationship 5. Diet | 21 items in total             | Not applicable   |
| Permama et al. [136] | Asian Diabetes Quality of Life (DQOL)-Malay-21                      | Malay                | Diabetes patients             | Diabetes-specific quality of life | 1. Financial 2. Energy levels 3. Memory and cognition 4. Relationship 5. Diet | 21 items in total             | Not applicable   |
| Reference                  | PROMs                          | Development language | Development target population | Construct(s) being measured                  | Names of (sub)scales                          | Number of items per (sub)scale | Comments                                                                 |
|---------------------------|--------------------------------|----------------------|-------------------------------|---------------------------------------------|---------------------------------------------|--------------------------------|---------------------------------------------------------------------------|
| Burroughs et al. [137]    | Diabetes Quality of Life       | English              | Diabetes patients             | (Diabetes-specific) quality of life         | 1. Satisfaction                            | 1.5 items                      |                                                                            |
| Dudzinska et al. [138]    | (DQOL-15)                      |                      |                               | 2. Impact                                   | 2.4 items                                   |                               |                                                                            |
| Magwood et al. [70]       |                                |                      |                               | 3. Social/worry                             | 3.4 items                                   |                               |                                                                            |
| Samah et al. [139]        |                                |                      |                               | 4. Vocational/worry                         | 4.2 items                                   |                               |                                                                            |
| Tang et al. [140]         |                                |                      |                               |                                             |                                             |                               |                                                                            |
| Diriba et al. [141]       | Diabetes Quality of Life       | Afaan Oromoo         | Type 2 diabetes               | Diabetes-related quality of life            | 1. Satisfaction                            | 1.13 items                     | Not applicable                                                            |
| (DQOL)-42                 |                                |                      |                               | 2. Impact                                   | 2.13 items                                  |                               |                                                                            |
|                             |                                |                      |                               | 3. Social/worry                             | 3.5 items                                   |                               |                                                                            |
|                             |                                |                      |                               | 4. Vocational/worry                         | 4.3 items                                   |                               |                                                                            |
| Cheng et al. [142]        | Diabetes Quality of Life       | Chinese              | Elderly diabetes patients     | Quality of life                             | 1. Satisfaction                            | 1.15 items                     | Cheng et al. [143] only reports that the PROM consists of 42 items in total |
| (DQOL)-42                 |                                |                      |                               | 2. Impact                                   | 2.20 items                                  |                               |                                                                            |
|                             |                                |                      |                               | 3. Diabetes-related worry                   | 3.7 items                                   |                               |                                                                            |
|                             |                                |                      |                               |                                             |                                             |                               |                                                                            |
| Yildirim et al. [145]     | Diabetes Quality of Life       | Turkish              | Diabetes patients             | (Diabetes-specific) quality of life         | 1. Satisfaction                            | 45 items in total              |                                                                            |
| (DQOL)-45                 |                                |                      |                               | 2. Impact                                   | 2.15 items                                  |                               |                                                                            |
|                             |                                |                      |                               | 3. Diabetes-related worry                   | 3.4 items                                   |                               |                                                                            |
|                             |                                |                      |                               | 4. Social/vocational worry                  | 4.3 items                                   |                               |                                                                            |
| Jacobson et al. [51]      | Diabetes Quality of Life       | English              | Diabetes patients             | (Diabetes-specific) quality of life         | 1. Satisfaction                            | 1.15 items                     | Not applicable                                                            |
| Pakpour et al. [146]      | (DQOL)-46                       |                      |                               | 2. Impact                                   | 2.20 items                                  |                               |                                                                            |
| Sao et al. [147]          |                                |                      |                               | 3. Diabetes-related worry                   | 3.4 items                                   |                               |                                                                            |
|                             |                                |                      |                               | 4. Social/vocational worry                  | 4.7 items                                   |                               |                                                                            |
| Bujang et al. [149]       | Diabetes Quality of Life       | Malay                | Diabetes patients             | (Diabetes-specific) quality of life         | 1. Diabetes life satisfaction scale         | 1.6 items                      |                                                                            |
| (DQOL)-60                 |                                |                      |                               | 2. Disease impact scale                     | 2.4 items                                   |                               |                                                                            |
|                             |                                |                      |                               | 3. Disease related worries scale            | 3.3 items                                   |                               |                                                                            |
|                             |                                |                      |                               | General health questionnaire                |                                             |                               |                                                                            |
| Bujang et al. [150]       | Diabetes Quality of Life       | Malay                | Diabetes patients             | (Diabetes-specific) quality of life         | 1. Diabetes life satisfaction scale         | 1.6 items                      |                                                                            |
| (DQOL)-revised version    |                                |                      |                               | 2. Disease impact scale                     | 2.4 items                                   |                               |                                                                            |
|                             |                                |                      |                               | 3. Disease related worries scale            | 3.3 items                                   |                               |                                                                            |
|                             |                                |                      |                               | General health questionnaire                |                                             |                               |                                                                            |
| Correr et al. [151]       | Diabetes Quality of Life       | Brazilian            | Diabetes patients             | (Diabetes-specific) quality of life         | 1. Satisfaction                            | 1.15 items                     | Correr et al. [151] performs the intercultural translation of the DQOL-Brazil to Portuguese |
| (DQOL)-Brazil             |                                |                      |                               | 2. Impact                                   | 2.18 items                                  |                               |                                                                            |
|                             |                                |                      |                               | 3. Concern: social/vocational               | 3.7 items                                   |                               |                                                                            |
|                             |                                |                      |                               | Concern: related to diabetes                | 4.4 items                                   |                               |                                                                            |
| Brasil et al. [152]       | Diabetes Quality of Life       | Brazilian            | Diabetes patients             | Health-related quality of life              | 1. Satisfaction                            | 1.2 items                      |                                                                            |
| (DQOL)-Brazil-8           |                                |                      |                               | 2. Impact                                   | 2.3 items                                   |                               |                                                                            |
|                             |                                |                      |                               | 3. Concern: social/vocational               | 3.1 item                                    |                               |                                                                            |
|                             |                                |                      |                               | Concern: related to diabetes                | 4.2 items                                   |                               |                                                                            |
Table 1 (continued)

