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Running title: Measuring diabetes-specific quality of life

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Author contributions

JS and DC conceived the study and designed it with EHT, EC and SH. EHT developed the survey, managed data collection, and conducted data cleaning and analysis. All authors provided input into interpretation of results. EHT and JS prepared the first draft of the manuscript. All authors contributed to manuscript revisions and approved the final version.

Disclosure of interests

JS is a Director of AHP Research, which owns the copyright of the 'Diabetes QoL-Q'. All other authors declare no conflict of interests.

Novelty Statement

- Several diabetes-specific quality of life (QoL) measures have been published, differing in conceptualisation, content, length, structure, as well as the level of evidence for their development, psychometric evaluation and user acceptability.
- We present the first empirical head-to-head comparison of contemporary diabetes-specific QoL scales, examining acceptability, reliability, validity, and across-country reproducibility among adults with type 1 diabetes in the UK and Australia.
- While most scales had equivalent psychometric performance and acceptability, the strongest performing scale overall was the 7-item DAWN Impact of Diabetes Profile.
- Findings may inform future assessment of diabetes-specific QoL in routine care and clinical trials.

Structured Abstract

Aims: To compare the acceptability, reliability and validity of five contemporary diabetes-specific quality of life (QoL) scales among adults with type 1 diabetes in the UK and Australia.

Methods: Adults with type 1 diabetes (UK=1139, Australia=439) completed a cross-sectional, online survey including: ADDQoL, DCP, DIDP, DSQOLS and Diabetes QoL-Q, presented in randomised order. After completing each scale, participants rated it for clarity, relevance, ease of completion, length, and comprehensiveness. We examined scale acceptability (scale completion and user ratings), response patterns, structure (exploratory and confirmatory factor analyses), and validity (convergent, confirmatory, divergent, and known-groups). To assess cross-country reproducibility, analyses conducted on the UK dataset were replicated in the Australian dataset.

Results: Findings were largely consistent between countries. All scales were acceptable to participants: $\geq 90\%$ completing all items, and $\geq 80\%$ positive user ratings, except for DSQOLS' length. Scale structure was not supported for the DCP. Overall, in terms of acceptability and psychometric evaluation, the DIDP was the strongest performing scale, while the ADDQoL and Diabetes QoL-Q scales also performed well.

Conclusions: These findings suggest that the recently developed brief (7-item), neutrally-worded DIDP scale is acceptable to adults with type 1 diabetes and has the strongest psychometric performance. However, questionnaire selection should always be considered in the context of the research aims, study design and population, as well as the wider published evidence regarding both the development and responsiveness of the scales.

Keywords

Quality of life, patient-reported outcomes, type 1 diabetes, psychometrics

Introduction

Preserving quality of life (QoL) is an important objective of type 1 diabetes care [1] and a critical factor in an individual's willingness to integrate new diabetes treatments, technologies and/or complex self-care behaviours into their daily lives.[2] Over the past three decades, clinicians and researchers have increasingly acknowledged the importance of QoL in maintaining health, healthy behaviour and glycaemia,[1-5] though only 17% of clinical trials evaluating diabetes self-management training assess QoL or patient-reported outcomes.[6] Regulatory authorities require robust evidence that new diabetes treatments and technologies do, indeed, benefit QoL if such claims are to be made.[7] However, the scales used in clinical trials often measure (generic or diabetes-specific) emotional well-being, treatment satisfaction or generic health status, rather than the broader impact on QoL.[8,9] While these outcomes are also important, they miss an opportunity to understand the impact of diabetes and/or diabetes treatment/technologies on QoL (i.e. diabetes-specific QoL).[1]

Diabetes-specific QoL can be defined as an individual's perception of how their diabetes affects aspects of life that they perceive as important for their overall QoL.[1] There are currently several questionnaire measures available that assess the impact of type 1 diabetes on QoL, though no single measure is fit for every research purpose or clinical situation.[8] It is essential that measures are selected with a clear rationale and justification, whilst considering the suitability and rigour (reliability and validity) of that measure for the target population.[8, 10] While some measures are 'well-established', with considerable evidence of reliability and validity,[11, 12] others have been published more recently.[13, 14] To our knowledge, measures designed to assess diabetes-specific QoL have not been subject to a 'head-to-head' comparison. Furthermore, there are limited data on the relevance, ease of completion and acceptability of each measure, as deemed by the end user, i.e. the person with diabetes. It is vital that such measures not only minimise burden, [15] but are acceptable to those who will be asked to complete them in research studies and clinical practice.

Consequently, our aim was to compare the acceptability, reliability and validity of contemporary diabetes-specific QoL questionnaires completed concurrently by adults with type 1 diabetes in the UK, and examine their reproducibility in an Australian sample.

Participants and methods

The "Your Self-management And You: Quality of Life" (YourSAY:QoL) study was a cross-sectional, online survey of adults with type 1 or type 2 diabetes living in Australia or the United Kingdom (UK) conducted 4 September to 31 October 2017.

Ethical approval was granted from the Deakin University Human Research Ethics Committee (HEAG-H 03_2017; Australia) and the Yorkshire & The Humber -

Bradford Leeds Research Ethics Committee (17/YH/0234) and the Health Research Authority (IRAS ID: 228898; UK).

