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PAID-11: A brief measure of diabetes distress validated in adults with type 1 diabetes

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ABSTRACT

Objective: The Problem Areas In Diabetes (PAID) questionnaire is widely used to assess emotional distress related to living with diabetes, although it is lengthy for routine clinical use. Our aim was to determine whether the original 20-item PAID questionnaire can be abbreviated, whilst maintaining its reliability, validity and utility.

Methods: We analysed data from the UK DAFNE (Dose Adjustment For Normal Eating) education programme for adults with Type 1 diabetes. Data were analysed at baseline (n = 1547) and 1-year post intervention (n = 846). Exploratory factor analysis (EFA) with principal axis factoring method was used to examine PAID responses within a random half of the baseline data (n = 746). Then, two confirmatory factor analyses (CFA) were conducted using the remaining baseline (n = 801) and 1-year data. Reliability, predictive validity, convergent validity and responsiveness were also examined.

Results: Based on the EFA results, which were corroborated by CFA, an 11-item PAID questionnaire was identified with a cut-off score of 18 indicating severe diabetes distress. In the current sample, this brief version had high internal consistency (Cronbach's $\alpha = 0.93$). Predictive validity was demonstrated with the PAID-11 identifying severe diabetes distress from the original 20-item measure, with 95% sensitivity and 96% specificity. Convergent validity was demonstrated by strong positive correlations with HADS anxiety and depressive symptoms (average $r = 0.65$ and $r = 0.55$, respectively), while divergent validity was shown with weaker correlations with EQ5D health status (average $r = 0.37$).

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Conclusions: Based on present results, PAID-11 appears to be a valid and reliable measure, which seems suitable for use as a brief tool for the detection of diabetes distress in adults with type 1 diabetes. Importantly, this tool may reduce participant burden in multi-measure studies. However, further studies are urgently needed to determine the validity and utility of PAID-11 beyond the UK DAFNE population.

1. Introduction

Type 1 diabetes is a complex condition involving a considerable burden of self-management with the risk of both acute and chronic complications [1]. The psychological impact can be profound. Emotional reactions, such as anger, guilt, shame, depression or anxiety are commonly experienced by individuals with diabetes [2]. Emotional factors contribute to the high burden of the condition, and increased risk of premature mortality [3]. Specifically, the emotional impact of living with diabetes has been termed diabetes distress [4]. Elevated or severe diabetes distress is experienced by around one quarter of adults with diabetes living in the UK, at any one time [5]. Similar, but also higher, rates of diabetes distress have been shown around the world [6,7].

High levels of diabetes distress, such as feeling overwhelmed by the demands of living with diabetes can lead to sub-optimal self-management (e.g., [8]). Both high HbA1c and severe hypoglycaemia are also associated with increased diabetes distress (e.g., [9]). Further, diabetes distress (but not depression or depressive symptoms) is associated with higher HbA1c (e.g., [10]), hence it is critical to have appropriate tools available to identify diabetes distress and enable early intervention.

Routine screening for distress in individuals with diabetes is increasingly recommended by professional bodies; for example, the most recent guidelines of the American Diabetes Association [11] and the UK National Institute for Clinical Excellence [1].

Six measures have been identified that capture the broad spectrum of diabetes distress [12]. The most widely used is the 20-item Problem Areas in Diabetes scale (PAID), developed by Polonsky et al. [4]. The psychometric characteristics of the PAID, together with its ability to detect change due to an intervention, have been supported in multiple studies, not only in clinical and research populations (e.g., [13–16]), but also to assess the effectiveness of interventions, including the DAFNE (Dose Adjustment For Normal Eating) structured type 1 diabetes education programme [17–19].

Despite the research pedigree of the PAID, its utility in a routine clinical setting may be limited due to its length and the time required to complete the questionnaire. It is possible that a version with fewer items but similar psychometric characteristics may prove equally reliable, particularly if applied to a selected population, such as those with type 1 diabetes only. Indeed, previous studies have noted that the 20-item PAID has high internal consistency reliability (Cronbach's $\alpha \geq 0.95$) (e.g., [20,21]), suggesting there may be some item redundancy in the scale [22]. Attempts have been made to develop 5-item and single-item versions of the PAID questionnaire [23]. However, these scale reductions have been conducted using datasets from mixed populations of adults with type 1 diabetes and type 2 diabetes. There may be limitations with regards to the applicability of these findings to the type 1 diabetes population. Moreover, while the reduction in length might be suitable for initial screening, the PAID-5 and PAID-1 will potentially offer little clinical utility for understanding the sources of distress, as they are likely to have reduced content validity.

Our aim was to investigate: (a) whether it is possible to construct a short-form of PAID with satisfactory psychometric properties using data from a large sample of adults with type 1 diabetes, and (b) the reproducibility of the short-form, and its responsiveness to an educational intervention, using one-year follow-up data.

2. Methods

2.1. *DAFNE research database*

The data used in this study were taken from the DAFNE Research Database (DB031). DAFNE (Dose Adjustment For Normal Eating) is a 5-day group structured education programme, which trains adults with type 1 diabetes in the skills required for self-management of flexible, intensive insulin therapy. DAFNE education provides adults with type 1 diabetes with the knowledge and self-management skills required for using optimal insulin dosing based on carbohydrate counting. DAFNE has been shown to improve glycaemic control, to reduce the frequency of episodes of severe hypoglycaemia and ketoacidosis, and to improve psychosocial outcomes, including diabetes-related distress (e.g., [18,24]). Offering structured education to individuals with diabetes has been a recommended part of routine care in the UK since 2001 [25]; to date, more than 43,000 adults with type 1 diabetes have undertaken DAFNE training [26] and many more have attended similar structured education courses, both in UK and other countries.