| Reference                        | PROMs                                | Development language | Development target population | Construct(s) being measured | Names of (sub)scales | Number of items per (sub)scale | Comments |
|----------------------------------|--------------------------------------|----------------------|-------------------------------|-----------------------------|---------------------|--------------------------------|----------|
| Jin et al. [153]                 | Diabetes Quality of Life (DQOL)-Chinese-24 | Chinese              | Diabetes patients             | Quality of life             | 1. Satisfaction 1.9 items | Not applicable                 |          |
| Al-Qerem et al. [154]            | Diabetes Quality of Life (DQOL)-Arabic-29 | Arabic               | Type 2 Diabetes patients     | Quality of life             | 1. Satisfaction 1.14 items | Not applicable                 |          |
| Millán et al. [155]              | Diabetes Quality of Life (DQOL)-Spanish-43 | Spanish              | Diabetes patients             | Relative burden of an intensive diabetes treatment regimen | 1. Satisfaction 1.15 items | Not applicable                 |          |
| Alavi et al. [156]               | Iranian Diabetes Quality of Life (IRDQOL)-41 | Farsi                | Diabetes patients             | General- and health-related quality of life | 1. General quality of life 41 items in total | Not applicable |          |
| Lee et al. [158]                 | Diabetes-specific Quality of Life scale (D-QOL)-34 | Korean               | Diabetes patients             | Health-related quality of life | 1. Emotional suffering 24 items in total | Not applicable |          |
| Grootenhuis et al. [159]         | Type 2 Diabetes Symptom Checklist (DSC) | Dutch                | Type 2 diabetes patients     | Diabetes symptom severity and changes over time | 1. Psychological fatigue 1.4 items | Not applicable |          |
| Arbuckle et al. [160]            | Diabetes Symptom Checklist-Revised (DSC-R) | Dutch                | Diabetes patients             | Symptom burden of diabetes | 1. Psychological fatigue 1.4 items | Naegeli et al. [161] validates a subset of items |          |
| Lee et al. [162]                 | Korean-Diabetes Symptom Checklist-Revised (K-DSC-R) | Korean               | Type 2 diabetes patients     | Symptom burden of diabetes and its possible complications | 1. Neurovascular 1.6 items | Not applicable |          |
| Garcia et al. [26]               | Diabetes Symptom Self-Care Inventory (DSSCI) | English Spanish       | Diabetes patients             | Diabetes symptoms and actions in response to those symptoms | Diabetes symptoms At least 48 items, including a list of 38 symptoms | The DSSCI is a decision tree rather than a scale |          |
| Reference          | PROMs                                      | Development language | Development target population | Construct(s) being measured                                      | Names of (sub)scales                                      | Number of items per (sub)scale | Comments                                      |
|--------------------|--------------------------------------------|----------------------|-------------------------------|------------------------------------------------------------------|----------------------------------------------------------|-------------------------------|---------------------------------------------|
| Araki et al. [36]  | Elderly Diabetes Burden Scale (EDBS)       | Japanese             | Elderly diabetes patients     | Diabetes-specific and non-specific quality of life                | 1. Symptom burden  
2. Social burden  
3. Dietary restrictions  
4. Worry  
5. about diabetes  
6. Treatment (dis-)satisfaction  
7. Burden by tablets or insulin | 1.4 items  
2.5 items  
3.4 items  
4.4 items  
5.3 items  
6.3 items | Not applicable                             |
| de Cock et al. [163]| Edinburgh Depression Scale (EDS)           | English              | Postnatal women               | Screening depression                                             | Depression                                               | 30 items in total              | The EDS is the renamed version of the Edinburgh Postnatal Depression Scale |
| Clarke et al. [164]| EuroQol (EQ)-5D-3L                         | Dutch, Finnish, Norwegian, Swedish, English | General population            | Generic measure of health status Health-related quality of life | 1. Mobility  
2. Self-care  
3. Usual activities  
4. Pain/discomfort  
5. Anxiety/depression | 1 item per subscale | Not applicable                             |
| Koh et al. [176]   | EuroQol (EQ)-5D-5L                         | Dutch, Finnish, Norwegian, Swedish, English | General population            | Generic measure of health status Health-related quality of life | 1. Mobility  
2. Self-care  
3. Usual activities  
4. Pain/discomfort  
5. Anxiety/depression | 1 item per subscale | Not applicable                             |
| Cinar et al. [180] | 13-item Fatigue subscale of the FACT-F     | English              | Chronic Diseases and Generic for Neoplasms | Fatigue | Fatigue | 13 items in total | Not applicable |
| Leonardson et al. [181]| General well-being schedule              | English              | General population            | Subjective feelings of psychological well-being and distress | 1. Self-esteem  
2. Depression  
3. Vitality  
4. Health concerns | 1.8 items  
2.6 items  
3.4 items  
4.4 items | Not applicable |
| Reference          | PROMs                                      | Development language | Development target population                                                                 | Construct(s) being measured | Names of (sub)scales                                                                 | Number of items per (sub)scale | Comments |
|--------------------|--------------------------------------------|----------------------|------------------------------------------------------------------------------------------------|-----------------------------|--------------------------------------------------------------------------------------|-------------------------------|----------|
| Amidu et al. [182] | Golombok-Rust Inventory of Sexual Satisfaction (GRISS) | English              | Heterosexual couples or individuals who have a current heterosexual relationship | Sexual functioning          | Male<br>1. Impotence<br>2. Premature ejaculation<br>3. Nonsensuality<br>4. Avoidance<br>5. Dissatisfaction<br>6. Infrequency<br>7. Noncommunication<br><br>Female<br>1. Vaginismus<br>2. Anorgasmia<br>3. Nonsensuality<br>4. Avoidance<br>5. Dissatisfaction<br>6. Infrequency<br>7. Noncommunication | 4 items per subscale             | Not applicable |
| Poole et al. [120] | Hand Function Disability Scale (HFDS)      | French               | Rheumatoid arthritis                                                                               | Hand function               | 1. Kitchen<br>2. Dressing<br>3. Hygiene<br>4. Office<br>5. Other                      | 1.8 items<br>2.2 items<br>3.2 items<br>4.2 items<br>5.4 items | The HFDS is also called Cochin Scale or Duruoz’s Hand Index |
| Hajos et al. [183] | the Worry subscale from the Hypoglycemia Fear Survey (HFS-W) | English              | Diabetes patients                                                                                  | Fear of hypoglycemia (worry subscale) | Fear of hypoglycemia (worry subscale) | 13 items in total | The HFS-W concerns the worry subscale from the Hypoglycemia Fear Survey (HFS) |
| Kawata et al. [184] | Hypoglycemia Perspectives Questionnaire (HPQ) | English              | Diabetes patients                                                                                  | Experience and impact of hypoglycemia | 1. Symptom concern<br>2. Compensatory behavior<br>3. Worry                                 | 1.6 items<br>2.5 items<br>3.5 items | Not applicable |
| Morgan et al. [38] | Health Status Questionnaire (HSQ) 2.0      | English              | General population                                                                                  | Quality of life in several dimensions | 1. Health perception<br>2. Physical functioning<br>3. Role limitations—physical health<br>4. Role limitations—emotional problems<br>5. Social functioning<br>6. Mental health<br>7. Bodily pain<br>8. Energy/fatigue | 39 items in total             | Not applicable |
| Maddigan et al. [40] | Health Utilities Index Mark 2 (HUI2)       | English              | General population                                                                                  | Health-related quality of life<br>Self-reported health status | 1. Sensation (hearing, vision and speech)<br>2. Mobility<br>3. Emotion<br>4. Cognition<br>5. Self-care<br>6. Pain<br>7. Fertility | 1 item per subscale | Maddigan et al. [40] did not use the ‘Fertility’ subscale |
| Reference                  | PROMs                                      | Development language | Development target population | Construct(s) being measured                                      | Names of (sub)scales                  | Number of items per (sub)scale | Comments                                                                 |
|----------------------------|--------------------------------------------|----------------------|-------------------------------|-------------------------------------------------------------------|--------------------------------------|----------------------------------|--------------------------------------------------------------------------|
| Maddigan et al. [40]       | Health Utilities Index Mark 3 (HUI3)       | English              | General population            | Health-related quality of life<br>Self-reported health status    | 1. Vision 2. Hearing 3. Speech 4. Ambulation 5. Dexterity 6. Emotion 7. Cognition 8. Pain/discomfort | 1. Not applicable               |                                                                          |
| Mo et al. [186]            |                                            |                      |                               |                                                                   |                                      |                                  |                                                                          |
| Kolotkin et al. [187]      | Impact of Weight on Quality of Life-Lite (IWQOL-lite) | English              | People with obesity          | Weight-related quality of life                              | 1. Physical function 2. Self-esteem 3. Sexual life 4. Public distress 5. Work 6. Emotion 7. Pain/discomfort 8. Pain 9. Fatigue 10. Fatigue 11. Anxiety 12. Depression 13. Anxiety 14. Anxiety 15. Anxiety 16. Anxiety 17. Anxiety 18. Anxiety 19. Anxiety 20. Anxiety 21. Anxiety 22. Anxiety 23. Anxiety 24. Anxiety 25. Anxiety 26. Anxiety 27. Anxiety 28. Anxiety 29. Anxiety 30. Anxiety 31. Anxiety 32. Anxiety 33. Anxiety 34. Anxiety 35. Anxiety 36. Anxiety 37. Anxiety 38. Anxiety 39. Anxiety 40. Anxiety | 1.11 items 2.7 items 3.4 items 4.5 items 5.4 items | Not applicable                   |                                                                          |
| Kolotkin et al. [188]      | Impact of Weight on Quality of Life-Lite-Clinical Trials (IWQOL-Lite-CT) | English              | People with obesity for obesity clinical trials | Health-related quality of life                              | 1. Physical 2. Psychosocial                   | 1.7 items 2.13 items | Kolotkin et al. [188] validates the pilot version of the IWQOL-Lite-CT which consists of 22 items |                                                                          |
| Tan et al. [129]           | Kessler-10 Psychological Distress scale (K10) | English              | General population            | Level of distress and severity associated with psychological symptoms | 1. Depressed mood 2. Motor agitation 3. Fatigue 4. Worthless guilt 5. Anxiety | 1.3 items 2.2 items 3.2 items 4.1 items 5.2 items | Not applicable                   |                                                                          |
| Hirsch et al. [48]         | LQD Quality of Life with Diabetes (LQD)    | German               | Diabetes patients            | Diabetes-specific quality of life                              | 1. Diabetes satisfaction 2. Diabetes stress 3. Blood glucose stress | 1.7 items 2.7 items 3.3 items | Not applicable                   |                                                                          |
| Hasan et al. [190]         | Menopause-specific Quality of Life (MENQOL) | English              | Menopause                     | Quality of life                                               | 1. Vasomotor 2. Physical 3. Psychosocial 4. Sexual functioning | 1.3 items 2.7 items 3.16 items 4.3 items | Not applicable                   |                                                                          |
| Poole et al. [120]         | Michigan Hand Outcomes Questionnaire (MHQ) | English              | Patients with hand disorders | Hand-specific outcome measure                                  | 1. Overall hand function 2. Activities of daily living 3. Work performance 4. Pain 5. Aesthetics 6. Satisfaction with hand function | 1.10 items 2.17 items 3.5 items 4.10 items 5.8 items 6.12 items | Not applicable                   |                                                                          |
| Kim et al. [191]           | MOS Six-Item Sleep Scale                   | English              | General population            | Quality of sleep                                              | Not clearly reported, but includes at least the following dimensions of sleep 1. Initiation 2. Maintenance 3. Adequacy 4. Somnolence 5. Respiratory impairments | 6 items in total                 | Not applicable                   |                                                                          |
| Reference | PROMs | Development language | Development target population | Construct(s) being measured | Names of (sub)scales | Number of items per (sub)scale | Comments |
|-----------|-------|-----------------------|-------------------------------|-----------------------------|---------------------|-------------------------------|----------|
| Borg et al. [192] Svedbo Engstrom et al. [193] Svedbo Engstrom et al. [194] | National Diabetes Register (NDR) survey | Swedish | Diabetes patients | Patient well-being, abilities to manage diabetes and judgements of their experience with diabetes care | 1. How you feel 2. our worries 3. Your capabilities to manage your diabetes 4. Barriers 5. Support from others 6. Support from diabetes care providers 7. Medical devices and medical treatment | 1.5 items 2.3 items 3.5 items 4.5 items 5.3 items 6.9 items 7.3 items | Svedbo Engstrom et al. [193] validates a pilot version of the NDR |
| Vileikyte et al. [195] | Neuropathy- and Foot Ulcer–Specific Quality of Life instrument (NeuroQoL) | English | Patients with diabetic peripheral neuropathy | Neuropathy- and foot ulcer–specific quality of life | Physical symptoms 1. Pain 2. Reduced feeling 3. Diffuse sensory motor Psychosocial symptoms 1. Interpersonal/emotional burden 2. Activity limitations | Physical symptoms 1.7 items 2.3 items 3.3 items Psychosocial symptoms 1.11 items 2.3 items | Not applicable |
| Keinanen et al. [196] | Nottingham Health Profile (NHP) | English | General population | Health-related quality of life | Current Health-related Quality of Life 1. Energy 2. Sleep 3. Pain 4. Emotional reactions 5. Social isolation 6. Physical mobility Health problems 1. Paid employment 2. Jobs around the house 3. Social life 4. Home life 5. Sex life 6. Hobbies 7. Holidays | Current health-related quality of life 1.3 items 2.5 items 3.8 items 4.9 items 5.5 items 6.8 items Health problems 7 items in total | Not applicable |
| McGuire et al. [197] | Short Form Problem Areas in Diabetes (PAID)-1 | English | Diabetes patients | Emotional impact of diabetes | Emotional problems 1 item in total | Not applicable |
| Lee et al. [198] McGuire et al. [197] Vislapuu et al. [199] | Problem areas in diabetes (PAID)-5 | English | Diabetes patients | Diabetes-related emotional functioning | Emotional problems 5 items in total | Not applicable |
| Siaw et al. [200] Venkataraman et al. [201] | Problem areas in diabetes (PAID)-16 | English | Diabetes patients | Diabetes-specific emotional distress | 1. Emotional and management problems 2. Diabetes problems 3. Support problems | 1.11 items 2.3 items 3.2 items | Not applicable |
| Reference | PROMs | Development language | Development target population | Construct(s) being measured | Names of (sub)scales | Number of items per (sub)scale | Comments |
|-----------|-------|-----------------------|-------------------------------|-----------------------------|---------------------|-------------------------------|----------|
| Arzaghi et al. [202] Belendez et al. [203] Eom et al. [204] Fenwick et al. [111] Graue et al. [112] Gross et al. [205] Huang et al. [206] Huis In ’t Veld et al. [207] Jannoo et al. [208] Miller et al. [209] Papaforthiou et al. [210] Polonsky et al. [211] Snoek et al. [212] Tan et al. [129] Venkataraman et al. [201] Welch et al. [213] Welch et al. [214] Welch et al. [215] Cichoń et al. [216] | Problem areas in diabetes (PAID)-20 Diabetes patients | English Diabetes-related emotional functioning Distress 1. Emotional problems 2. Treatment problems 3. Food-related problems 4. Social support problems | 1.12 items 2.2 items 3.3 items 4.3 items | Not applicable |
| Matza et al. [169] | Psychological General Well-Being Index (PGWBI) | English General population Subjective feelings of psychological well-being and distress 1. Anxiety 2. Depressed mood 3. Positive well-being 4. Self-control 5. General health 6. Vitality | 1.5 items 2.3 items 3.4 items 4.3 items 5.3 items 6.4 items | Not applicable |
| Chuayruang et al. [26] | Patient-reported outcomes in Thai patients with type 2 diabetes mellitus (PRO-DM-Thai) | Thai Type 2 diabetes patients Patient-reported outcomes (outcomes of diabetes care) 1. Physical function 2. Symptoms 3. Psychological well-being 4. Self-care management 5. Social well-being 6. Global judgements of health 7. Satisfaction with care and flexibility of treatment | 1.5 items 2.7 items 3.5 items 4.12 items 5.5 items 6.5 items 7.5 items | Not applicable |
| Zhu et al. [217] | Pittsburg Sleep Quality Index (PSQI) | English Adults Sleep quality 1. Subjective sleep quality 2. Sleep latency 3. Sleep duration 4. Habitual sleep efficiency 5. Sleep disturbances 6. Use of sleep medication 7. Daytime dysfunction | 1.1 item 2.2 items 3.1 item 4.3 items 5.9 items 6.1 item 7.2 items | Zhu et al. [217] removed ‘use of sleep medication’ from the PSQI questionnaire |
| Oobe et al. [37] | Quality of life (QOL) questionnaire | Japanese Diabetes patients Quality of life 1. Degree of apprehension 2. Degree of distress 3. Degree of satisfaction with life 4. Degree of satisfaction with treatments | 1.5 items 2.5 items 3.4 items 4.4 items | Not applicable |
| Reference                  | PROMs                                                                 | Development language | Development target population | Construct(s) being measured | Names of (sub)scales                          | Number of items per (sub)scale | Comments                      |
|---------------------------|-------------------------------------------------------------------------------------------------|----------------------|-------------------------------|-----------------------------|---------------------------------------------|-------------------------------|--------------------------------|
| Orozco-Beltran et al.     | Impact of hypoglycemia on the HRQoL of type 2 diabetes patients (QoLHYPO©) questionnaire      | Spanish              | Type 2 diabetes patients      | Quality of life             | Health-related quality of life              | 13 items in total            | Not applicable                 |
| Nagpal et al. [34]        | Quality of Life for Indian diabetes Patients (QOLID)                                           | Indian               | Type 2 diabetes patients      | Quality of life             | 1. Social life, work and travel             | 1.6 items                    | Not applicable                 |
|                           |                                                                                                 |                      |                               | 2. Physical endurance       | 2.6 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 3. General health            | 3.3 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 4. Treatment satisfaction    | 4.4 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 5. Symptom botherness        | 5.3 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 6. Financial worries         | 6.4 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 7. Emotional/mental health   | 7.5 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 8. Diet advise tolerance     | 8.3 items                                  |                               |                                |
| Mikhael et al. [219]      | Quality of life scale for Iraqi Diabetes patients (QOLSID)                                     | Irak                 | Diabetes patients             | Quality of life             | 1. Satisfaction                            | 1.8 items                    | Not applicable                 |
|                           |                                                                                                 |                      |                               | 2. Stress                   | 2.2 items                                  |                               |                                |
| Whitty et al. [220]       | Self-completion instrument for diabetes                                                          | English              | Diabetes patients             | Subjective health status    | The instrument consists of six multi-item scales |                               |                                |
|                           |                                                                                                 |                      |                               | 1. Physical function and energy | 1. Physical function 10 items and Energy 4 items |                               |                                |
|                           |                                                                                                 |                      |                               | 2. Depression                | 2.7 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 3. Psychological distress    | 3. Psychological distress 16 items and Barriers to activity 15 items |                               |                                |
|                           |                                                                                                 |                      |                               | and barriers to activity    | 4.9 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 4. Symptoms                  | 4.9 items                                  |                               |                                |
| Rao et al. [39]           | Self-perception of health                                                                       | English              | Type 2 diabetes patients      | Subjective feelings of psychological well-being and distress | 1. Positive self-feeling | 1.6 items | Not applicable                 |
|                           |                                                                                                 |                      |                               | 2. Sociality                 | 2.6 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 3. Attention seeking         | 3.4 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 4. Feel healthy              | 4.5 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 5. Worry about health        | 5.2 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 6. Dependence                | 6.4 items                                  |                               |                                |
| Maddigan et al. [40]      | 12-item Short Form Health Survey (SF-12)                                                        | English              | General population            | Health-related quality of life | 1. Physical functioning | 1.2 items | Not applicable                 |
| Maurischat et al. [41]    |                                                                                                 |                      |                               | 2. Role physical             | 2.2 items                                  |                               |                                |
| Wan et al. [42]           |                                                                                                 |                      |                               | 3. Role emotional            | 3.2 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 4. Pain                      | 4.1 item                                   |                               |                                |
|                           |                                                                                                 |                      |                               | 5. Vitality                  | 5.1 item                                   |                               |                                |
|                           |                                                                                                 |                      |                               | 6. General health            | 6.1 item                                   |                               |                                |
|                           |                                                                                                 |                      |                               | 7. Social functioning        | 7.1 item                                   |                               |                                |
|                           |                                                                                                 |                      |                               | 8. Mental health             | 8.2 items                                  |                               |                                |
| Westaway et al. [43]      | 20-item Short Form Health Survey (SF-20)                                                         | English              | General patient population    | Health-related quality of life | 1. Physical functioning | 1.6 items | Not applicable                 |
|                           |                                                                                                 |                      |                               | 2. Role functioning          | 2.2 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 3. Social functioning        | 3.1 item                                   |                               |                                |
|                           |                                                                                                 |                      |                               | 4. Mental health             | 4.5 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 5. General health            | 5.5 items                                  |                               |                                |
|                           |                                                                                                 |                      |                               | 6. Bodily pain               | 6.1 item                                   |                               |                                |
| Reference | PROMs | Development language | Development target population | Construct(s) being measured | Names of (sub)scales | Number of items per (sub)scale | Comments |
|-----------|-------|-----------------------|-------------------------------|----------------------------|---------------------|-------------------------------|----------|
| Ahroni et al. [45] | 36-Item Short Form Health Survey (SF-36) | English | General population | Generic health concepts Health-related quality of life | 1. Physical functioning 2. Social functioning 3. Role limitations due to physical problems 4. Role limitation due to emotional problems 5. Mental health 6. Energy and vitality 7. Pain 8. General perception of health 9. Perceived change in health | 1.00 items 2.2 items 3.4 items 4.3 items 5.5 items 6.4 items 7.2 items 8.5 items 9.1 item | Ahroni et al. [45], Bagheri et al. [46], Jacobson et al. [51] and Martin et al. [53] analyzed specific subscales of the SF-36 questionnaire |
| Anderson et al. [29] | Short Form Problem Areas in Diabetes in Chinese (SF-PAID-C) | Chinese | Diabetes patients | Diabetes-specific emotional distress | 1. Diabetes-related emotional problems 2. Problems related to food | 1.6 items 2.2 items | Not applicable |
| Wicaksana et al. [222] | Patient Health Questionnaire (PHQ)-4 | English | General population | Psychological distress | 1. Depression 2. Anxiety | 1.2 items 2.2 items | Not applicable |
| Lupascu et al. [223] | Patient Health Questionnaire (PHQ)-9 | English | General population | Depressive symptoms Depression | Depressive symptoms/ depression | 9 items in total | Not applicable |
| Klis et al. [27] | Pictorial Representation of Illness and Self Measure Revised II (PRISM-RII) | Dutch | Diabetes patients | Diabetes-related suffering | 1. Self illness separation (SIS) 2. Illness perception measure | Not applicable | The PRISM-RII is a visual interactive PROM |
| Duran et al. [227] | Questionnaire on Stress in Diabetic Patients (QSD) | German | Diabetes patients | Diabetes distress | 1. Fear of long-term complications 2. Dietary restrictions 3. Problems with hypoglycemia 4. Difficulties with treatment regimen 5. Problems with acceptance 6. Reduction of performance 7. Problems with work 8. Strained doctor-patient relationship 9. Problems with relationship or family 10. Feeling patronized | 1.7 items 2.4 items 3.9 items 4.10 items 5.15 items 6.11 items 7.6 items 8.5 items 9.12 items 10.6 items | Not applicable |
Table 1 (continued)