Participants and recruitment

Participants were eligible if they were adults (aged 18+ years), self-reporting a diagnosis of type 1 or type 2 diabetes, resident in the UK or Australia, and had access to an internet-enabled device (for survey completion). The target sample size was N=2000 (n=500 per diabetes type and country); sufficient to enable confirmatory factor analyses (>5 participants per item for any given questionnaire of interest). The overall eligible sample included 4,166 participants. The current study includes only those with type 1 diabetes (n=1,946, 47%) who attempted ≥ 1 of the diabetes-specific QoL questionnaires of interest (see Measures). Participants who exited the survey without attempting any diabetes-specific QoL questionnaire (n=368, 19%) were ineligible. Thus, the final eligible sample for this study is N=1,578.

Participants were recruited using convenience sampling through websites, e-newsletters/blogs and social media (Twitter, Facebook) via the researchers' professional and organisational accounts. A panel of 1,921 people with type 1 diabetes at Sheffield Teaching Hospitals NHS Trust who previously consented to be contacted for diabetes research studies were invited to participate via letter or email. In addition, a social media company was contracted to develop and promote targeted Facebook advertisements.

Procedure

Advertisements directed potential participants to the study website, which displayed study information and linked to the online survey hosted via Qualtrics™. Potential participants indicated consent (tick box), before completing eligibility screening and the survey. Ineligible participants were screened out automatically. Participants received a pop-up notification if survey items were missed, but completion was not compulsory. The median (interquartile range) time spent viewing the survey, regardless of diabetes type or early exit, was 25 (13-37) minutes.

Measures

The survey (described in Appendix S1) included variables relevant to the current study (described below) plus demographic characteristics (e.g. age, gender) and clinical characteristics (e.g. diabetes duration, insulin administration modality, diabetes-related complication diagnosis).

Contemporary diabetes-specific QoL questionnaires were identified for inclusion via published reviews [e.g. 8, 10] and a targeted literature search (published within the previous five years; search conducted December 2016 via Scopus). Scales (or relevant subscales of broader questionnaires) were selected for inclusion if they met the following criteria:

- a) published in academic journals (or known to the study team [13])
- b) available in English language
- c) developed for, or validated among, adults with type 1 diabetes.
- d) suitable for self-completion by adults

- e) assess diabetes-specific QoL, i.e. focused explicitly on aspects of life important for QoL and requiring respondents to rate the impact of diabetes on those aspects of life.

Five diabetes-specific QoL questionnaires were selected for inclusion.[11-14,16] Their development, scoring, and established psychometric properties are detailed in Table 1. Diabetes-specific QoL questionnaires were presented for completion in random order to reduce 'order effects', i.e. the possibility that respondents' answers are influenced by previous questions.

Following completion of each diabetes-specific QoL questionnaire, participants indicated their level of agreement ((5-point scale:1=strongly disagree, 3=neither agree nor disagree, to 5=strongly agree) with five statements relating to the clarity, relevance, completion ease, length, and comprehensiveness of each questionnaire. For example: "The questions were relevant to me".

The survey also included validated questionnaires and study-specific questions for the purposes of assessing the validity of the diabetes-specific QoL questionnaires. Specifically, validity was considered confirmed as follows:

- Concurrent validity: if correlations ≥ 0.4 were observed between diabetes specific QoL questionnaires.
- Convergent validity: if correlations ≥ 0.4 were observed with measures of similar, but distinct, constructs: generic health status (EQ-5D visual analogue scale, [19]), general emotional wellbeing (WHO-5, [20]), diabetes-specific distress (PAID, [21]), and diabetes-specific positive wellbeing (WBQ-28 subscale, [22]).
- Discriminant validity: if correlations ≤ 0.3 were observed with HbA1c, age and diabetes duration.
- Known-groups validity: if significant differences in scores were observed by insulin administration type (pump versus injection); presence of diabetes complications (none vs ≥ 1), and; experience of severe hypoglycaemia over the last 12 months (none vs ≥ 1). Use of insulin injections, presence of complications and experience of severe hypoglycaemia were expected to be associated with worse diabetes-specific QoL.

Statistical analysis

Data were analysed using IBM SPSS for Windows version 24 or Amos version 24 (Chicago, IL, USA), with $p < 0.05$ taken to indicate statistical significance.

Missing data were handled according to published guidance. Where unavailable (e.g. DSQOLS), composite scores were computed only for complete cases. Unless otherwise noted, separate analyses were conducted for each questionnaire, for the UK and Australian samples, to assess cross-cultural reproducibility.

Data screening and descriptive statistics

Descriptive statistics were calculated for demographic and clinical characteristics, as well as general and diabetes-specific well-being and QoL.

Diabetes specific QoL questionnaire item response patterns were examined and descriptive statistics were calculated at item- and scale-levels. Kolmogorov-Smirnov tests demonstrated that questionnaire data had non-normal distributions, necessitating use of non-parametric statistics. Ceiling and floor effects were identified at item- and scale-levels. The proportion of missing item responses were calculated, with high overall completion rates ($\geq 90\%$) taken as evidence of questionnaire acceptability. The n(%) of participants responding '(strongly) agree/disagree' to the 'user rating' questions was calculated.

Scale structure

Scale structure analyses were conducted on complete cases only. Two-tailed Spearman's rho correlations (r_s) were used to identify items with very high (>0.7) or very low (<0.3) inter-item correlations. Barlett's Test of Sphericity was assessed to check for inter-item correlations and the determinant was screened for multicollinearity.

