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Assessing the perceived impact of diabetes on quality of life: Psychometric validation of the DAWN2 Impact of Diabetes Profile in the second Diabetes MILES – Australia (MILES-2) survey

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ABSTRACT

Aims: To investigate the validity and reliability of the 6-item DAWN2 Impact of Diabetes Profile (DIDP), and the modified 7-item DIDP, which includes assessment of dietary freedom.

Methods: The online, cross-sectional, Australian MILES-2 survey included the DIDP and other validated measures, to examine convergent, discriminant and known-groups validity. The DIDP was completed by 2207 adults with diabetes (Type 1: n = 1012; Type 2 insulin: n = 504; non-insulin: n = 691). Data were subjected to exploratory factor analysis, internal consistency reliability and univariate statistics, conducted separately by diabetes type/treatment.

Results: The DIDP was highly acceptable: 99% completion rate. One-factor solutions were supported for the 6-item and 7-item DIDP scales, in all diabetes type/treatment groups (variance explained range: 6-item: 59–67%, 7-item: 55–62%), with satisfactory internal consistency ($\alpha = 0.85$–0.90). Known-groups validity was demonstrated, by diabetes type and complications presence/absence, as was satisfactory convergent and discriminant validity.

Conclusions: The DIDP meets the need for a brief, contemporary, valid and reliable measure of the perceived impact of diabetes on quality of life, suitable for adults with Type 1 or Type 2 diabetes mellitus. The 6-item and 7-item scales have psychometric equivalence. Use of the seventh item can be informed by research questions.

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1. Introduction

As living with diabetes permeates every aspect of life and is relentless across the lifespan, it is widely acknowledged that diabetes can impair quality of life [1,2]. Furthermore, quality of life has long been recognised as an important clinical outcome, in addition to biomedical risk markers and outcomes, and indicator of whether or not a medical treatment is beneficial [3].

Thirty years ago, there was considerable academic and clinical interest in recognising the impact of diabetes on *quality* of life, resulting in the development of three measures of diabetes-specific quality of life [4–6]. While interest has remained, the complexity of assessing and interpreting quality of life measures has been recognised [7,8]. Meanwhile, attention has turned to the assessment of other diabetes-specific psychological constructs that may have greater clinical utility, e.g. diabetes distress [9] and fear of hypoglycaemia [10]. While such constructs have been referred to as 'markers' of quality of life [11], they assess the person's feelings about managing various aspects of their diabetes rather than assessing how diabetes affects various aspects of their life. Currently, the measures designed to assess the impact of diabetes on quality of life are typically lengthy (e.g. three widely used measures: >40 items [4–6]) and may be complex for both the respondent and the clinician/researcher [7,8]. Thus, there is currently an unmet need for a simple, brief measure focused on the impact of diabetes on key dimensions of life of importance to people with diabetes.

The DAWN2 Impact of Diabetes Profile (DIDP) was designed for inclusion in the multi-national DAWN2 study to provide a brief assessment of the perceived impact of diabetes on six key dimensions of life (see Table 1) [12,13]. Spanning 17 countries, DAWN2 surveyed 9040 adults with Type 1 (T1DM) and Type 2 diabetes mellitus (T2DM). DAWN2 findings, including DIDP descriptive statistics and correlates, have been published elsewhere [13,14]. However, the psychometric properties of the DIDP have not yet been examined separately by diabetes type/treatment. The aim of the current study was to investigate the psychometric properties of the DIDP among adults with T1DM and T2DM (insulin and non-insulin treated) in a large Australian sample, using data from the second Diabetes MILES – Australia Study (MILES-2) [15].

2. Participants, material and methods

2.1. Study design

MILES-2 was a large-scale national online survey of Australians with diabetes, completed in 2015. A detailed description of MILES-2, including methods and response rates, has been published elsewhere [15]. The study was conducted according to the CHEcklist for Reporting Results of Internet E-Surveys (CHERRIES) [16]. Ethics approval: Deakin University Human Ethics Committee (2011-046).

2.2. Participants, recruitment and procedure

Eligible participants were aged 18–75 years, with a self-reported diagnosis of T1DM or T2DM, English speaking, and currently residing in Australia. Study invitations were posted to a computer-generated random sample of 20,000 consenting National Diabetes Services Scheme (NDSS) registrants (stratified according Australian state/territory, and by diabetes type/treatment). The NDSS provides subsidised products, information and support services to >1.2 million Australians with diagnosed diabetes [17]. Invitations were also distributed to consenting participants of the first Diabetes MILES – Australia (2011) survey (N = 2065), and promoted online (i.e. website, e-newsletters, and social media sites).

Participants were directed to a website including the study plain language statement and survey (securely hosted by Qualtrics, Copyright © 2015, Provo, UT). After indicating consent and being screened for eligibility, participants proceeded to the survey proper. The final eligible MILES-2 sample included 2342 participants [15]. Survey responses were saved automatically, whereby the participant data are available for the portion of the survey they completed prior to exiting the survey. A total of 130 (5.6%) participants exited the survey prior to commencing the DIDP and are excluded from analysis.