| Reference | PROMs | Development language | Development target population | Construct(s) being measured | Names of (sub)scales | Number of items per (sub)scale | Comments |
|-----------|-------|-----------------------|-------------------------------|-----------------------------|---------------------|-------------------------------|----------|
| Herschbach et al. [228] | Questionnaire on Stress in Patients with Diabetes-Revised (QSD-R) | German | Diabetes patients | Diabetes distress | 1. Leisure time 2. Depression/fear of future 3. Hypoglycemia 4. Treatment regimen/diet 5. Physical complaints 6. Work 7. Partner 8. Doctor-patient relationship | 1.4 items 2.6 items 3.4 items 4.9 items 5.6 items 6.6 items 7.6 items 8.4 items | Not applicable |
| Kinik and Çamlicali [229] | Questionnaire on Stress in Patients with Diabetes-Revised-Turkish (QSD-R-TR) | Turkish | Diabetes patients | (Diabetes) distress | 1. Leisure time 2. Work 3. Relationship with partner 4. Doctor-patient relationship 5. Problems with hypoglycemia 6. Treatment regimen 7. Physical complaints 8. Worries about long-term complications | 1.4 items 2.6 items 3.6 items 4.4 items 5.4 items 6.7 items 7.6 items 8.6 items | Not applicable |
| Fraim et al. [230] | Questionnaire on Stress in Patients with Diabetes-Revised-Turkish-Cyprus (QSD-R-TR) | Turkish | Diabetes patients | (Diabetes) distress | 1. Psycho-physiological aspects 2. Social 3. Accountability 4. Psychosocial distress 5. Fear/depression 6. Outcomes 7. Medical relationships | 1.11 items 2.6 items 3.6 items 4.4 items 5.4 items 6.3 items 7.4 items | Not applicable |
| Pakpour et al. [231] | Sexual Quality of Life questionnaire-Female (SQOL-F) | English | Women with sexual dysfunction | Impact of sexual dysfunction on quality of life | Impact of sexual dysfunction on quality of life | 18 items in total | Not applicable |
| Polonsky et al. [232] | Type 2 Diabetes Distress Assessment System (T2-DDAS) | English | Adults with T2D | Diabetes Distress | 1. Core distress 2. Management demands 3. Hypoglycemia 4. Long-term health 5. Health care provider 6. Interpersonal issues 7. Shame 8. Healthcare access | 1.8 items 2.3 items 3.3 items 4.3 items 5.3 items 6.3 items 7.3 items 8.3 items | Not applicable |
| Pouwer et al. [233], Pouwer et al. [234] | Well-being questionnaire (W-BQ) 12 | Dutch | Patients in clinical trials and other studies | Several aspects of psychological well-being | 1. Negative well-being 2. Energy 3. Positive well-being | 1.4 items 2.4 items 3.4 items | Not applicable |
| Hirsch et al. [48], Kolawole et al. [235], Kolawole et al. [24] | Well-being questionnaire (W-BQ) 22 | English | Diabetes patients | Well-being Quality of life | 1. Depression 2. Anxiety 3. Energy 4. Positive well-being 5. (General well-being) | 1.6 items 2.6 items 3.4 items 4.6 items 5.22 items | Not applicable |
### Table 1 (continued)