Using random selection, the UK cohort was split into two independent subsamples of near-equal size to conduct exploratory factor analysis (EFA; subsample A) and confirmatory factor analysis (CFA; subsample B). EFA enables identification of problematic items where CFA does not support the published factor structure. CFA was replicated in the Australian sample to test for cross-country reproducibility; EFA was not conducted due to sample size. CFA, EFA, and internal consistency assess complete cases with list-wise deletion, treating non-applicable responses as missing. As such, analyses were replicated for the ADDQOL-19, DIDP and Diabetes QoL-Q, whereby non-applicable responses were temporarily recoded to a 'neutral' response (0=no impact or unimportant, and 3=neither agree nor disagree, respectively).[11]

A Kaiser-Meyer-Olkin statistic of >0.05 indicates sample size adequacy for EFA. Following unforced principal axis factor analysis with direct oblimin rotation (not shown), forced factor analyses were conducted based on published scale structure guidelines. Eigenvalues (>1), scree plots, percentage variance explained, and factor loadings were examined. Factor loadings ≥ 0.5 were considered meaningful, with multiple loadings of this magnitude indicative of strong, stable factors.[23]

CFA was conducted using maximum likelihood estimation to examine whether the factor structure of the diabetes-specific QoL scales reflects that published in the original validation studies. Factors were allowed to correlate. Model fit was evaluated according to established criteria: normed chi-square ≤ 5 , root mean square error of approximation (RMSEA) ≤ 0.06 , comparative fit index (CFI) ≥ 0.95 . [24] Factor loadings were considered meaningful if ≥ 0.5 .

Internal consistency reliability was considered satisfactory if Cronbach's alpha (α) >0.8 . [25]

Validity

A-priori validity hypotheses (described above) were tested to establish concurrent, convergent, and discriminant validity of the scale scores, using two-tailed correlations (r_s). Known-groups validity was examined with Mann-Whitney U tests.

Results

Table 2 details full sample characteristics (N=1,578) by cohort. Australian participants were more likely than UK participants to attempt all five diabetes-specific QoL questionnaires (n=390, 89% vs. n=773, 68%). Overall, 63% (n=1,003) completed all five (i.e. no missing data across questionnaires).

Questionnaire acceptability

For each questionnaire, completion rates were equivalent across cohorts ($\geq 91\%$) and indicated acceptability. They were highest for the DIDP (99%). Item-level missing data was minimal ($\leq 5\%$ missing on any given item), with no stand-out items (Appendix S2a-e). Questionnaire completion rates and maximum missing data on any given item are shown in Table 3.

User ratings were largely consistent across questionnaires and cohorts (Table 3): $>80\%$ of respondents endorsed the questionnaires as 'clear', 'easy to answer', and 'relevant'; while 12%-17% reported that important items were missing. The proportion indicating that questionnaires included too many items varied by questionnaire length, from 9% and 10% for the DCP and DIDP respectively (Australian sample), to 29% for the DSQOLS (UK sample).

Response patterns

Response patterns and item-level descriptive statistics for each of the questionnaires, split by cohort, are shown in Appendix S2a-e. Across cohorts, although substantial ceiling/floor effects were observed at an item-level for ADDQoL, DCP and DSQOLS (Table 3), ceiling/floor effects at a scale level were observed for $\leq 9\%$ of participants across questionnaires and cohorts.

Scale structure and reliability

Within scales, most ($\geq 93\%$) inter-item correlations were medium ($r_s=0.3-0.7$), except for the DCP. Weak correlations were observed for 22% of DCP inter-item relationships, with item 12 ('paying for my diabetes...is a problem') associated ($r_s<0.03$) with all other DCP items. Multicollinearity was indicated for ADDQoL and DSQOLS (determinant value >0.0001). However, $\leq 2\%$ of inter-item correlations were very strong ($r_s>0.7$). Bartlett's test of Sphericity indicated acceptable inter-item relatedness for all questionnaires.

Table 4 summarises the internal consistency reliability, EFA and CFA results for each of the scales. Detailed EFA and CFA factor loadings are shown in Appendix S3a-e. All (sub)scales had strong internal consistency reliability ($\alpha>0.88$). The variance accounted for by single-factor scales ranged from 43% (ADDQoL-19) to 48% (DIDP). All items loaded >0.5 on a forced single-factor, with two exceptions

each for the DCP (12: financial impact; 7: dietary freedom) and Diabetes QoL-Q (13: faith/community life; 17: pets/animals reported not applicable by $\geq 42\%$ and $\geq 19\%$ respectively). A forced six-factor EFA provided little support for the published DSQOLS structure, [12, 18] with 38% of items not loading as expected and inspection of eigenvalues suggesting a five-factor solution.

With regard to CFA (UK Sample B), permissible normed chi-squared results were observed for the DIDP, Diabetes QOL-Q (Australia only) and DSQOLS six-factor structure. However, permissible RMSEA and CFI were observed only for the DIDP, suggesting poor model fit for all other scales. In particular, poor model fit was observed for the DCP across all inspected indices. All items loaded >0.5 , as expected, for the DIDP and ADDQoL-19 across cohorts. Replication of the CFA with listwise deletion when respondents reported ADDQOL-19, DIDP and Diabetes QOL-Q items as N/A did not substantially improve model fit for those questionnaires (data not shown).

Validity

Table 5 displays concurrent, convergent and discriminant validity, which were confirmed for each questionnaire across cohorts. Moderate correlations ($r_s \geq 0.5$) were observed between the five diabetes-specific QoL scales (highest with the DSQOLS). All five scales correlated ≥ 0.4 with measures of diabetes distress, diabetes-specific positive wellbeing, general emotional wellbeing, whereby greater QoL was associated with better general and diabetes-specific and emotional wellbeing. A similar association was shown with generic health status (except ADDQoL-19). The strongest correlation ($r_s = -0.86$) was observed between DSQOLS and PAID (diabetes distress). Weak correlations ($r_s < 0.3$) were observed with Hba1c, age and diabetes duration.