2.3. Measures

Full details of the measures included in MILES-2 are published elsewhere [15].

2.3.1. DAWN2 Impact of Diabetes Profile

The DAWN2 survey design, including development of the DIDP, was overseen by the Global DAWN2 Survey Working Group and is detailed elsewhere [12]. Survey refinement involved input from representatives of all countries participating in DAWN2, including study partners and multiple collaborating organisations, scientific experts, and participant groups (e.g. people with diabetes).

Several criteria guided the design of the DIDP: it should be very brief; include main global dimensions of life as identified from past multi-national qualitative research [12,18]; be easy to read and understand (suitable for people with low literacy); enable respondents to express both negative and positive impacts of diabetes; enable comparison across diverse populations (within and across diabetes types, treatments); be suitable for development of comparable versions for completion by caregivers and for the development of cross-culturally equivalent versions in multiple languages. Development of the English version of the DIDP involved user-testing with seven people with diabetes to assess and improve face validity, acceptability and readability [12]. Following approval of the English version, national experts reviewed and approved 22 local language versions applied in each of the 17 countries. Where feasible, the wording of each version was reviewed by people with diabetes in relevant countries. DIDP versions were also developed for completion by family members

Table 1 – Demographic, clinical and psychosocial characteristics (n = 2207).

	T1DM		T2DM: Insulin		T2DM: Non-insulin	
	n	n(%) or mean ± SD	n	n(%) or mean ± SD	n	n(%) or mean ± SD
Demographic characteristics						
Gender: Women	1012	598 (5.1)	504	197 (39.1)	691	312 (45.2)
Age, years	1012	44.2 ± 15.2	504	61.3 ± 8.9	691	61.2 ± 9.5
Relationship status: In a relationship	1008	711 (70.5)	504	357 (70.8)	688	512 (74.4)
Employment status: In paid employment	1012	715 (70.7)	504	173 (34.3)	691	271 (39.2)
Education	1009		504		689	
Less than year 12		127 (12.6)		156 (30.9)		153 (22.2)
Completed high school		168 (16.7)		55 (10.9)		80 (11.6)
Vocational education/diploma		237 (23.5)		160 (31.7)		203 (29.5)
University – undergraduate		251 (24.9)		73 (14.5)		139 (20.2)
University – postgraduate		226 (22.4)		60 (11.9)		114 (16.5)
Country of birth: Australia	1012	780 (77.1)	504	368 (73)	691	470 (68.0)
Main language: English	1011	991 (98.0)	503	486 (96.6)	691	665 (96.2)
Clinical characteristics						
Diabetes duration, years	1012	19.2 ± 14.4	502	14.5 ± 7.5	687	8.7 ± 6.3
Primary treatment	1012		504		691	
Insulin pump		357 (35.3)		2 (0.4)		–
Insulin injections		655 (64.7)		502 (99.6)		–
Exenatide injections		–		–		40 (5.8)
Blood glucose lowering tablets		–		–		488 (70.6)
Lifestyle modifications		–		–		163 (23.6)
Diabetes-related complications	999		503		687	
N		0.6 ± 1.1		1.4 ± 1.5		0.8 ± 1.2
≥1 complication		344 (34)		341 (68)		299 (44)
HbA1c in past 6 months	795		349		404	
%		7.4 ± 1.3		7.5 ± 1.6		6.8 ± 1.7
Mmol/mol		57 ± 14		59 ± 17		51 ± 18
Severe hypoglycaemia in past 6 months[a]	912		351		215	
None		760 (83.3)		322 (91.7)		205 (95.3)
≥1		145 (16.7)		29 (8.3)		10 (4.7)
	n	mean ± SDmedian (IQR)	n	mean ± SDmedian (IQR)	n	mean ± SDmedian (IQR)
Psychosocial characteristics						
Diabetes-specific distress: PAID[b]	882	25.1 ± 21.118.8 (7.5, 38.8)	446	23.0 ± 20.7 17.5 (6.3, 34.0)	588	15.9 ± 17.7 10 (2.8, 21.2)
Depressive symptoms: PHQ-8	1009	6.0 ± 5.45.0 (2.0, 9.0)	502	7.7 ± 6.16.5 (2.0, 12.0)	687	5.6 ± 5.14.0 (1.0, 9.0)
Anxiety Symptoms: GAD-7	1010	4.7 ± 4.9 3.0 (1.0, 7.0)	502	5.3 ± 5.44.0 (1.0, 8.0)	690	4.0 ± 4.52.0 (0.0, 6.0)
Prospective and retrospective memory: PRMQ	991	35.5 ± 10.734.0 (28.0, 42.0)	493	36.5 ± 10.9 35.0 (29.0, 43.0)	666	35.0 ± 9.934.0 (28.0, 41.0)
DIDP Physical health[c]	1012	4.8 ± 1.4 5 (4,6)	504	4.8 ± 1.4 5 (4,6)	690	4.4 ± 1.4 5 (4,5)
DIDP Financial situation[c]	1012	5.0 ± 1.15 (4,6)	504	4.6 ± 1.34 (4,5)	691	4.5 ± 1.14 (4,6)
DIDP Relationships[c]	1012	4.2 ± 1.04 (4,5)	504	4.2 ± 1.14 (4,5)	691	4.1 ± 1.04 (4,4)
DIDP Leisure activities[c]	1011	4.7 ± 1.25 (4,5)	504	4.6 ± 1.34 (4,5)	691	4.2 ± 1.34 (4,5)
DIDP Work or studies[c]	1012	4.7 ± 1.15 (4,5)	502	4.4 ± 1.14 (4,5)	690	4.3 ± 1.04 (4,4)
DIDP Emotional wellbeing[c]	1011	5.0 ± 1.25 (4,6)	503	4.7 ± 1.35 (4,6)	690	4.6 ± 1.24 (4,5)
DIDP Dietary freedom[c]	1012	5.1 ± 1.45 (4,6)	503	5.0 ± 1.65 (4,6)	691	5.0 ± 1.45 (4,6)
DIDP 6-item scale	1001	4.7 ± 0.94.7	500	4.6 ± 1.04.5	673	4.4 ± 0.94.3
Composite score		(4.3,5.3)		(4.0,5.2)		(4.0,4.7)
Percentage score		62.3 ± 15.061.1 (55.6, 72.2)		59.3 ± 16.558.3 (50.0, 69.4)		55.8 ± 15.655.5 (50.0, 61.1)