| Reference | PROMs | Development language | Development target population | Construct(s) being measured | Names of (sub)scales | Number of items per (sub)scale | Comments |
|-----------|-------|-----------------------|--------------------------------|-----------------------------|---------------------|-------------------------------|----------|
| Speight et al. [236] | Well-being questionnaire (W-BQ) 28 | English | Diabetes patients | Well-being Health-related quality of life | 1. Generic negative well-being 2. Generic positive well-being 3. Energy 4. Generic stress 5. Diabetes-specific negative well-being 6. Diabetes-specific positive well-being 7. Well-being 8. Diabetes-specific stress | 1.4 items 2.4 items 3.4 items 4.4 items 5.4 items 6.4 items 7.4 items | Not applicable |
| Bradley et al. [237] | Well-being scale | English | Diabetes patients | Well-being an treatment satisfaction | 1. Depression 2. Anxiety 3. Positive well-being | 1.6 items 2.6 items 3.6 items | Not applicable |
| Mannucci et al. [56] | Well-being Enquiry for Diabetics (WED) | Italian | Diabetes patients | Diabetes-related quality of life | 1. Symptoms 2. Discomfort 3. Serenity 4. Impact | 1.10 items 2.10 items 3.10 items 4.20 items | Not applicable |
| Awata et al. [238] Cichón et al. [239] Hajos et al. [240] Halliday et al. [241] Yordanova et al. [55] | The World Health Organisation- Five Well-Being Index (WHO-5) | Danish English | General population | Positive psychological well-being | 1. Cheerful and in good spirits 2. Calm and relaxed 3. Active and vigorous 4. Feeling fresh and rested 5. Filled with things that interest me | 1 item per subscale | Not applicable |
| Pibernik-Okanovic et al. [23] | World Health Organisation Quality of Life (WHOQOL-100) | Australian Croatian French Indian Israeli Japanese Dutch Panamees Russian Spanish Thai English Shona | General population | Overall quality of life General health | Overall quality of life and general health Quality of life domains 1. Physical 2. Psychological 3. Social relationships 4. Environment | Overall quality of life and general health Not reported Quality of life domains 1.7 facets 2.6 facets 3.3 facets 4.8 facets Each facet consists of 4 questions | Pibernik-Okanovic et al. [23] uses a modified four-domain structure. The standard WHOQOL-100 consists of six domains (i.e. includes domains level of independence and spirituality) |
| Jahanlou et al. [157] Kolawole et al. [24] Reha et al. [242] Sreedevi et al. [25] Abbass-Ghahramanloo et al. [44] | World Health Organisation Quality of Life (WHOQOL)-BREF | Australian Croatian French Indian Israeli Japanese Dutch Panamees Russian Spanish Thai English Shona | General population | Quality of life | 1. Physical health 2. Psychological 3. Social relationships 4. Environment | 1.7 items 2.6 items 3.3 items 4.8 items | Not applicable |

**Bold** represents the development paper of the PROM. Not for all of the PROMs a development paper is listed in the table, while those PROMs were not developed in a diabetes population.
### Table 2 Overview of the specific levels of HRQOL that the included PROMs measure based on the Wilson and Cleary model [4]

| PROM | Health-related quality of life | Other | General health perception | Overall quality of life | Characteristics of individual/environment or PREM |
|------|--------------------------------|-------|--------------------------|------------------------|-----------------------------------------------|
|      | Symptom status                 |       |                          |                        |                                               |
|      | Functional status              |       |                          |                        |                                               |
|      | Diabetes related symptoms      |       |                          |                        |                                               |
|      | Physical symptoms              | Mental symptoms |                          |                        |                                               |
|      | Pain                           | Distress | Anxiety/worry | Depression | Physical function | Psychological function | Social function | General health perceptions, self-rated health | Overall health | Overall quality of life | Characteristics of individual/environment or PREM |
|      | Energy/fatigue                 | Sleep |                          |                        | Activities of daily living | Sexual function | Emotional function | Social function/participation |                                  |
|      | Emotional function/cognition |                          |                        |                        |                              |                      |                              |                                  |}

- 15D standardized measure of health-related quality of life Finnish (15D Finnish) [57]
- Audit of Diabetes Dependent Quality of Life (ADDQOL)-13 [58, 59]
- Audit of Diabetes Dependent Quality of life (ADDQOL)-16 [60]
- Audit of Diabetes Dependent Quality of life (ADDQOL)-17-senior [61]
- Audit of Diabetes Dependent Quality of Life (ADDQOL)-18 [62–64]
- Audit of Diabetes Dependent Quality of Life (ADDQOL)-19 [65–75]
| PROM | Health-related quality of life | Functional status | General health perception | Overall quality of life | Characteristics of individual/environment or PREM |
|------|-------------------------------|-------------------|--------------------------|------------------------|-----------------------------------|
|      | Symptom status                |                   |                          |                        |                                   |
|      | Diabetic related symptoms     | Physical symptoms | Mental symptoms           |                        |                                   |
|      | Physical function             | Psychological function | Social function | Overall health | Overall quality of life | Characteristics of individual/environment or PREM |
|      | Pain                          | Distress          | Anxiety/ worry           | Depression              | Activities of daily living | Sexual function | Emotional function/ cognition | Social function/ participation | General health perceptions, self-rated health | Overall quality of life |
|      | Energy/fatigue                |                   |                          |                        |                                   |                          |                                   |                                   |                                   |                                   |
|      | Sleep                         |                   |                          |                        |                                   |                          |                                   |                                   |                                   |                                   |
|      | A Health status instrument developed for South-African women [76] | ● | ● | | | |
|      | The Ability to Perform Physical Activities of Daily Living Questionnaire (APPADL) [77, 78] | | | | | |
|      | Attitudes to Diabetes (ATT)-19 [79, 80] | | | | | |
|      | Attitude to Diabetes (ATT)-39 [81] | ● | | ● | | |
|      | Chinese Diabetes Distress screening (CDDS)-15 [82] | ● | ● | ● | | |
|      | Centre for Epidemiological Studies Depression Scale (CESD) [83–87] | | | | | |
|      | Clinically Useful Depression Outcome Scale (CUDOS) [88] | | | | | |
|      | Cardiff Wound Impact Schedule (CWIS) [89–93] | | | | | |
Table 2 (continued)

| PROM                                                                 | Health-related quality of life                                      | Other                                                                 |
|---------------------------------------------------------------------|---------------------------------------------------------------------|----------------------------------------------------------------------|
|                                                                     | Symptom status                                                     | Functional status                                                   | General health perception | Overall quality of life | Characteristics of individual/environment or PREM |
|                                                                     | Diabetes related symptoms                                          |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Physical symptoms                                                  |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Pain                                                               |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Energy/fatigue                                                     |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Sleep                                                              |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Mental symptoms                                                    |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Distress                                                           |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Anxiety/worry                                                      |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Depression                                                         |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Physical function                                                  |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Pain                                                               |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Energy/fatigue                                                     |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Sleep                                                              |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Mental symptoms                                                    |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Distress                                                           |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Anxiety/worry                                                      |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Depression                                                         |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Functional status                                                  |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Activities of daily living                                         |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Sexual function                                                    |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Emotional function/cognition                                       |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Social function/cognition                                           |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Social function                                                    |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Overall health                                                     |                                                                 |                                                                      |                           |                                                         |
|                                                                     | General health perceptions, self-rated health                      |                                                                 |                                                                      |                           |                                                         |
|                                                                     | Overall quality of life                                            |                                                                 |                                                                      |                           |                                                         |
| Chinese Cardiff Wound Impact Schedule (CCWIS) [94]                  | ●                                                                  | ●                                                                  | ●                                                                      | ●                                                                  | ●                                                          |
| Diabetes-39 (D-39) [48, 50, 95–99]                                  | ●                                                                  | ●                                                                  | ●                                                                      | ●                                                                  | ●                                                          |
| Diabetes-39 scale (D-39) Short Form [100]                           | ●                                                                  | ●                                                                  | ●                                                                      | ●                                                                  | ●                                                          |
| Diabetes Care Profile (DCP) [29, 30, 101]                            | ●                                                                  | ●                                                                  | ●                                                                      | ●                                                                  | ●                                                          |
| Depressive Cognition Scale (DCS) [102, 103]                         | ●                                                                  | ●                                                                  | ●                                                                      | ●                                                                  | ●                                                          |
| Diabetes Diet-Related Quality of Life (DDRQOL) Scale [104]          | ●                                                                  | ●                                                                  | ●                                                                      | ●                                                                  | ●                                                          |
| Diabetes Diet-Related Quality of Life (DDRQOL)-R [105]              | ●                                                                  | ●                                                                  | ●                                                                      | ●                                                                  | ●                                                          |
| Diabetes Diet-Related Quality of Life (DDRQOL)-R Short Form [105]   | ●                                                                  | ●                                                                  | ●                                                                      | ●                                                                  | ●                                                          |
| Brief Diabetes Distress Screening (DDS)-2 [106]                     | ●                                                                  | ●                                                                  | ●                                                                      | ●                                                                  | ●                                                          |
| 17-item Diabetes Distress Scale (DDS-17) [107–117]                  | ●                                                                  | ●                                                                  | ●                                                                      | ●                                                                  | ●                                                          |
| PROM                                      | Health-related quality of life | Other                                                                                                                                 |
|-------------------------------------------|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
|                                           | Symptom status                | General health perception                                                                                                              |
|                                           | Functional status             | Overall quality of life                                                                                                                |
|                                           | Characteristics of individual/environment or PREM |                                                                                                                                        |
| Diabetes Distress Scale (DDS)-Thai [118]  | ●                             | ●                                                                                                                                       |
| Diabetes Distress Scale (DDS)-Saudi-Arabian [116] | ●                             | ●                                                                                                                                       |
| Depression in Diabetes Self-Rating Scale [119] | ●                             |                                                                                                                                        |
| Dreiser's Functional Hand Index (DFI) [120] | ●                             |                                                                                                                                        |
| Diabetes Foot Ulcer Scale (DFS) [31]      | ●                             | ●                                                                                                                                       |
| Diabetes Foot Ulcer Scale (DFS-SF) [121–125] | ●                             | ●                                                                                                                                       |
| Diabetes Health Profile (DHP)-18 [126–130] | ●                             | ●                                                                                                                                       |
| Diabetes Health Profile (DHP)-31 [131]    | ●                             | ●                                                                                                                                       |
| DAWN2 Impact of Diabetes Profile (DIDP)-6 [32] | ●                             | ●                                                                                                                                       |
| DAWN2 Impact of Diabetes Profile (DIDP)-7 [32] | ●                             | ●                                                                                                                                       |
| Diabetes Impact Measurement Scales (DIMS) [132, 133] | ●                             | ●                                                                                                                                       |
Table 2 (continued)