Table 5 displays the effect sizes for known-group comparisons, with hypotheses partially confirmed. Significant differences across all five scales, and across cohorts, were observed for presence/absence of complications and severe hypoglycaemia, albeit with small effect sizes. Only DSQOLS detected significant differences by insulin administration type.

Discussion

This study identified that these five contemporary diabetes-specific QoL scales are relatively comparable in terms of acceptability, reliability and validity of, with consistent between-country findings. All scales were acceptable to participants, with $\geq 90\%$ completing all items, and $\geq 80\%$ positive user ratings (except for length of DSQOLS). All scales performed relatively well in EFA, though CFA revealed permissible model fit for the DIDP only. Overall, the strongest performing scale (across user ratings and psychometrics) was the DIDP, followed by the ADDQOL-19 and Diabetes QOL-Q. These data can be used to guide questionnaire selection, in the context of other characteristics (e.g. responsiveness, available languages, administration time). [10]

Developed for use in the international DAWN2 study [17], the DIDP is unique among these five scales in terms of its brevity (7 items [14]), neutral wording, and balanced response scale. Importantly, it is also freely available for use in 23 languages. While the DIDP was reportedly developed with input from people with diabetes,[17] it is unclear whether these seven global domains reflect those rated as most important by people with type 1 diabetes. However, despite its brevity, just 16% of YourSAY:QoL participants reported that the DIDP omitted important issues; a similar rate to longer scales. While the lack of ceiling effects suggests its potential sensitivity, known-group differences had small effect sizes, and the lack of published responsiveness data remains a limitation of this relatively new measure.

ADDQOL-19 and Diabetes QOL-Q also performed relatively well, demonstrating acceptability among participants and satisfactory psychometric properties across cohorts (excluding CFA outcomes). These lengthier scales might be considered for use where a more comprehensive needs assessment of the impact of diabetes on QoL is sought, or for testing intervention effectiveness. Indeed, both scales have previously demonstrated responsiveness.[10, 26] ADDQoL-19 is the most widely used of those compared, available in over 80 languages. However, ADDQoL-19 has been criticised previously for its length (i.e. up to 45 separate questions) and use of hypothetical scenarios (i.e. “if I did not have diabetes...”).[8] While 20% of respondents reported ‘too many questions’, most (89%) found them relevant. Further, positive user ratings indicate that most respondents had no difficulty completing the ADDQoL. Nonetheless, the issue remains that interpretation of the person’s responses is challenging without further interrogation. Qualitative research could explore whether respondents rely on recall of a period prior to diagnosis or on comparison to their peers, and whether they use the same reference point to answer all questions or choose different reference points for different domains. Importantly, previous studies have demonstrated the ADDQoL to be responsive. [10] Finally, internal consistency ($\alpha > 0.9$) suggests that item reduction is possible without loss of reliability, which may enhance its acceptability in both research and clinical settings. Thus, further research into an ADDQoL short-form is warranted.

The responsiveness of DSQOLS has also been demonstrated previously following group-based structured education.[27-29] However, its length may be a practical limitation. With 57 items, the DSQOLS includes 27%-714% more items than other questionnaires assessed, and was rated as too long by $\geq 27\%$ participants. Further, the DSQOLS item profile is dissimilar to other questionnaires assessed, as many items refer to concepts outside the scope of diabetes-specific QoL, such as symptom experience (e.g. “I suffer from thirst or having a dry mouth”) and fear of hypoglycaemia (“I am worried that I could easily panic in the event of an episode of low blood sugar”). Thus, it is unsurprising that the DSQOLS has a much stronger correlation with a measure of diabetes distress (PAID scale $r_s \geq 0.85$), than with other diabetes-specific QoL questionnaires. This suggests that the DSQOLS may be best described as assessing the emotional burden of living with diabetes, and concern about hypoglycaemia, rather than the impact of diabetes on QoL.

Finally, though acceptable to participants, the DCP appeared to have the worst model fit. Further, there is limited evidence of the DCP's responsiveness, despite its development some 20 years ago.[30]

The strengths of our study include the large sample size, random questionnaire order to minimise order effects, comprehensive dataset, cross-country validation (UK and Australia), and the opportunity for adults with type 1 diabetes to provide 'user ratings' for each questionnaire. A key limitation is the cross-sectional design, which did not enable assessment of test-retest reliability, predictive validity, or responsiveness. The lack of ceiling effects and small known-group differences observed suggest the questionnaires' potential for responsiveness, though longitudinal research is needed. Further limitations include the self-selected sample, the majority of whom were locally-born women with English as their first language. Further assessment is warranted among specific subgroups (e.g. younger and older adults, culturally and linguistically diverse persons), those with low English-proficiency and/or (health) literacy, and within non-western populations. Additionally, the strict questionnaire selection criteria adopted may have resulted in the exclusion of potentially relevant measures, such as those published in a language other than English, or diabetes-specific questionnaires not yet validated among adults with type 1 diabetes. Finally, the use of non-parametric statistics for validity assessments may lack power compared to parametric methods when the normality assumption holds true.

While the selection of diabetes-specific QoL measures necessitates consideration of study design and research questions (or the context of the clinical practice), our findings support consideration of the DAWN Impact of Diabetes Profile, which was highly acceptable to study participants and displayed the strongest psychometric properties. In conclusion, this study offers novel evidence to inform selection of the most acceptable and strongest performing diabetes-specific QoL measure for use with adults with type 1 diabetes in research and clinical practice.