(*continued on next page*)

Table 1 – (continued)

	n	mean ± SDmedian (IQR)	n	mean ± SDmedian (IQR)	n	mean ± SDmedian (IQR)
DIDP 7-item scale Composite score Percentage score	1007	4.8 ± 0.94.9 (4.3,5.3) 63.3 ± 14.964.3 (55.5,71.4)	502	4.6 ± 1.04.6 (4.0,5.3) 60.3 ± 16.859.5 (52.4, 71.4)	678	4.4 ± 0.94.4 (4.0,4.9) 57.3 ± 15.457.1 (50.0, 64.3)

DIDP: DAWN2 Impact of Diabetes Profile, PAID: Problem Areas in Diabetes, GAD-7: Generalized Anxiety Disorder questionnaire, PHQ-8: Patient Health Questionnaire, PRMQ: Prospective and Retrospective Memory Questionnaire, T1DM: Type 1 diabetes mellitus, T2DM: Type 2 diabetes mellitus.

[a] Question only asked of persons who previously reported having "ever" experience hypoglycaemia.

[b] PAID data were not available for a subsample of participants ($n = 247$; 11%), who were part of a longitudinal Diabetes MILES cohort and completed an alternate measure of distress consistent with the one they completed in 2011 [15].

[c] For DIDP global dimensions, n includes those who reported the item was "not applicable". These responses were not included in the calculation of summary statistics.

Table 2 – Scale structure and internal consistency reliability for the 6-item and 7-item DIDP scales by diabetes type/treatment.

	6-item DIDP scale			7-item DIDP scale		
	T1DM	T2DM: insulin	T2DM: non-insulin	T1DM	T2DM: insulin	T2DM: non-insulin
Factor loadings[a]						
Physical health	0.67	0.70	0.65	0.67	0.72	0.67
Financial situation	0.53	0.67	0.69	0.54	0.67	0.70
Relationships	0.66	0.57	0.83	0.65	0.56	0.82
Leisure activities	0.80	0.83	0.80	0.79	0.81	0.79
Work or studies	0.78	0.77	0.85	0.78	0.73	0.84
Emotional wellbeing	0.81	0.82	0.84	0.82	0.85	0.87
Dietary freedom	–	–	–	0.58	0.63	0.50
Eigenvalue	3.5	3.5	4.0	3.9	4.1	4.3
Variance explained, %	58.6	60.8	67.4	55.4	58.0	61.8
Reliability						
Cronbach's alpha	0.85	0.87	0.90	0.86	0.87	0.88
Guttman's Lambda	0.86	0.88	0.91	0.85	0.87	0.86

T1DM: Type 1 diabetes mellitus, T2DM: Type 2 diabetes mellitus.

[a] Factor loadings for unforced one-factor solution using principal axis factor analysis.

[12,13,19]. The current study focuses solely on the English DIDP version developed for completion by adults with diabetes.

The final DIDP scale, as used in DAWN2 [12], asks respondents to rate how diabetes currently impacts upon each of six dimensions of their life (See Supplementary file 2). Each item is rated on a 7-point scale (1 = very positive impact, 4 = no impact, 7 = very negative impact). A 'not applicable' (N/A) response option is also available for each item. At the point of using the DIDP in the Australian MILES-2 study, a seventh dimension (dietary freedom) was added based upon the established highly negative impact of diabetes on dietary freedom and its importance for overall quality of life [20–22].