| PROM | Health-related quality of life |
|------|-----------------------------|
|      | Symptom status              | Functional status | Other |
|      | Diabetes related symptoms   | Physical symptoms | Mental symptoms | Physical function | Psychological function | Social function | Overall health | Overall quality of life | Characteristics of individual/environment or PREM |
|      | Pain | Energy/ fatigue | Sleep | Distress | Anxiety/ worry | Depression | Activities of daily living | Sexual function | Emotional function/ cognition | Social function/ participation | General health perceptions, self-rated health | General health perceptions, self-rated health |

| Diabetes-Specific Quality of Life Questionnaire (DMQoL) [134, 135] | ● | ● | ● | ● | ● | ● | ● | ● |
| Diabetes Quality of Life Clinical Trial Questionnaire (DQLCTQ) [35] | ● | ● | ● | ● | ● | ● | ● | ● |
| Diabetes Quality of Life Clinical Trial Questionnaire-Revised (DQLCTQ-Rev) [35] | ● | ● | ● | ● | ● | ● | ● | ● |
| Asian Diabetes Quality of Life (DQOL)-Chinese-18 [33] | ● | ● | ● | ● | ● | ● | ● | ● |
| Asian Diabetes Quality of Life (DQOL)-English-21 [33, 136] | ● | ● | ● | ● | ● | ● | ● | ● |
| Asian Diabetes Quality of Life (DQOL)-Malay-21 [33] | ● | ● | ● | ● | ● | ● | ● | ● |
| Diabetes Quality of Life (DQOL-15) [70, 137-140] | ● | ● | ● | ● | ● | ● | ● | ● |
| Diabetes Quality of Life (DQOL)-Afaan Oromoo-34 [141] | ● | ● | ● | ● | ● | ● | ● | ● |
| PROM | Health-related quality of life | Functional status | Other |
|------|--------------------------------|-------------------|-------|
|      | Symptom status                 |                   |       |
|      | Diabetes related symptoms      |                   |       |
|      | Physical symptoms              |                   |       |
|      | Mental symptoms                |                   |       |
|      | Physical function              |                   |       |
|      | Psychological function         |                   |       |
|      | Social function                |                   |       |
|      | Overall health                 |                   |       |
|      | Overall quality of life        |                   |       |
|      | Characteristics of individual/environment or PREM |                   |       |
| Diabetes Quality of Life (DQOL)-42 | ● | ● | ● |
| Diabetes Quality of Life (DQOL)-45 | ● | ● | ● |
| Diabetes Quality of Life (DQOL)-46 [51, 146–148] | ● | ● | ● |
| Diabetes Quality of Life (DQOL)-60 | ● | ● | ● |
| Diabetes Quality of Life (DQOL) revised version | ● | ● | ● |
| Diabetes Quality of Life (DQOL)-Brazil | ● | ● | ● |
| Diabetes Quality of Life (DQOL)-Brazil-8 | ● | ● | ● |
| Diabetes Quality of Life (DQOL)-Chinese-24 | ● | ● | ● |
| Diabetes Quality of Life (DQOL)-Arabic-29 | ● | ● | ● |
| Diabetes Quality of Life (DQOL)-Spanish-43 | ● | ● | ● |
### Table 2 (continued)

| PROM | Health-related quality of life | Other |
|------|--------------------------------|-------|
|      | Symptom status | Functional status | General health perception | Overall quality of life | Characteristics of individual/environment or PREM |
|      | Diabetes related symptoms | Physical symptoms | Mental symptoms | Physical function | Psychological function | Social function | Overall health | Overall quality of life | General health perceptions, self-rated health | Overall quality of life/ well-being |
|      | Pain | Energy/ fatigue | Sleep | Distress | Anxiety/ worry | Depression | Activities of daily living | Sexual function | Emotional function/ cognition | Social function/ participation |  |
| Iranian Diabetes Quality of Life (IRDQoL)-41 | [156, 157] |  |  |  |  |  |  |  |  |  |  |  |
| Diabetes-specific Quality of Life scale (D-QOL)-34 | ● |  |  |  |  |  |  |  |  |  |  |  |
| Type 2 Diabetes Symptom Checklist (DSC) | [159] | ● |  |  |  |  |  |  |  |  |  |  |
| Diabetes Symptom Checklist-Revised (DSC-R) | [160, 161] | ● |  |  |  |  |  |  |  |  |  |  |
| Korean- Diabetes Symptom Checklist-Revised (K-DSC-R) | [162] | ● |  |  |  |  |  |  |  |  |  |  |
| Diabetes Symptom Self-Care Inventory (DSSCI) | ● |  |  |  |  |  |  |  |  |  |  |  |
| Elderly Diabetes Burden Scale (EDBS) | [36] | ● |  |  |  |  |  |  |  |  |  |  |
| Edinburgh Depression Scale (EDS) | [163] | ● |  |  |  |  |  |  |  |  |  |  |
| EuroQol (EQ)-5D-3L | [47, 55, 72, 127, 164–175] | ● |  |  |  |  |  |  |  |  |  |  |
| EuroQol (EQ)-5D-5L | [170–173, 175–179] | ● |  |  |  |  |  |  |  |  |  |  |
| PROM | Health-related quality of life | Other |
|------|--------------------------------|-------|
|      | **Symptom status**            | **Functional status** | **General health perception** | **Overall quality of life** | **Characteristics of individual/environment or PREM** |
|      | Diabetes related symptoms     | Physical symptoms | Mental symptoms | Physical function | Psychological function | Social function | Overall health | Overall quality of life |        |
|      | Pain                          | Energy/ fatigue | Sleep          | Distress         | Anxiety/ worry | Depression        | Activities of daily living | Sexual function | Emotional function/ cognition | Social function/ participation | Overall health perceptions, self-rated health | Overall quality of life/ well-being |
|      | 13-item Fatigue subscale of the FACIT-F [180] | | | | | | | | | | | |
|      | General well-being schedule [181] | | | | | | | | | | | |
|      | Golombok-Rust Inventory of Sexual Satisfaction (GRISS) [182] | | | | | | | | | | | |
|      | Hand Function Disability Scale (HFDS) [120] | | | | | | | | | | | |
|      | the Worry subscale from the Hypoglycemia Fear Survey (HFS-W) [183] | | | | | | | | | | | |
|      | Hypoglycemia Perspectives Questionnaire (HPQ) [184] | | | | | | | | | | | |
|      | Health Status Questionnaire (HSQ) 2.0 [38] | | | | | | | | | | | |
|      | Health Utilities Index Mark 2 (HUI2) [40] | | | | | | | | | | | |
|      | Health Utilities Index Mark 3 (HUI3) [40, 185, 186] | | | | | | | | | | | |
|      | Impact of Weight on Quality of Life-Lite (IWQOL-lite) [187] | | | | | | | | | | | |
| PROM                                      | Health-related quality of life | Other                                                                 |
|-------------------------------------------|-------------------------------|----------------------------------------------------------------------|
|                                            | Symptom status                | General health perception | Overall quality of life | Characteristics of individual/environment or PREM |
|                                            | Functional status             |                          |                          |                                                      |
|                                            | Diabetes related symptoms     | Physical function | Psychological function | Social function | Overall health | Overall quality of life |                                                      |
|                                            | Physical symptoms             | Mental symptoms          |                           |                          |              |                          |                                                      |
|                                            | Pain                          |                        | Distress                  | Anxiety/ worry | Depression | Activities of daily living | Sexual function | Emotional function/cognition | Social function/participation | General health perceptions, self-rated health | Overall health | Overall quality of life/ well-being |
|                                            | Energy/ fatigue               |                        |                           |                          |              |                          |                                                      |
|                                            | Sleep                         |                        |                           |                          |              |                          |                                                      |
|                                            |                                |                        |                           |                          |              |                          |                                                      |