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Tables

Table 1. Key characteristics of the five diabetes-specific quality of life scales assessed

	ADDQoL-19 [11]	Diabetes QOL-Q[†] [13]	DSQOLS[‡] [12,18]	DIDP [14,17]	DCP[‡] [16]
Target population	Adults with type 1 & type 2 diabetes	Adults with type 1 & type 2 diabetes	Adults with type 1 diabetes	Adults with type 1 & type 2 diabetes	Adults with type 1 & type 2 diabetes
Original language and translations	English (UK) Translation(s): available for 80+ languages	English (UK)	German Translation(s): English	English (USA) Translation(s): 23 languages, for use across 17 countries	English (USA)
Questionnaire content and structure	Single factor structure: Average Weighted Impact (AWI) of diabetes on QoL	Single factor structure: Overall impact of diabetes on QoL	Single-factor structure: Total Burden Score. 6-factor structure: Social Aspects, Fear of Hypos, Dietary Restrictions, Physical Complaints, Anxiety about Future, Daily Hassles	Single factor structure: Overall impact of diabetes on QoL	Single factor structure: Overall impact of diabetes on QoL
No. of Items	≤45 questions: 2 overview items; 19 domain-specific items, each with 2 parts (impact and importance), and 4 with an initial screening question to assess domain relevance; 1 free text-question.	23 domain-specific items	57 items	6 domain-specific items + optional 7 th item [14]	2 overview items; 11 domain-specific items
Response options	Impact items: 5-point scale (very much more/ better to less/worse); Importance: 4-point scale (very important to not at all important) General QoL overview item: 7-point	5-point scale (strongly disagree to strongly agree, or not applicable)	5-point scale (very strongly agree to do not agree at all)	7-point scale (very negative impact to very positive impact, or not applicable)	5-point scale (never to often; strongly disagree to strongly agree)

	ADDQoL-19 [11]	Diabetes QOL-Q [†] [13]	DSQOLS [‡] [12,18]	DIDP [14,17]	DCP [‡] [16]
	scale (Excellent to extremely bad); Diabetes QoL overview item: 5-point scale (very much more to worse)				
Question framing	Negatively worded and hypothetical	Positively worded	Negatively worded	Neutrally worded	Negatively worded
Timeframe	'now' or in general	'your life right now'	'last 4 weeks'	'currently'	'past year' or in general
Scoring	AWI: Sum of weighted domains (impact * importance) / no. of valid responses Range: -9 to +3, higher scores = greater positive impact. 2 overview items reported independently (scoring= response items)	Composite score: Sum of items (reversed) / no. of valid responses Range: 1-5, higher scores = less negative impact	Subscale and Total scores: Sum of items / no. of valid responses, converted to percentage. Range: 0-100, higher scores = less negative impact	Composite score: Sum of items (reversed) / no. of valid responses Range: 1-7, higher scores = greater negative impact. Domain score can be used independently	Composite score: Sum of items / no. of valid responses. Range: 1-5, higher scores = greater negative impact
Established Psychometric Properties	Yes [11]	Yes (unpublished)	Yes [12, 18]	Yes [14]	Yes [16]
Copyright holder (permissions & costs)	Health Psychology Research (permission required for use, license fees apply)	AHP Research (permission required from Mapi Research Trust, license fees may apply)	Authors: Bott et al. (permission required for use)	DAWN/ Authors: Soren Skovlund (free for public use)	Michigan Diabetes Research Centre (permission required from Mapi Research Trust, license fees may apply)

[†]Validation has been conducted by Speight and colleagues and publication is in preparation.[‡]

Relevant subscales only.

ADDQOL: Audit of Diabetes-Dependent Quality of Life [11]; DCP: Diabetes Care Profile: Social & Personal Factors Scale [16]; Diabetes QOL-Q: Diabetes Quality of Life Questionnaire [13]; DIDP: DAWN Impact of Diabetes Profile [14, 17]; DSQOLS: Diabetes-Specific Quality of Life Scale [12, 18];