Each DIDP item was developed to reflect a distinct dimension of life that can be interpreted and reported individually [12]. To reflect total impact of diabetes across all life dimensions, a DIDP composite scores can be calculated by summing responses for each item and dividing by the number of complete responses (i.e. not missing or N/A). In the current study both composite raw composite scores (1–7) and converted percentage (0–100%) scale scores are reported. Lower scores indicate greater positive impact and higher scores indicate greater negative impact across global life dimensions.

2.3.2. *Measures used for validation purposes*

Several measures (described below) were included in the current study to assess the convergent, divergent and known-groups validity of the DIDP scale scores (described in Statistical Analyses). It was hypothesised that DIDP composite scale scores would show a strong positive association with diabetes-specific distress, and moderate positive associations with depressive and anxiety symptoms (convergent validity); while weak correlations would be observed with general prospective and retrospective memory, diabetes duration and self-reported HbA_{1c} (divergent validity). All patient-reported outcome measures used for validation purposes in this study exhibited acceptable internal consistency reliability (Cronbach's $\alpha > 0.85$). Drawing on the existing literature [e.g. 5,6,14,22,32,33], expected differences between known groups were examined by diabetes type/treatment, insulin modality,

Table 3 – Convergent and divergent validity of the DIDP dimensions and 6-item and 7-item scale composite scores, by diabetes subgroup.

DIDP dimension/scale score	Diabetes type/treatment	PAID	PHQ-8	GAD-7	PRMQ	Diabetes duration	HbA1c
Physical health	T1DM	0.45*	0.39*	0.32*	0.21*	0.01 ns	0.17*
	T2DM: insulin	0.34*	0.25*	0.18	0.14	0.03 ns	0.17
	T2DM: NI	0.25	0.25	0.16	0.17	0.18	0.17
Financial situation	T1DM	0.32*	0.27*	0.23*	0.15*	0.01 ns	0.05 ns
	T2DM: insulin	0.18*	0.16*	0.11	0.12*	−0.04 ns	0.14
	T2DM: NI	0.18*	0.17*	0.11*	0.15*	−0.02 ns	0.10
Relationships	T1DM	0.37*	0.29*	0.26*	0.16*	0.01 ns	0.06*
	T2DM: insulin	0.15	0.12	0.16*	0.11	−0.08 ns	0.06 ns
	T2DM: NI	0.17*	0.14*	0.13	0.14*	−0.01 ns	−0.00 ns
Leisure activities	T1DM	0.44*	0.29*	0.27*	0.17*	−0.05 ns	0.07 ns
	T2DM: insulin	0.27*	0.18*	0.15	0.17*	−0.00 ns	0.12
	T2DM: NI	0.19*	0.25*	0.16*	0.18*	0.13	0.13
Work or studies	T1DM	0.46*	0.40*	0.35*	0.24*	−0.08	0.09
	T2DM: insulin	0.21*	0.20*	0.19*	0.21*	−0.09	0.11
	T2DM: NI	0.17*	0.16*	0.15*	0.17*	−0.04 ns	0.02 ns
Emotional wellbeing	T1DM	0.66*	0.52*	0.50*	0.28*	−0.11*	0.13*
	T2DM: insulin	0.45*	0.37*	0.35*	0.25*	−0.09	0.21*
	T2DM: NI	0.44*	0.34*	0.32*	0.24*	0.03 ns	0.13*
Dietary freedom	T1DM	0.40*	0.23*	0.22*	0.18*	−0.15*	0.05 ns
	T2DM: insulin	0.36*	0.17*	0.19*	0.12	−0.02 ns	0.10 ns
	T2DM: NI	0.44*	0.25*	0.23*	0.17*	0.00 ns	0.19*
6−item scale	T1DM	**0.62***	**0.49***	**0.44***	**0.27***	**−0.05 ns**	**0.14***
	T2DM: insulin	0.38*	0.27*	0.24*	**0.20***	**−0.04 ns**	**0.21***
	T2DM: NI	0.35*	**0.32***	0.24*	**0.24***	**0.12**	**0.15**
7−item scale	T1DM	**0.62***	**0.47***	**0.43***	**0.27***	**−0.07**	**0.13***
	T2DM: insulin	**0.40***	0.27*	0.25*	**0.19***	**−0.03 ns**	**0.20***
	T2DM: NI	0.38*	**0.33***	0.25*	**0.24***	**0.11**	**0.18***

Data are Spearman's rho correlations. Correlations consistent with hypothesised convergent and divergent validity of the DIDP scale scores are shown in bold text.
All correlations are significant at a p-value < 0.05, unless otherwise noted: ns = not significant ($p > .05$).
GAD-7: Generalized Anxiety Disorder questionnaire, NI: non-insulin, PAID: Problem Areas in Diabetes, PHQ-8: Patient Health Questionnaire, PRMQ: Prospective and Retrospective Memory Questionnaire, T1DM: Type 1 diabetes mellitus, T2DM: Type 2 diabetes mellitus.
* $p < .001$.

experience of severe hypoglycaemia, and presence of diabetes-related complications.