- Impact of Weight on Quality of Life-Lite-Clinical Trials (IWQOL-Lite-CT) [188, 189]
- Kessler-10 Psychological Distress scale (K10) [129]
- LQD Quality of Life with Diabetes (LQD) [48]
- Menopause-specific Quality of Life (MENQOL) [190]
- Michigan Hand Outcomes Questionnaire (MHQ) [120]
- MOS Six-Item Sleep Scale [191]
- National Diabetes Register (NDR) survey [192–194]
- Neuropathy- and Foot Ulcer–Specific Quality of Life Instrument (NeuroQoL) [195]
| PROM | Health-related quality of life | Functional status | Other | General health perception | Overall quality of life | Characteristics of individual/environment or PREM |
|------|-------------------------------|-------------------|-------|--------------------------|------------------------|----------------------------------|
|      | Symptom status                |                   |       |                          |                        |                                  |
|      | Diabetes related symptoms     | Physical symptoms | Mental symptoms | Physical function | Psychological function | Social function | Overall health | Overall quality of life |
|      | Pain                          | Energy/fatigue    | Sleep  | Distress                  | Anxiety/worry          | Depression             | Activities of daily living | Sexual function | Emotional function/cognition | Social function/participation | General health perceptions, self-rated health | Overall quality of life/ well-being |
|      | Physical function             | Psychological function | Social function | Overall health | Overall quality of life |
|      | Psychological function        | Social function | Overall quality of life |
|      | Overall quality of life       | Characteristics of individual/environment or PREM |
|      |                               |                   |       |                          |                        |                                  |
|      |                               |                   |       |                          |                        |                                  |
| Nottingham Health Profile (NHP) [196] | ● ● ● ● ● ● ● ● ● | ● ● ● ● ● ● ● ● ● | ● ● ● ● ● ● ● ● ● | ● ● ● ● ● ● ● ● ● | ● ● ● ● ● ● ● ● ● | ● ● ● ● ● ● ● ● ● |
| Short Form Problem Areas in Diabetes (PAID)-1 [197] | ● ● ● | ● ● ● |
| Problem areas in diabetes (PAID)-5 [197–199] | ● ● ● |
| Problem areas in diabetes (PAID)-16 [200, 201] | ● ● ● |
| Problem areas in diabetes (PAID)-20 [111, 112, 129, 201–216] | ● ● ● |
| Psychological General Well-Being Index (PGWB) [169] | ● ● ● |
| Patient-reported outcomes in Thai patients with type 2 diabetes mellitus (PRO-DM-Thai) [28] | ● | ● ● ● ● ● ● ● ● ● |
| Pittsburg Sleep Quality Index (PSQI) [217] | ● |
| Quality of life (QOL) questionnaire [37] | ● ● | ● ● |

Table 2 (continued)
| PROM | Health-related quality of life | Other |
|------|--------------------------------|-------|
|      | Symptom status                |       |
|      | Functional status             |       |
|      | General health perception     |       |
|      | Overall quality of life       |       |
|      | Characteristics of individual/environment or PREM | |
|      | Diabetes related symptoms     |       |
|      | Physical symptoms             |       |
|      | Mental symptoms               |       |
|      | Physical function             |       |
|      | Psychological function        |       |
|      | Social function               |       |
|      | Overall health                |       |
|      | Overall quality of life       |       |
|      | Characteristics of life       |       |
|      | Characteristics of living     |       |

- Impact of hypoglycemia on the HRQoL of type 2 diabetes patients (QoLHYPO©) questionnaire [218]
- Quality of Life for Indian diabetes Patients (QOLID) [34]
- Quality of life scale for Iraqi Diabetes patients (QOLSID) [219]
- Self-completion instrument for diabetes [220]
- Self-perception of health [39]
- 12-Item Short Form Health Survey (SF-12) [40–42]
- 20-item Short Form Health Survey (SF-20) [43]
- 36-Item Short Form Health Survey (SF-36) [29, 44–55]
| PROM | Health-related quality of life |          |          |          |          |          |          |          |          |          | Overall quality of life | Characteristics of individual/ environment or PREM |
|------|--------------------------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------------------------|-----------------------------------------------|
|      | Symptom status                 |          | Functional status | General health perception |          |          |          |          |          |          | Overall quality of life | Characteristics of individual/ environment or PREM |
|      | Diabetes related symptoms      | Physical symptoms | Mental symptoms | Physical function | Psychological function | Social function | Overall health |          |          |          | Overall quality of life | Characteristics of individual/ environment or PREM |
|      | Pain                           | Energy/ fatigue | Sleep      | Distress | Anxiety/ worry | Depression | Activities of daily living | Sexual function | Emotional function/ cognition | Social function/ participation | Overall health | Characteristics of individual/ environment or PREM |
| Short Form Problem Areas in Diabetes in Chinese (SF-PAID-C) | ● ● ● ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● |
| Patient Health Questionnaire (PHQ)-4 | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● |
| Patient Health Questionnaire (PHQ)-9 | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● |
| Pictorial Representation of Illness and Self Measure Revised II (PRISM-RII) | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● |
| Questionnaire on Stress in Diabetic Patients (QSD) | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● |
| Questionnaire on Stress in Patients with Diabetes-Revised (QSD-R) | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● |
| Questionnaire on Stress in Patients with Diabetes-Revised-Turkish (QSD-R-TR) | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● | ● |
Table 2 (continued)

| PROM | Health-related quality of life | Other |
|------|--------------------------------|-------|
|      |Symptom status                 |       |
|      |Functional status              |       |
|      |Overall quality of life        |       |
|      |Characteristics of individual/environment or PREM |
| PROM | Diabetes related symptoms | Physical symptoms | Mental symptoms | Physical function | Psychological function | Social function | Overall health | Overall quality of life | General health perception |
|      | symptom status | Pain | Energy/fatigue | Sleep | Distress | Anxiety/worry | Depression | Activities of daily living | Sexual function | Emotional function/cognition | Social function/participation | General health perceptions, self-rated health | Overall quality of life/ well-being |
| Questionnaire on Stress in Patients with Diabetes-Revised-Turkish-Cyprus (QSD-R-TR) [230] | | | | | | | | | | | | |
| Sexual Quality of Life questionnaire-Female (SQOL-F) [231] | | | | | | | | | | | | |
| Type 2 Diabetes Distress Assessment System (T2-DDAS) [232] | | | | | | | | | | | | |
| Well-being questionnaire (W-BQ) 12 [233, 234] | | | | | | | | | | | | |
| Well-being questionnaire (W-BQ) 22 [24, 48, 235] | | | | | | | | | | | | |
| Well-being questionnaire (W-BQ) 28 [236] | | | | | | | | | | | | |
| Well-being and Treatment Satisfaction scales (W-BQ) [237] | | | | | | | | | | | | |
| Well-being Enquiry for Diabetics (WED) [56] | | | | | | | | | | | | |
| The World Health Organisation-Five Well-Being Index (WHO-5) [55, 238–241] | | | | | | | | | | | | |
| PROM | Health-related quality of life | Functional status | Other |
|------|-------------------------------|-------------------|-------|
|      | Symptom status                |                   |       |
|      | Diabetic related symptoms     |                   |       |
|      | Physical symptoms             |                   |       |
|      | Mental symptoms               |                   |       |
|      | Diabetes related symptoms     |                   |       |
|      | Physical symptoms             |                   |       |
|      | Mental symptoms               |                   |       |
|      | Functional status             |                   |       |
|      | Physical function             |                   |       |
|      | Psychological function        |                   |       |
|      | Social function               |                   |       |
|      | Overall health                |                   |       |
|      | Overall quality of life       |                   |       |
|      | Characteristics of individual/ environment or PREM | | |

| World Health Organisation Quality of Life (WHOQOL-100) [23] | ● | ● | ● | ● | ● | ● |
| World Health Organisation Quality of Life (WHOQOL-BREF [24, 25, 44, 157, 242] | ● | ● | ● | ● | ● | ● |
heterogeneity, for example in the social function level, with many different constructs being measured, such as social well-being, restriction of social function, social role fulfillment and psychosocial disabilities, but also having friends, work and relationships, alienation, barriers and social burden.

In addition, 16/116 of the PROMs measured global quality of life. 61/116 of the HRQOL PROMs also include characteristics of the individual or environment and even PREMs, rather than only aspects of HRQOL. This includes characteristics of the individual, for example positive attitude [29–31], characteristics of the environment such as financial situation [31–34] or PREMs, such as treatment satisfaction [28, 34–37]. For one PROM it was specifically mentioned that demographics were also assessed as part of the PROM, namely the Diabetes Quality of Life Clinical Trial Questionnaire (DQLCTQ) [35].

Finally, only 9/116 of the HRQOL PROMs measured all aspects of HRQOL based on the Wilson & Cleary model. These PROMs include the DQLCTQ [35], Health Status Questionnaire (HSQ) 2.0 [38], PRO-DM-Thai [28], Quality of Life for Indian diabetes Patients (QOLID) [34], Self-perception of health [39], 12-Item Short Form Health Survey (SF-12) [40–42], 20-item Short Form Health Survey (SF-20) [43], 36-Item Short Form Health Survey (SF-36) [29, 44–55] and Well-being Enquiry for Diabetics (WED) [56]. Also, despite the fact that the authors of the included papers claimed that the PROM aims to measure at least (aspects of) symptom status, functional status, general health perceptions or HRQOL, 8/116 of the PROMs measured only global quality of life or PREMs and no HRQOL construct(s).

5 Discussion

In our systematic review of the literature, from a total of 220 studies, we identified 116 unique PROMs aiming to measure (aspects of) HRQOL in people with type 2 diabetes. Of these HRQOL PROMs, 80% (of the subscales) measured symptom status, 50% measured functional status and 20% measured general health perceptions. In the PROMs, 15% of the PROMs (subscales) measured global quality of life. 50% of the 116 PROMs (subscales) also include characteristics of the individual (e.g. aspects of personality, coping) or environment (e.g. social or financial support) and patient-reported experience measures (PREMs, e.g. measure of a patient’s perception of their personal experience of the healthcare they have received, e.g. treatment satisfaction), which are not part of the HRQOL construct. The (sub-)scales of these PROMs thus presented a great heterogeneity of constructs, with about 5% of the PROMs measuring all aspects of HRQOL based on the Wilson & Cleary model and about 5% not measuring HRQOL (constructs) at all. This review shows the great amount of PROMs developed. Furthermore, some PROMs are very long, which may suggest poor acceptability.

When conducting this review we faced multiple challenges. First, the terminology used for the constructs the (subscales of the) PROMs measure was unclear and definitions of the constructs are mostly lacking. It was therefore unclear to us whether names of the PROMs and subscales represent different or the same concepts. This large variability in operationalization of HRQOL made it difficult to classify the PROMs. This lack of clarity about what a PROM actually measures also makes it difficult or even impossible to know whether a PROM has good validity (i.e. whether it measures what it is supposed to measure). A second challenge was that information regarding the characteristics of the PROMs was often lacking or misleading. For example, the availability and the number and names of (sub-)scales and the number of items per (sub-)scale were often not presented in the paper. As a result we had to consult additional resources, such as other articles, Google (e.g. manuals or websites) or the PROQOLID database [22]. However, even this strategy sometimes failed, which may have resulted in an incomplete overview of the PROMs (Table 1). This poor reporting is possibly due to older papers not meeting our modern day standards, but hampers researchers and health care providers to select the best PROM for their purpose. The poor information status and very large heterogeneity in PROMs (subscales) is not unique to the diabetes field [243]. PROMs are increasingly used as primary outcome measures in studies and tools for clinical decision making. The poor state makes it very difficult, and potentially even impossible, to compare study results or cohorts directly, since all PROMs measure different constructs and thus different outcomes. In this review, we did not systematically evaluate the measurement properties of the PROMs, such as content validity, construct validity, reliability and responsiveness. Therefore, researchers should be careful when using this review to select PROMs as we cannot guarantee that the content of the PROMs or subscales really match the intended construct and we cannot guarantee that the PROMs are reliable and responsive to change [244].