Table 2. Participant characteristics by country

Variable		UK sample ^{† ‡} (N=1.139)		Australia sample (N=439)
Gender: women	1139	832(73)	439	304(69)
Age, years	1139	39.5±14.6, 39.0(26.0, 51.0)	439	47.3±14.9, 47.0(35.0, 59.0)
Country of birth:	1139		439	
Australia		2(0)		341(78)
England		866(76)		36(8)
Scotland		125(11)		9(2)
Wales		62(5)		3(1)
N. Ireland		45(4)		0(0)
Other		39(3)		50(11)
Main Language: English	1139	1128(99)	439	436(99)
Relationship status: Married / de facto	1139	640(56)	439	281(64)
Currently employed: yes	1139	741(65)	439	285(65)
BMI	593	27.3±6.6, 26.0(23.1, 29.7)	387	27.0±5.5, 26.1(23.7, 29.4)
Diabetes duration, years	1139	20.6±14.3, 18.0(9.0, 30.0)	439	23.8±15.0, 22.0(12.0, 34.0)
Insulin administration: Pump	1139	282(25)	439	196(45)
HbA1c (within past 6 months):	632		381	
%		8.2±1.8, 7.9(7.0,9.0)		7.4±1.2, 7.2(6.7,8.0)
Mmol/mol		66.2±19.6, 63.0(53.0, 74.9)		57.1±13.4, 55.2(49.7, 63.9)
Diabetes-related complications: ≥1	1138	561(49)	439	156(36)
Severe hypoglycaemia in past 12 months: ≥1	1124	371(33)	437	109(25)
Health status: EQ-5D VAS (range: 0-100)	1128	65.6±22.6, 70.0(50.0, 82.0)	438	74.0±18.3, 80.0(66.0, 87.0)
General emotional well-being: WHO-5 total (range: 0-100)	1130	47.6±23.2, 48.0(28.0, 68.0)	438	58.5±20.9, 60.0(44.0, 76.0)
Diabetes distress: PAID total score (range: 0-100)	735	41.6±26.3, 41.3(18.8, 62.5)	382	31.1±23.1, 26.3(12.5, 46.3)
Diabetes-specific Positive Well-being: subscale score of the W-BQ28 (range:0-16)	745	5.5±3.2, 5.0(3.0,8.0)	383	6.7±2.9, 7.0(5.0,8.0)
ADDQoL-19: AWI score	941	-3.3±2.2, -3.0(-4.8, -1.5)	414	-2.9±2.1, -2.4(-4.2, -1.3)
DCP: Social and Personal subscale score	933	2.8±0.9, 2.9(2.2,3.5)	415	2.8±0.9, 2.8(2.2,3.5)
DIDP: composite score	919	5.1±0.9, 5.0(4.6,5.7)	412	5.0±0.9, 5.0(4.4,5.6)
Diabetes QoL-Q: composite score	898	3.2±0.9, 3.2(2.5,3.8)	403	3.3±0.9, 3.4(2.7,4.0)
DSQOLS: total score	837	50.1±23.7, 50.5(31.9, 68.1)	396	57.9±22.1, 59.1(40.0, 75.0)
DSQOLS subscales:				
Social Aspects	877	56.7±25.5, 58.9(36.7, 77.8)	404	64.2±23.8, 68.9(46.7, 83.3)
Fear of Hypoglycaemia	889	52.7±28.6, 56.4(29.1, 76.4)	405	61.2±26.8, 65.5(40.0, 83.6)
Dietary Restrictions	889	53.3±29.2, 52.5(27.5, 80.0)	408	55.4±28.3, 57.5(35.0, 80.0)
Complaints	893	51.4±26.7, 52.0(30.0, 72.0)	410	64.9±23.4, 68.0(48.0, 84.0)

Anxiety about the Future	902	30.5±25.9, 24.0(8.0, 48.0)	411	38.1±28.5, 36.0(16.0, 60.0)
Daily Hassles	902	35.2±27.0, 32.0(12.0, 56.0)	410	38.9±26.4, 36.0(16.0, 56.0)

Data are n(%) or mean±SD, median(LQ, UQ). *Study-specific single-item

†Compared to Australian participants, UK participants were younger ($t(1576)=9.5$, $p<0.001$, $d=0.23$), had been living with diabetes for marginally fewer years ($t(1576)=4.0$, $p<0.001$, $d=0.1$), were less likely to be in a relationship ($\chi^2=(1)8.3$, $p=0.004$) or using an insulin pump ($\chi^2=(1)59.4$, $p<0.001$), reported a higher Hba1c level ($t(1093)=-9.8$, $p<0.001$, $d=0.29$), and were more likely to report at least one diabetes-related complication ($\chi^2=(1)24.2$, $p<0.001$), and recent experience of severe hypoglycaemia ($\chi^2=(1)9.6$, $p=0.002$). *UK subsamples A and B were statistically equivalent on all key demographic and clinical characteristics.

ADDQOL AWI: Audit of Diabetes-Dependent Quality of Life average weighted impact score [11]; DCP: Diabetes Care Profile: Social & Personal Factors Scale[16]; Diabetes QOL-Q: Diabetes Quality of Life Questionnaire [13]; DIDP: DAWN Impact of Diabetes Profile [14, 17]; DSQOLS: Diabetes-Specific Quality of Life Scale [12, 18]; EQ-5D VAS: Visual analogue scale [19]; PAID: Problem Areas In Diabetes scale [21];W-BQ28: Well-being questionnaire 28 [22]; WHO-5:World Health Organisation-Five Well-being Index [20]

Table 3. Acceptability of diabetes-specific QoL scales: scale completion, user ratings, item- and scale-level floor and ceiling effects

		ADDQoL -19	DCP	DIDP	Diabetes QoL-Q	DSQOLS
UK sample (N=1139)						
Acceptability	Completed scale	914 (93)	888 (94)	929 (99)	874 (97)	837 (91)
	Max. missing for given item	51 (5)	16 (2)	7 (1)	7 (1)	20 (2)
User ratings: (strongly) agree	The instructions were clear	884 (95)	870 (94)	870 (93)	809 (91)	860 (95)
	The questions were relevant to me	820 (89)	784 (84)	807 (87)	755 (85)	766 (85)
	The questions were easy to answer	836 (91)	837 (91)	841 (91)	788 (89)	837 (92)
	There were too many questions	183 (20)	127 (14)	129 (14)	172 (19)	261 (29)
	Important issues were missing	144 (16)	131 (14)	151 (16)	106 (12)	125 (14)
Item-level effects[^]	Floor (Negative)	15 (79)	1 (8)	2 (29)	4 (17)	22 (39)
	Ceiling (Pos / neutral)	0 (0)	7 (54)	0 (0)	6 (26)	29 (51)
Scale-level effects[†]	Floor (Negative)	30 (3)	12 (1)	71 (8)	26 (3)	34 (4)
	Ceiling (Pos / neutral)	0 (0)	63 (7)	3 (0)	47 (5)	38 (5)
Australia sample (n=439)						
Acceptability	Completed scale	394 (94)	397 (96)	412 (99)	401 (98)	396 (96)
	Max. missing for given item	6 (1)	11 (3)	3 (1)	6 (1)	6 (1)
User ratings: (strongly) agree	The instructions were clear	399 (97)	402 (97)	398 (96)	360 (89)	396 (97)
	The questions were relevant to me	364 (89)	371 (90)	366 (88)	340 (84)	359 (88)
	The questions were easy to answer	370 (90)	383 (93)	390 (94)	343 (85)	385 (94)
	There were too many questions	70 (17)	37 (9)	40 (10)	50 (12)	112 (27)
	Important issues were missing	64 (16)	68 (16)	71 (17)	55 (14)	62 (15)
Item-level effects[^]	Floor (Negative)	9 (47)	1 (8)	0 (0)	1 (4)	11 (19)
	Ceiling (Positive / Neutral)	0 (0)	5 (38)	0 (0)	12 (52)	36 (63)
Scale-level effects[†]	Floor (Negative)	7 (2)	6 (1)	19 (5)	7 (2)	5 (1)
	Ceiling (Positive / Neutral)	0 (0)	26 (6)	3 (1)	37 (9)	24 (6)