2.3.2.1. Diabetes-specific distress. Diabetes-specific distress was assessed using the 20-item Problem Areas In Diabetes Scale (PAID) scale [9]. Respondents indicate how much of a problem each statement is for them on a 5-point Likert scale (0 = not a problem to 4 = serious problem). Items are summed and converted to a percentage score (0–100), with higher scores indicating greater diabetes distress.

2.3.2.2. Depression and anxiety symptoms. General depressive and anxiety symptoms were measured with the Patient Health Questionnaire 8-item scale (PHQ-8) [23] and Generalised Anxiety Disorder 7-item scale (GAD-7) [24]. Respondents indicate how frequently they have experienced symptoms of depression or anxiety over the past two weeks on a four-point Likert scale (0 = not at all to 3 = nearly every day). Higher scores indicate more depressive/anxiety symptoms. Responses are summed to produce a total score (range: PHQ-8 = 0–24, GAD-7 = 0–21).

2.3.2.3. Prospective and retrospective memory. Prospective and Retrospective Memory Questionnaire (PRMQ) assesses general prospective and retrospective memory [25]. Respondents indicate how frequently they experience 16 memory 'slips' on a 5-point Likert scale (1 = never to 5 = very often). Responses are summed to produce a total score (range: 16–80), with higher scores indicating more memory problems.

2.3.2.4. Demographic and clinical characteristics. Participants were asked to self-report demographic characteristics and clinical characteristics (see Table 1).

2.4. Statistical analyses

Unless noted otherwise, all statistical analyses were conducted separately for three groups: T1DM, non-insulin-treated and insulin-treated T2DM. Missing data was minimal

(<5%) on measures used to assess validity. Pairwise deletion of missing values was used to minimise loss of data. Valid percentage is reported.

High completion rates (≥90%) are taken as evidence of the acceptability of the DIDP. Descriptive statistics were used to identify response patterns, item floor/ceiling effects (i.e. >20% participants rating minimum/maximum possible response) [26].The Kolmogorov-Smirnov test of normality was applied to assess the distribution of the data. All data were distributed non-normally, necessitating the use of non-parametric statistics.

Barlett's Test of Sphericity was assessed to check for correlation between items and the determinant was screened for multicollinearity. Two-tailed inter-item Spearman's rho (r_s) correlations were used to identify items with very high ($r_s > 0.7$) or very low ($r_s < 0.3$) inter-item correlations. A Kaiser-Meyer-Olkin statistic of >0.05 for all subgroups indicated sample size adequacy [27]. The structural validity of the questionnaire was assessed using principal axis factoring analysis. The Kaiser-criterion (Eigenvalue ≥ 1), percentage variance explained by each factor, and factor loadings were inspected to assess whether the expected single-factor structure was supported. Factor loadings were considered meaningful if ≥0.5 [28]. Cronbach's alpha and Guttman's Lambda [29] were used to assess internal consistency reliability (i.e. how well the items in a scale measure the same underlying construct), with $\alpha \geq 0.7$ considered satisfactory and $\alpha > 0.95$ indicating item redundancy.

Correlations with measures used for validation purposes were calculated for scale scores and individual dimensions. Moderate ($r_s > \pm 0.3$) and strong ($r_s > \pm 0.5$) correlations were taken as evidence for convergent validity (i.e. whether two measures that should be related are actually related). Weak correlations ($r_s < \pm 0.3$) were taken as evidence of discriminant validity (i.e. whether two measures that should be unrelated actually measure dissimilar constructs) [30]. Known groups validity is a test of whether a measure can discriminate between two groups on the variable of interest. It was examined by comparing (Mann-Whitney test or Kruskal-Wallis test) item and DIDP scale scores by: diabetes type/treatment (T1DM; T2DM insulin-treated type 2; T2DM non-insulin-treated); insulin administration (injections/pump, T1DM sample only); severe hypoglycaemia episode in past 6 months (yes/no, insulin-treated samples only); diabetes-related complications (none/≥1).

Statistical analyses were conducted using IBM SPSS version 22 (Chicago, IL, USA). An alpha level of $p < 0.05$ was taken to indicate significance. Data are reported as mean ± SD, median (quartile 1, quartile 3) or n(%).

3. Results

3.1. Sample characteristics

The DIDP was attempted (completion of ≥1 item) by 2207 participants (T1DM: n = 1012, T2DM non-insulin-treated: n = 691, T2DM insulin-treated: n = 504). Participant demographic, clinical and psychosocial characteristics are shown in Table 1 (N = 2207).