This review highlights the great amount of PROMs developed and used and the heterogeneity of their content. We feel there is a need to reach consensus on which PROM to measure HRQOL as well as which HRQOL aspects are most important to measure for people with type 2 diabetes. One solution is the development of Core Outcome Sets (COS) or Standard Sets, which are agreed sets of outcomes (and associated measurement instruments) to be measured in all trials or clinical practice. International organizations such as COMET (https://www.comet-initiative.org/) and ICHOM (www.ichom.org) have developed such COSs for type 2 diabetes [245–247]. However, the value of these COSs is limited, because they have a strong focus on biological outcomes, such as glycemic control [199–201] and there was limited input from people with expertise in PRO measurement or people with type 2 diabetes. This resulted in dissimilar recommendations regarding PROMs between the initiatives, but also inclusion of
the ‘Diabetes Treatment Satisfaction Questionnaire’ (which is a PREM) and only inclusion of activities of daily living and overall quality of life, and no other aspects of HRQOL [245–247]. Qualitative studies show the importance of ‘To live a good life with diabetes’ for people with type 2 diabetes [248].

6 Limitations and strengths

This systematic review has several limitations and strengths. The first limitation is that the classification of the constructs was made based on reviewing the names of (sub)scales and not their content. We acknowledge that this may have resulted in misclassification, because of misleading construct names that do not reflect the content. It would have been better to look at the content of the PROMs to determine what aspects of HRQOL they measure, rather than using the names of the instrument (scales). We have done so for part of the PROMs, i.e. only the disease-specific HRQOL PROMs, in a separate review [244] where we did a full content validity assessment of these PROMs. However, the fact that there might be a mismatch between our classification and what the PROMs actually measure is a striking finding of this review. It is problematic that the name and description of a PROM as published in the literature does not tell us, or may even mislead us about what the PROM actually measures. This strongly hampers researchers and clinicians to select the optimal PROM for their purpose. Second, even though using an extensive search string, we identified 27% of the included studies from reference lists. However, by using this extensive search strategy our review is more complete than previous reviews specifically on HRQOL in those with type 2 diabetes. For example, we identified over 50 HRQOL PROMs with our search that were not found in the Wee et al. review [15]. We speculate this discrepancy is due to their lack of reference checking. Strengths of this systematic review were the extensive search with no restrictions on publication data or language as well as reference checking. Second, the use of a conceptual model to assess which aspects of HRQOL were measured by PROM (sub)scales provides helpful information for researchers and health care providers searching for a PROM to measure one or more specific aspects of HRQOL, that is not provided in previous reviews. As stated before, instrument selection should be based on which relevant aspects of HRQOL one wants to measure and different aspects of HRQOL can be measured with subscales from different PROMs. Even though the Wilson and Cleary model is the most frequently used, other conceptual models are available that might be preferred by other researchers [4]. However, our conclusion on the heterogeneity and lack of clarity of constructs being measured with PROMs in the diabetes field would not have been different. Finally, despite our systematic review providing an overview and identifying the difficulties of the field, it also provides caution and food for thought regarding the use of the PROMs. Future studies are needed to provide definitive recommendations on which PROMs to use in people with type 2 diabetes.

7 Conclusion

A large number of PROMs are available for people with type 2 diabetes, which intend to measure (aspects of) HRQOL. These PROMs measure a large variety of (sub)constructs, which are not all HRQOL constructs, with a small amount of PROMs not measuring HRQOL at all. There is a need for consensus on which aspects of HRQOL should be measured in people with type 2 diabetes and which PROMs to use in research and daily practice.

Appendix 1 Search strategy

PubMed type 2

#1 Diabetes type 2

((Diabet*[tiab] AND (“non insulin*[tiab] AND depend*[tiab]) OR (“noninsulin*[tiab] AND depend*[tiab]) OR “type 2”[tiab] OR “type II” [tiab]) OR iddm*[tiab] OR niddm*[tiab] OR “glucose intolerance”[tiab] OR “insulin resistant”[tiab] OR “insulin resistance”[tiab]).

#2 Modified filter for studies on measurement properties*

"Validation Studies”[pt] OR “psychometrics”[MeSH] OR psychometr*[tiab] OR clinimetr*[tw] OR clinometr*[tw] OR "outcome assessment (health care)”[MeSH] OR "outcome assessment”[tiab] OR "outcome measure”[tw] OR "observer variation”[MeSH] OR "observer variation”[tiab] OR "reproducibility of results”[MeSH] OR reproducib*[tiab] OR "discriminant analysis”[MeSH] OR reliab*[tiab] OR unreliab*[tiab] OR valid*[tiab] OR "coefficient of variation”[tiab] OR homogeneity[tiab] OR homogeneous[tiab] OR "internal consistency”[tiab] OR (cronbach*[tiab] AND (alpha[tiab] OR alphas[tiab])) OR (item[tiab] AND (correlation*[tiab] OR selection*[tiab] OR reduction*[tiab])) OR agreement[tw] OR precision[tw] OR imprecision[tw] OR "precise values”[tw] OR test–retest[tiab] OR (test[tiab] AND retest[tiab]) OR (reliab*[tiab] AND test[tiab] OR retest[tiab]) OR stability[tiab] OR interrater[tiab] OR inter-rater[tiab] OR intra-rater[tiab] OR intra-rater[tiab] OR intertest[tiab] OR inter-tester[tiab] OR intra-tester[tiab] OR intra-tester[tiab] OR interobserver[tiab] OR inter-observer[tiab] OR intraobserver[tiab] OR intra-observer[tiab] OR intertechnician[tiab] OR inter-technician[tiab]
OR intratechnician[tiab] OR intra-technician[tiab] OR interexaminer[tiab] OR inter-examiner[tiab] OR intraexaminer[tiab] OR intra-examiner[tiab] OR inter-assay[tiab] OR intraassay[tiab] OR intra-assay[tiab] OR interindividual[tiab] OR inter-individual[tiab] OR intra-individual[tiab] OR interparticipan[tiab] OR inter-participan[tiab] OR intraparticipan[tiab] OR intra-participan[tiab] OR kappa[tiab] OR kappas[tiab] OR kappas[tiab] OR repeatab*[tw] OR (replciab*[tw] OR repeated[tw]) AND (measure[tw] OR measures[tw] OR findings[tw] OR test[tw] OR tests[tw])) OR generalizat*[tiab] OR generalisa*[tiab] OR concordance[tiab] OR (intraclass[tiab] AND correlation*[tiab]) OR discriminative[tiab] OR "known group"[tiab] OR "factor analysis"[tiab] OR "factor analyses"[tiab] OR "factor structure"[tiab] OR "factor structures"[tiab] OR subscale*[tiab] OR (multitrait[tiab] AND scaling[tiab] AND (analysis[tiab] OR analyses[tiab])) OR "item discriminant"[tiab] OR "interscale correlation*"[tiab] OR error[tiab] OR errors[tiab] OR "individual variability"[tiab] OR "interval variability"[tiab] OR "rate variability"[tiab] OR (variability[tiab] AND (analysis[tiab] OR values[tiab])) OR "standard error of measurement"[tiab] OR responsive[tiab] OR (limit[tiab] AND detection[tiab]) OR "minimal detectable concentration"[tiab] OR interpretab*[tiab] OR (minimal[tiab] OR minimally[tiab] OR clinical[tiab] OR clinically[tiab]) AND (important[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR (small*[tiab] AND (real[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR "meaningful change"[tiab] OR "ceiling effect"[tiab] OR "floor effect"[tiab] OR "Item response model"[tiab] OR IRT[tiab] OR Rasch[tiab] OR "Differential item functioning"[tiab] OR DIF[tiab] OR "computer adaptive testing"[tiab] OR "item bank"[tiab] OR "cross-cultural equivalence"[tiab] OR scale[tiab] OR scales[tiab] OR score[tiab] OR scores[tiab] OR status[tiab] OR survey[tiab] OR surveys[tiab]).

(#1 AND #2 AND #3) NOT ("addresses"[Publication Type] OR "biography"[Publication Type] OR "case reports"[Publication Type] OR "comment"[Publication Type] OR "directory"[Publication Type] OR "editorial"[Publication Type] OR "festschrift"[Publication Type] OR "interview"[Publication Type] OR "letter"[Publication Type] OR "news"[Publication Type] OR "newspaper article"[Publication Type] OR "patient education handout"[Publication Type] OR "popular works"[Publication Type] OR "congresses"[Publication Type] OR "consensus development conference"[Publication Type] OR "consensus development conference, nih"[Publication Type] OR "practice guideline"[Publication Type] NOT ("animals"[MeSH Terms] NOT "humans"[MeSH Terms]).

EMBASE search April 29, 2019

#1 Diabetes type 2

(‘Diabet*:ti,ab AND (((non insulin*:ti,ab AND depend*:ti,ab) OR (noninsulin:ti,ab AND depend*:ti,ab) OR 'type 2':ti,ab OR 'type II':ti,ab)) OR iddm:ti,ab OR niddm:ti,ab OR 'glucose intolerance':ti,ab OR 'insulin resistant':ti,ab OR insulin resistance':ti,ab.