[^]Item-level effect: n(%) of items on a given scale where $\geq 20\%$ of the sample endorsed the minimum/maximum response option. [†]Scale-level effects: n(%) participants whose total/composite score is on the 90th/10th percentile.

ADDQoL: Audit of Diabetes-Dependent Quality of Life [11]; DCP: Diabetes Care Profile: Social & Personal Factors Scale [160]; Diabetes QoL-Q: Diabetes Quality of Life Questionnaire [13]; DIDP: DAWN Impact of Diabetes Profile [14, 17]; DSQOLS: Diabetes-Specific Quality of Life Scale [12, 18]

Table 4. Scale structure for the diabetes-specific QoL scales: internal consistency reliability and summarised EFA (UK sample A) and CFA (UK sample B and Australia sample)

	ADDQoL-19	DCP	DIDP	Diabetes QoL-Q	DSQOLS	
Expected structure	Single: 19 items	Single: 13 items	Single: 7 items	Single: 23 items	Single: 57 items	6-factor structure
UK sample A						
n	460	437	469	434	415	432-450
Cronbach's alpha	0.93	0.90	0.86	0.95	0.98	0.88-0.95
Eigenvalue	8.20	5.9	3.38	10.89	25.93	0.88-26.09
Variance accounted for	43.2%	44.5%	48.3%	47.3%	45.5%	62.3%
Items loading >0.5[^]	19 (100)	11 (85)	7 (100)	21 (91)	57 (100)	36 (63)
UK sample B						
n	459	451	460	440	422	445-453
Cronbach's alpha	0.93	0.92	0.88	0.95	0.98	0.90-0.95
Normed Chi-square	5.7***	11.1***	4.7***	5.3***	5.0***	2.9***
RMSEA (CI)	0.10 (0.09–0.11)	0.15 (0.14–0.16)	0.09 (0.07–.11)	0.10 (0.09–0.11)	0.097 (0.095–.099)	0.067 (0.065–0.069)
CFI	0.844	0.807	0.964	0.844	0.709	0.864
Items loading >0.5	19 (100)	12 (92)	7 (100)	21 (91)	57 (100)	57 (100)
Australia sample						
n	396	397	412	401	396	404-411
Cronbach's alpha	0.94	0.93	0.89	0.96	0.98	0.89-0.95
Normed Chi-square	5.8***	12.7***	1.9*	2.8***	5.1***	2.8***
RMSEA (CI)	0.11 (0.10–0.12)	0.17 (0.16–0.18)	0.05 (0.02–0.07)	0.10 (0.09–0.11)	0.102 (0.100–0.104)	0.068 (0.065–0.070)
CFI	0.825	0.784	0.991	0.853	0.670	0.855
Items loading >0.5	19 (100)	13 (100)	7 (100)	22 (96)	55 (96)	57 (100)

Data are n (%) *p<.05 **p<.01 ***p<.001

[^]Factor loadings are considered meaningful if significant ≥ 0.5 . For CFA (UK sample B and Australia sample), model fit is evaluated according to established criteria: normed chi-square ≤ 5 , root mean square error of approximation (RMSEA) ≤ 0.06 , comparative fit index (CFI) ≥ 0.95 . [24]

ADDQOL: Audit of Diabetes-Dependent Quality of Life [11]; DCP: Diabetes Care Profile: Social & Personal Factors Scale [160]; Diabetes QOL-Q: Diabetes Quality of Life Questionnaire [13]; DIDP: DAWN Impact of Diabetes Profile [14, 17]; DSQOLS: Diabetes-Specific Quality of Life Scale [12, 18]

Table 5. Concurrent, convergent, discriminant and known group validity for diabetes-specific quality of life questionnaires, by cohort.