3.2. Acceptability, applicability and response patterns

The DIDP was received by 2212 participants and 99.4% completed all 7 DIDP items. Five participants skipped the entire scale, one skipped two items, and seven skipped a single item. Most participants perceived all DIDP items to be applicable (T1DM: 91%, n = 917; insulin-treated T2DM: 85%, n = 427; non-insulin-treated T2DM: 84%, n = 582). The item most commonly reported as N/A was 'work/studies' (10.5%, n = 232) while all other items were reported as N/A by ≤3.5%. Response patterns by diabetes subgroup are available in Supplement 1. The full range of response options was used for every item. Where the aspect of life was deemed applicable, the distribution of responses was negatively skewed, with the majority of responses indicating no impact to a slight negative impact. No ceiling or floor effects were observed for any items. Descriptive statistics for each dimension are shown in Table 1.

3.3. Scale structure

Within the DIDP, medium-to-large inter-item relationships were observed ($r_s = 0.30–0.63$) and multicollinearity was not a problem (determinant value >0.0001). Table 2 displays scale structure and internal consistency reliability for the 6-item and 7-item scales, by diabetes type/treatment.

For the 6-item scale, a single-factor structure was observed, explaining between 59 and 67% of total scale variance. Internal consistency was high across diabetes type/treatment groups ($\alpha = 0.85–0.90$). The additional item ('dietary freedom') loaded >0.5 for all groups, but a small decrease was observed in the total scale variance explained (difference: −2.8 to −5.6%), and marginally different reliability results were observed ($\alpha = 0.86–0.88$) across groups.

To assess how many complete responses (i.e. not missing or N/A) per participant are required to retain strong internal consistency, Cronbach's alpha was recalculated iteratively (after deleting the item with the strongest item-total correlation) until reliability was compromised ($\alpha < 0.70$). Across groups, ≤2 missing or N/A responses were tolerated on the 6-item scale, and ≤3 on the 7-item scale. DIDP composite scores (Table 1) are calculated using this approach. Mean scale scores trend towards a slight negative impact of diabetes across dimensions of life.

3.4. Convergent, divergent, and known-groups validity

Table 3 displays correlations between the DIDP dimensions, scale scores and various self-reported clinical and psychosocial measures. Hypothesised convergent validity was supported for the T1DM sample: strong correlations were observed with diabetes-specific distress (PAID), and moderate correlations with generic anxiety (GAD-7) and depressive symptoms (PHQ-8), for the 6-item and 7-item DIDP scale scores. In the T2DM samples, regardless of treatment type, convergent validity hypotheses were not supported for the scale scores, with one exception. Moderate positive correlations were observed for both the 6-item and 7-item DIDP scale scores and depressive symptoms (PHQ-8) for participants with non-insulin treated T2DM.

Table 4 – Known-groups comparison for the DIDP dimension and composite scores.

DIDP dimension/scale score	Diabetes Type/Treatment[a]			Insulin administration: Inject vs Pump[b]	Diabetes-related complications: ≥1 vs none			Severe hypoglycaemia in past 6 months: ≥1 vs none[c]	
	T1DM vs T2DM: Insulin	T1DM vs T2DM: NI	T2DM: Insulin vs NI	T1DM	T1DM	T2DM: Insulin	T2DM: NI	T1DM	T2DM: Insulin
Physical health	−0.01 ^{ns}	0.15*	0.16*	0.01 ^{ns}	0.16*	0.18*	0.14*	0.10	−0.01 ^{ns}
Financial situation	0.17*	0.26*	0.08	−0.15*	0.14*	0.07 ^{ns}	0.02 ^{ns}	0.08	0.00 ^{ns}
Relationships	0.03 ^{ns}	0.08	0.05 ^{ns}	0.01 ^{ns}	0.13*	0.07 ^{ns}	0.02 ^{ns}	0.10	0.15
Leisure activities	0.08	0.24*	0.16*	−0.04 ^{ns}	0.10	0.17*	0.20*	0.10	0.05 ^{ns}
Work or studies	0.16*	0.25*	0.09	0.01 ^{ns}	0.11	0.14	0.07 ^{ns}	0.11	0.15
Emotional wellbeing	0.12*	0.22*	0.09	−0.04 ^{ns}	0.09	0.05 ^{ns}	0.04 ^{ns}	0.09	0.02 ^{ns}
Dietary freedom	nc	nc	nc	0.14*	0.05 ^{ns}	0.09 ^{ns}	0.00 ^{ns}	−0.01 ^{ns}	0.00 ^{ns}
6-item scale	0.12*	0.27*	0.15*	−0.06 ^{ns}	0.15*	0.14	0.13	0.12*	0.04 ^{ns}
7-item scale	0.11*	0.24*	0.13*	−0.01 ^{ns}	0.15*	0.13	0.12	0.10	0.04 ^{ns}

Effect size (r) and p-levels reported are for pair-wise comparisons. Negative effect size indicates less negative impact reported by the reference group (first category/group listed) compared to the comparison group (second listed).