#2 Modified filter for studies on measurement properties*

'data collection method'/exp OR 'validation study'/exp OR 'feasibility study'/exp OR 'pilot study'/exp OR 'psychometry'/exp OR 'reproducibility'/exp OR 'reproducibility'/exp OR 'reproducibility'/exp OR 'reproducibility'/exp OR 'reproducibility'/exp OR 'reproducibility'/exp OR 'validity'/exp OR 'reliability'/exp OR 'audit':ti,ab OR 'alpha':ti,ab OR 'alphas':ti,ab OR psychometr*:ab,ti OR clinimetr*:ab,ti OR clinometr*:ab,ti OR 'observer variation'/exp OR 'observer variation':ab,ti OR 'discriminant analysis'/exp OR 'validity'/exp OR 'reliability'/exp OR 'valid*':ab,ti OR valid*:ab,ti OR 'internal consistency':ab,ti OR (cronbach*:ab,ti AND ('alpha':ab,ti OR 'alphas':ab,ti)) OR 'item correlation':ab,ti OR 'item correlations':ab,ti OR 'item selection':ab,ti OR 'item selections':ab,ti OR 'item reduction':ab,ti OR 'item reductions':ab,ti OR 'agreement':ab,ti OR 'precision':ab,ti OR 'imprecision':ab,ti OR 'precise values':ab,ti OR 'test–retest':ab,ti OR 'test':ab,ti AND 'retest':ab,ti) OR (reliab*:ab,ti AND ('test':ab,ti OR 'retest':ab,ti) OR 'stability':ab,ti OR 'inter-rater':ab,ti OR 'inter-rater':ab,ti OR 'intrarater':ab,ti OR 'intrarater':ab,ti OR 'intrarater':ab,ti OR 'inter-rater':ab,ti OR 'inter-tester':ab,ti OR 'interrater':ab,ti OR 'intra-rater':ab,ti OR 'intranrater':ab,ti OR 'intrarater':ab,ti OR 'intranrater':ab,ti OR 'intradisc':ab,ti OR 'intradisc':ab,ti OR 'intra-assay':ab,ti OR 'intra-observer':ab,ti OR 'intraobserver':ab,ti OR 'intra-examiner':ab,ti OR 'intra-technician':ab,ti OR 'intra-technician':ab,ti OR 'intraexaminer':ab,ti OR 'intra-examiner':ab,ti OR 'intra-technician':ab,ti OR 'intra-technician':ab,ti OR 'intra-examiner':ab,ti OR 'intra-assay':ab,ti OR 'intra-assay':ab,ti

* #3 PROM filter (developed by the University of Oxford, see www.comin.nl)

(HR-PRO[tiab] OR HPROM[tiab] OR HRQL[tiab] OR HRQoL[tiab] OR QL[tiab] OR QOL[tiab] OR quality of life[tw] OR life quality[tw] OR health index*[tiab] OR health indices[tiab] OR health profile*[tiab] OR health status[tw] OR ((patient[tiab] OR self[tiab] OR child[tiab] OR parent[tiab] OR carer[tiab] OR proxy[tiab]) AND ((report[tiab] OR reported[tiab] OR reporting[tiab]) OR (rated[tiab] OR rating[tiab] OR ratings[tiab]) OR based[tiab] OR assessed[tiab] OR assessment[tiab] OR assessments[tiab]))) OR ((disability[tiab] OR function[tiab] OR functional[tiab] OR functions[tiab] OR subjective[tiab] OR utility[tiab] OR utilities[tiab] OR wellbeing[tiab] OR well being[tiab]) AND (index[tiab] OR indices[tiab] OR instrument[tiab] OR instruments[tiab] OR measure[tiab] OR measures[tiab] OR questionnaire[tiab] OR questionnaires[tiab] OR profile[tiab] OR profiles[tiab] OR scale[tiab] OR scales[tiab] OR score[tiab] OR scores[tiab] OR status[tiab] OR survey[tiab] OR surveys[tiab]).

(#1 AND #2 AND #3) NOT ("addresses"[Publication Type] OR "biography"[Publication Type] OR "case reports"[Publication Type] OR "comment"[Publication Type] OR "directory"[Publication Type] OR "editorial"[Publication Type] OR "festschrift"[Publication Type] OR "interview"[Publication Type] OR "letter"[Publication Type] OR "news"[Publication Type] OR "newspaper article"[Publication Type] OR "patient education handout"[Publication Type] OR "popular works"[Publication Type] OR "congresses"[Publication Type] OR "consensus development conference"[Publication Type] OR "consensus development conference, nih"[Publication Type] OR "practice guideline"[Publication Type] NOT ("animals"[MeSH Terms] NOT "humans"[MeSH Terms]).
OR 'interindividual':ab,ti OR 'inter-individual':ab,ti OR 'intraindividual':ab,ti OR 'intra-individual':ab,ti OR 'interparticipant':ab,ti OR 'inter-participant':ab,ti OR 'intraparticipant':ab,ti OR 'intra-participant':ab,ti OR 'kappa':ab,ti OR 'kappas':ab,ti OR 'coefficient of variation':ab,ti OR 'repeatable':ab,ti OR 'repeated':ab,ti AND (measure':ab,ti OR measures':ab,ti OR 'findings':ab,ti OR 'test':ab,ti OR 'tests':ab,ti) OR generalize*:ab,ti OR generalises*:ab,ti OR 'concordance':ab,ti OR (intraclass':ab,ti AND correlation*:ab,ti) OR 'discriminative':ab,ti OR 'known group':ab,ti OR 'factor analysis':ab,ti OR 'factor analyses':ab,ti OR 'factor structure':ab,ti OR 'factor structures':ab,ti OR 'dimensionality':ab,ti OR subscale*:ab,ti OR 'multitrait scaling analysis':ab,ti OR 'multitrait scaling analyses':ab,ti OR 'item discriminant':ab,ti OR 'item discriminant':ab,ti OR 'interitem correlation':ab,ti OR 'interitem correlations':ab,ti OR 'error':ab,ti OR 'errors':ab,ti AND (measure':ab,ti OR correlat':ab,ti OR evaluate':ab,ti OR 'accuracy':ab,ti OR 'accurate':ab,ti OR 'precision':ab,ti OR 'mean':ab,ti) OR 'individual variability':ab,ti OR 'interval variability':ab,ti OR 'rate variability':ab,ti OR 'variability analysis':ab,ti OR 'standard error of measurement':ab,ti OR 'small':ab,ti OR 'limit':ab,ti AND 'detection':ab,ti OR 'minimal detectable concentration':ab,ti OR interpret':ab,ti OR (small':ab,ti AND 'real':ab,ti OR 'detectable':ab,ti) OR 'meaningful change':ab,ti OR 'minimal important change':ab,ti OR 'minimal important difference':ab,ti OR 'minimally important change':ab,ti OR 'minimally important difference':ab,ti OR 'minimal detectable change':ab,ti OR 'minimal detectable difference':ab,ti OR 'minimally detectable change':ab,ti OR 'minimally detectable difference':ab,ti OR 'minimal real change':ab,ti OR 'minimal real difference':ab,ti OR 'minimally real change':ab,ti OR 'minimally real difference':ab,ti OR 'ceiling effect':ab,ti OR 'floor effect':ab,ti OR 'item response model':ab,ti OR 'irt':ab,ti OR 'rasch':ab,ti OR 'differential item functioning':ab,ti OR 'dif':ab,ti OR 'computer adaptive testing':ab,ti OR 'item bank':ab,ti OR 'cross-cultural equivalence':ab,ti.

#3 PROM filter (developed by the University of Oxford, see www.comin.nl)

(HP-PRO:ti,ab OR HRPRO:ti,ab OR HRPQoL:ti,ab OR HRPQL:ti,ab OR HRQoL:ti,ab OR QL:ti,ab OR QoL:ti,ab OR 'quality of life':ti,ab OR 'life quality':ti,ab OR 'health index':*ti,ab OR 'health indices':ti,ab OR 'health profile':*ti,ab OR 'health status':ti,ab OR ((patient:ti,ab OR self:ti,ab OR child:ti,ab OR parent:ti,ab OR carer:ti,ab OR proxy:ti,ab) AND ((report:ti,ab OR reported:ti,ab OR reporting:ti,ab) OR (rated:ti,ab OR rating:ti,ab OR ratings:ti,ab) OR based:ti,ab OR (assessed:ti,ab OR assessment:ti,ab OR assessments:ti,ab))) OR ((disability:ti,ab OR function:ti,ab OR functional:ti,ab OR functions:ti,ab OR subjective:ti,ab OR utility:ti,ab OR utilities:ti,ab OR wellbeing:ti,ab OR 'well being':ti,ab) AND (index:ti,ab OR indices:ti,ab OR instrument:ti,ab OR instruments:ti,ab OR measure:ti,ab OR measures:ti,ab OR questionnaire:ti,ab OR questionnaire:ti,ab OR profile:ti,ab OR profiles:ti,ab OR scale:ti,ab OR scales:ti,ab OR score:ti,ab OR scores:ti,ab OR status:ti,ab OR survey:ti,ab OR surveys:ti,ab)).

#4 publicatie types

#3 AND ('article'/it OR 'article in press'/it OR 'review'/it).

#5 not animals

#4 NOT ([animals]/lim NOT [humans]/lim).

* Modified from Terwee et al. (19): a few search terms were left out to decrease the number of abstracts needed to be read.

Supplementary information

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Author contributions

All authors have contributed in a meaningful way. CBT and CACP had the original idea, and CBT completed the searches. JWB, PJME, AAH, IH, MLG, GM, CACP, FR, CBT and MW conducted the screening for relevant papers and LG, MLG, FR and CBT extracted the data. MLG, LG, FR and CBT conducted the analyses and made the first draft of the manuscript. All authors (JWB, PJME, IH, LG, MLG, GM, CACP, FR and CBT) have commented on the manuscript and likewise, all authors have read and approved the final manuscript. FR and CBT are the guarantors of this work.

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# Declarations

Conflict of interest

The authors declare that there is no conflict of interest that could be perceived as prejudicing the impartiality of the research reported.

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Authors and Affiliations

Marlous Langendoen-Gort\textsuperscript{1,3} · Lenka Groeneveld\textsuperscript{2,3} · Cecilia A. C. Prinsen\textsuperscript{2,4} · Joline W. Beulens\textsuperscript{2,3,5} · Petra J. M. Elders\textsuperscript{1,3,5} · Ilana Halperin\textsuperscript{6} · Geetha Mukerji\textsuperscript{6,7} · Caroline B. Terwee\textsuperscript{2,4} · Femke Rutters\textsuperscript{2,3,5}

\textsuperscript{1} General Practice, Amsterdam UMC, Location Vrije Universiteit Amsterdam, de Boelelaan 1117, Amsterdam, Netherlands
\textsuperscript{2} Epidemiology and Data Science, Amsterdam UMC, Location Vrije Universiteit Amsterdam, de Boelelaan 1117, Amsterdam, Netherlands
\textsuperscript{3} Amsterdam Public Health, Health Behaviors & Chronic Diseases, Amsterdam, The Netherlands
\textsuperscript{4} Amsterdam Public Health, Methodology, Amsterdam, The Netherlands
\textsuperscript{5} Amsterdam Cardiovascular Sciences, Diabetes & Metabolism, Amsterdam, The Netherlands
\textsuperscript{6} Department of Medicine, Temerty Faculty of Medicine, Sunnybrook Health Sciences Center, King’s College Circle, University of Toronto, Toronto, ON, Canada
\textsuperscript{7} Women’s College Hospital Institute for Health System Solutions and Virtual Care, 76 Grenville Street, Toronto, ON, Canada