	Concurrent validity [†]					Convergent Validity [†]				Discriminant Validity [†]			Known Groups Validity [‡]		
	1	2	3	4	5	EQ-5D VAS	WHO-5	PAID	W-BQ 28 Pos	HbA1c	Age	Diab. duration	Insulin: pump vs MDI	Diabetes complications: 0 vs ≥1	Severe Hypoglycaemia: 0 vs ≥1
UK sample															
1. ADDQoL-19	-	-.67***	-.65***	.57***	.77***	.37***	.40***	-.72**	.51***	-.26***	.20***	.12***	ns	-0.13***	-0.18***
2. DCP	-.67***	-	.63***	-.67***	-.77***	-.46***	-.48***	.71**	-.56***	.23***	-.17***	-.15***	ns	0.16***	0.17***
3. DIDP	-.65***	.63***	-	-.62***	-.69***	-.42***	-.50***	.66**	-.52***	.23***	-.10**	-.05	ns	0.23***	0.15***
4. Diabetes QOL-Q	.57***	-.67***	-.62***	-	.69***	.44***	.56***	-.61**	.53***	-.18***	.06*	.04	ns	-0.16***	-0.14***
5. DSQOLS total	.77***	-.77***	-.69***	.69***	-	.50***	.52***	-.86**	.63***	-.29***	.23***	.18***	0.10**	-0.14***	-0.22***
DSQOLS subscales:															
Social aspects	.80***	-.80***	-.73***	.68***	.95***	.49***	.52***	-.85**	.62***	-.27***	.26***	.12*	ns	-0.17***	-0.20***
Fear of hypo	.62***	-.63***	-.52***	.54***	.87***	.37***	.41***	-.74**	.50***	-.25***	.23***	.16**	ns	ns	-0.24***

	Concurrent validity [†]					Convergent Validity [†]				Discriminant Validity [†]			Known Groups Validity [‡]		
	1	2	3	4	5	EQ-5D VAS	WHO-5	PAID	W-BQ 28 Pos	HbA1c	Age	Diab. duration [†]	Insulin: pump vs MDI	Diabetes complications: 0 vs ≥1	Severe Hypoglycaemia: 0 vs ≥1
Dietary restrict	.59***	-.59***	-.50***	.45***	.79***	.30***	.29***	-.65**	.47***	-.23***	.22***	.28***	0.19***	ns	-0.08*
Phys complaints	.70***	-.72***	-.68***	.62***	.85***	.58***	.62***	-.77**	.60***	-.38***	.28***	.15**	0.12**	-0.21***	-0.23***
Anxiety: future	.65***	-.56***	-.61***	.49***	.80***	.36***	.37***	-.71**	.51***	-.25***	.22***	.03	ns	-0.14***	-0.12**
Daily hassles	.69***	-.64***	-.58***	.54***	.85***	.34***	.39***	-.79**	.60***	-.26***	.30***	.20***	0.10**	-0.07*	-0.11**

Australia sample

1. ADDQoL-19	-	-.73***	-.70***	.65***	.80***	.39***	.45***	-.75**	.58***	-.18***	.25***	.12**	ns	-0.17**	-0.15**
2. DCP	-.73***	-	.65***	-.75***	-.79***	-.43***	-.48***	.71**	-.62***	.17***	-.22***	-.12**	ns	0.14**	0.16**
3. DIDP	-.70***	.65***	-	-.64***	-.72***	-.46***	-.54***	.69**	-.60***	.18***	-.24***	-.05	ns	0.23***	0.11*
4. Diabetes QOL-Q	.65***	-.75***	-.64***	-	.68***	.51***	.57***	-.65**	.61***	.17***	.14**	.04	ns	-.20***	-0.11*
5. DSQOLS total	.78***	-.79***	-.72***	.68***	-	.43***	.48***	-.85**	.67***	-.22***	.27***	.13**	ns	-0.12*	-0.12*

	Concurrent validity [†]					Convergent Validity [†]				Discriminant Validity [†]			Known Groups Validity [‡]		
	1	2	3	4	5	EQ-5D VAS	WHO-5	PAID	W-BQ 28 Pos	HbA1c	Age	Diab. duration	Insulin: pump vs MDI	Diabetes complications: 0 vs ≥1	Severe Hypoglycaemia: 0 vs ≥1
DSQOLS subscales:															
Social aspects	.81***	-.82***	-.73***	.75***	.94***	.49***	.54***	-.82**	.69***	-.20***	.24***	.09	ns	-0.17**	-0.13**
Fear of hypo	.63***	-.64***	-.51***	.50***	.87***	.30***	.31***	-.68**	.50***	-.16**	.13*	.06	ns	ns	-0.21***
Dietary restrict	.59***	-.62***	-.57***	.47***	.77***	.26***	.32***	-.65**	.52***	-.11*	.23***	.21***	0.17***	ns	ns
Phys complaints	.71***	-.72***	-.69***	.65***	.85***	.55***	.55***	-.76**	.68***	-.31***	.24***	.07	ns	-0.19***	ns
Anxiety: future	.74***	-.65***	-.68***	.56***	.87***	.47***	.49***	-.80**	.64***	-.22***	.24***	.03	ns	-0.18***	ns
Daily hassles	.73***	-.65***	-.64***	.54***	.87***	.32***	.44***	-.84**	.65***	-.16**	.30***	.17**	ns	ns	ns

*p<.05, **p<.001, ***p<.001

[†]Results are Spearman's Rho correlations and significant indicators

[‡]Results are effect size (*r*) and significance indicators, only shown where a significant non-parametric tests revealed between group differences.

ADDQOL: Audit of Diabetes-Dependent Quality of Life [11]; DCP: Diabetes Care Profile: Social & Personal Factors Scale[16]; Diabetes QOL-Q: Diabetes Quality of Life Questionnaire [13]; DIDP: DAWN Impact of Diabetes Profile [14, 17]; DSQOLS: Diabetes-Specific Quality of Life Scale [12, 18]; EQ-5D VAS: Visual analogue scale [19]; PAID: Problem Areas In Diabetes scale [21]; W-BQ28: Well-being questionnaire 28 [22]; WHO-5:World Health Organisation-Five Well-being Index [20]