All comparisons are significant at p-value < 0.05, unless otherwise noted: ns = not significant ($p > .05$).

nc = not calculated. NI = non-insulin using, T1DM: Type 1 diabetes mellitus, T2DM: Type 2 diabetes mellitus.

* $p < .001$.

[a] Statistics refer to pairwise comparisons conducting Kruskal-Wallis test comparing DIDP dimension and scale scores by diabetes type/treatment groups (T1DM, insulin-treated T2DM, non-insulin-treated T2DM). Pairwise comparisons only conducted where a significant difference by diabetes type/treatment was observed.

[b] Insulin administration comparison conducted for T1DM group only.

[c] Comparison conducted for T1DM and T2DM insulin-treated only.

At the item level, diabetes-specific distress was at least moderately ($r_s \geq 0.36$) positively associated with: each of the DIDP dimensions for participants with T1DM; 'emotional wellbeing' and 'dietary freedom' dimensions for participants with T2DM (regardless of treatment); and 'physical health' among those with insulin-treated T2DM. Moderate correlations ($r_s \geq 0.32$) between general emotional wellbeing (PHQ-8, GAD-7) and the 'emotional wellbeing' dimension were observed across groups, and with 'physical health' and 'work/studies' dimensions among participants with T1DM.

Divergent validity of the 6-item and 7-item DIDP scales was confirmed across diabetes type/treatment groups.

Table 4 details non-parametric known-group comparisons for the DIDP dimensions and 6-item and 7-item scale scores. Where signification differences were observed, effect sizes were small ($r \leq 0.3$).

With the exception of dietary freedom, all scores differed significantly by diabetes type/treatment group. Pairwise comparisons revealed that participants with T1DM reported significantly more negative DIDP scores compared to those with T2DM (both insulin and non-insulin treated), and participants with insulin-treated T2DM reported significantly more negative DIDP scores than those not using insulin.

Among those with T1DM, no significant differences in DIDP scale scores were observed by insulin administration (injection versus pump), but differences were observed on two dimensions ('finances' and 'dietary freedom'). Significant differences in all DIDP scale scores were observed by presence/absence of diabetes-related complications (all groups) and by experience of severe hypoglycaemia (T1DM only).

4. Discussion

The DIDP meets the need for a brief, contemporary measure assessing the impact of diabetes on key dimensions of life. High acceptability, strong internal consistency, and a robust single-scale structure are evidenced, separately by diabetes type and treatment, for the original, and modified 7-item, scale.

Divergent validity was demonstrated across diabetes type/treatment groups for the 6-item and 7-item scales. Importantly, DIDP scales scores were weakly associated with HbA1c and diabetes duration, demonstrating that the impact of diabetes on life cannot, and should not [31], be presumed from clinical characteristics alone. For the 6-item and 7-item scales, convergent validity was confirmed in the T1DM sample, but not as strongly in the T2DM sample (regardless of treatment type). However, the 'emotional wellbeing' dimension was at least moderately associated with diabetes-specific distress and general emotional wellbeing across all groups. Further research is needed to investigate convergent validity in T2DM samples.

Known-groups validity was established for the 6-item and 7-item DIDP and results were largely consistent with DAWN2 findings [14] and with long-form measures of diabetes-specific quality life [e.g. 5,6,22,32,33]. These results suggest that the DIDP may be able to discriminate at a population level between diabetes types, absence/presence of complications and severe hypoglycaemia (T1DM only), and major treatment types (e.g. tablets vs injections), but lacks sensitivity to more subtle differences (e.g. insulin administration modality: injection vs infusion). The DIDP assesses the broad impact of diabetes on various dimensions of life, which can include the impact of treatment but was not designed to focus on treatment-specific issues, e.g. convenience, efficacy, or side effects. When evaluating new treatments and technologies, it is important to use relevant measures of treatment satisfaction/burden [e.g. 34,35].

Given the brevity of the DIDP, we must consider whether the most appropriate dimensions of life are included and to what extent comprehensiveness is sacrificed for brevity. The DIDP dimensions cover several of the most discriminatory items of the ADDQoL [5,22], one of the most widely used measures of diabetes-specific quality of life [36]. However, one potential omission of the 6-item DIDP is dietary freedom, which has been found to be the most negatively impaired aspect of life in several studies using the ADDQoL across diabetes types/treatments [20–22]. When dietary freedom was added to the DIDP, acceptability and reliability remained satisfactory, but the amount of variance explained by the scale dropped slightly. The seventh item performed as expected in terms of convergent and divergent validity but added little discriminatory power to known-groups analyses, except in relation to the difference between insulin administration modality (T1DM sample only). However, participants (especially those with T2DM) reported the most negative impact of diabetes on the dietary freedom dimension. It may be that dietary freedom is more indicative of treatment satisfaction than quality of life per se. Indeed, the impact of insulin use on dietary freedom (what and when you eat) are included in the validated Insulin Treatment Satisfaction Questionnaire [34]. Regardless, further investigation of the relevance and importance of each of the DIDP's dimensions, and consideration of other dimensions not currently captured (e.g. driving, independence), is warranted. For those considering use of the DIDP, inclusion of the dietary freedom item will depend upon the investigators' study population and research question. For example, it would likely be useful in the evaluation of trials promoting flexible, intensive insulin therapy or a restricted low-carbohydrate dietary regimens [20].

The DIDP was deliberately worded neutrally with a bi-directional response scale to capture both positive and negative impacts of diabetes. It has been suggested that solely negatively-worded questionnaires may be upsetting or frustrating to respondents and susceptible to social desirability bias [37,38]. Further, some people with diabetes perceive positive consequences of having diabetes (e.g. healthier lifestyles, friendships) [5,39]. In the current study, positive impact of diabetes was reported by 5–17% of participants across life dimensions and groups, and all response options were used, confirming the previously described utility and acceptability of bi-directional response scales to assess the impact of diabetes [5].

A strength of this study is the large sample, which enabled analyses to be conducted by diabetes type and treatment. DAWN2 results, including DIDP score distributions, internal consistency, and correlations with key clinical, demographic and psychosocial variable, have been reported elsewhere [13,14]. However, psychometric properties were not reported

in detail or examined separately by diabetes type/treatment. Thus, the current study provides important psychometric evidence in support of the future use of the English version of the original 6-item and modified 7-item DIDP separately for adults with T1DM and T2DM. Future research should investigate cultural and linguistic equivalence, and psychometric properties of other DIDP language versions, as well as the caregiver versions [12,13,19,40].

Limitations of MILES-2 have been reported elsewhere [15]. Limitations described here are those specific to the current study. The MILES-2 study was designed to assess a wide range of constructs, enabling the examination of the hypothesised relationships between the DIDP and other clinical and psychosocial constructs for assessment of scale validity. However, clinical characteristics were self-reported and the study sample is relatively homogeneous [15]. Further, our ability to assess other forms of scale validity was limited due to the cross-sectional and non-interventional nature of the study as well as the exclusion of established long-form measures of diabetes-specific quality of life [4–6]. Future research should investigate the test–retest reliability (reproducibility), concurrent and predictive validity of the DIDP as well as its sensitivity to change. Finally, MILES-2 participants were more likely to be English-speaking, highly educated, and employed compared to the Australian general population [15]. Future research examining the psychometric properties and acceptability of the DIDP (all language versions) should include hard-to-reach groups.

In conclusion, the current study adds to the evidence for the DIDP, showing the 6-item and 7-item scales are acceptable, valid and reliable brief measures of the perceived impact of diabetes in both T1DM and T2DM. The DIDP enables clinicians and researchers to take a holistic approach, reflecting on the values and preferences of people with diabetes, considering the perceived impact of their condition on various life dimensions. Further studies are needed to establish its utility in assessing the effect of clinical interventions, quality improvement programmes and policy, as well as the clinical utility of the DIDP in the delivery of individualised diabetes care.

5. Enquiries

The DAWN2 Impact of Diabetes Profile is freely available for use. A copy of the 7-item DIDP (English) for completion by adults with diabetes is shown in Supplement 2. For further information about publicly available DIDP language versions, please email: sskovlund@dcm.aau.dk.

6. Data statement

All Diabetes MILES-2 data, including data that support the findings of this study, are available on reasonable request. Data requests should be emailed to Dr Elizabeth Holmes-Truscott at etruscott@acbrd.org.au.

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Duality of interest

SS was employed by Novo Nordisk at the time the DIDP was designed for use in DAWN2. MP received consultancy fees and research funding in relation to his role as Chair of the DAWN2 Scientific Board. FP received an unrestricted grant from Novo Nordisk to appoint a postdoctoral researcher to analyse data from the DAWN2 study. EHT, CH and JS have no relevant disclosures in relation to the DIDP questionnaire.

Author contributions

SS drafted the original items for the DIDP and led the finalisation process. MP contributed to design of the DIDP and provided final approval as the Scientific Chair of the DAWN2 study. FP and JS provided input into design of the DIDP. FP reviewed and approved the final questionnaire used in DAWN2.

JS conceived The Diabetes MILES Study and, together with FP, developed The Diabetes MILES Study International Collaborative. JS, EHT and CH contributed to the development of the MILES-2 study design and survey content. EHT developed the analysis plan, with guidance from all authors, conducted data cleaning and analysis, and prepared the results. EHT and JS prepared the first draft of the manuscript. All authors provided substantial intellectual contributions to subsequent revisions. All authors approved the final manuscript. EHT is the guarantor of this work and, as such, had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.diabres.2019.03.020.

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