The DAFNE Research Database was developed as part of an NIHR-funded programme to evaluate and improve DAFNE structured education [27]. The sample used in this study included adults with type 1 diabetes using multiple daily injections, recruited from 10 hospital sites in the UK, who participated in the DAFNE programme between 2008 and 2013. Participants were required to give written, informed consent for their data to be included in the database. The DAFNE Research Database incorporates anonymised baseline and post-course demographic, biomedical and psychosocial data,

including PAID [15], Hospital Anxiety and Depression Scale (HADS: A and D; [28]) and EuroQol 5D (EQ5D; [29]).

2.2. Participants

From 2008 to 2013, 3184 adults with type 1 diabetes were recruited to the DAFNE Research Database. As we were determining and comparing PAID scores at baseline and at follow-up, we excluded those with no or incomplete PAID data and those experiencing major changes in circumstances that may, independently, have affected PAID scores, i.e. including pregnancy (n = 49) and those that converted to insulin pump therapy (n = 289) (at baseline or follow up). Of the remainder, complete PAID questionnaire data were available at baseline for N = 1,547 participants, at baseline but not at follow up for N = 644, and at both baseline and one-year post course follow-up for N = 846 participants.

2.3. Statistical analysis

All statistical analyses were conducted using IBM SPSS Statistics for Windows, Version 25.0 (Armonk, NY: IBM Corp) unless specified otherwise. We used descriptive statistics to examine participant characteristics.

We split the baseline dataset into two samples (A: n = 746 and B: n = 801) determined at random. There were no significant differences between these two samples (see Table 1). Sample A was used for an initial Exploratory Factor Analysis (EFA). Baseline data were only marginally skewed, and so the method of principal axis factoring was implemented, as recommended in the literature [30]. The sample size (n = 746; i.e., sample A) was deemed adequate for the analysis (sample A: KMO = 0.95, $p < .0001$).

Consistent with McGuire et al.'s approach [23], we removed items that loaded <0.50 (item 15), and items that had high double-loadings on other factors (i.e. item 1, 2, and 18), especially as they did not meet the recommended thresholds for retaining (i.e., loading of 0.50–0.60 on first factor, and loadings <0.20–0.30 on second highest factor, and secondly the difference between cross-loadings was not >0.30–0.40) [31]. Removing such items is suggested to clarify the solution [32]. Lastly, we removed all remaining items with scores ≤1.0 (i.e., rated on average as minor problems by the respondents) (excluded PAID items at this stage: 4, 5, 10, 14, and 17).

The EFA was run twice (see Table 2), since if items are removed, it is recommended that the whole analysis is repeated [32]. We then determined whether the structure obtained in sample A was reproducible by conducting confirmatory factor analyses (CFA) on data from sample B (n = 801) and the one-year post-course dataset (n = 846). The criteria specified for a good model fit were based on the following statistics: Cmin/df <5.0, CFI > 0.95, NFI >0.95, and RMSEA <0.08 [33]. We used AMOS software (version 25; Chicago, USA) to perform CFA, with the maximum likelihood method. We assessed the internal consistency reliability of the PAID short-form using Cronbach's alpha in all three samples.

We used Pearson's correlation analysis to examine the convergent and divergent validity of the PAID short-form (baseline data) with the HADS and EQ5D, respectively. In accordance with established thresholds [34], it was expected

Table 1 – Demographic, clinical and psychological characteristics of study participants in the DAFNE Research Database.

Characteristics	Full Baseline sample (n = 1547)		Baseline sample A (n = 746)*	Baseline sample B (n = 801)*		Baseline and follow-up sample (n = 903)		Paired data (n = 846)			
								Baseline		Year 1	
	N	Mean(SD)	Mean(SD)	Mean(SD)	p	N	Mean(SD)	Mean(SD)	N	Mean(SD)	p
Age	1547	45.48(14.09)	45.55(14.28)	45.41(13.92)	0.85	903	47.70(14.08)	48.10(14.06)	846		
Gender: Women	1545	719(46.5%)	352(47.2%)	367(45.8%)	0.62	902	(443)49%	406(48%)	845		
Duration of diabetes: years	1533	22.77(13.28)	22.48(13.29)	23.04(13.27)	0.42	900	23.39(13.85)	23.46(13.89)	845		
HbA1c: mmol/mol	1125	68.85(16.84)	73.05(18.20)	72.86(18.00)	0.85	881	70.88(16.84)	70.78(16.89)	757	67.84(15.62)	<0.001
HbA1c: %	1125	8.45(1.54)	8.83(1.67)	8.82(1.64)	0.86	881	8.64(1.54)	8.63(1.54)	757	8.36(1.43)	< 0.001
BMI	1460	26.44(5.01)	26.34(4.88)	26.55(5.12)	0.38	851	26.48(4.82)	26.49(4.51)	708	26.43(4.59)	0.32
PAID-20 diabetes distress	1547	28.92(20.14)	29.01(20.47)	28.84(19.84)	0.87	903	27.31(19.36)	27.05(19.24)	846	20.28(17.46)	< 0.001
HADS anxiety symptoms	1476	6.48(4.31)	6.49(4.19)	6.47(4.42)	0.91	856	6.27(4.18)	6.20(4.14)	788	5.65(4.08)	< 0.001
HADS depression symptoms	1472	3.95(3.61)	3.98(3.61)	3.93(3.61)	0.78	851	3.86(3.52)	3.83(3.49)	784	3.36(3.61)	< 0.001
EQ5D Health status	1500	6.10(1.48)	6.16(1.53)	6.04(1.43)	0.12	877	6.07(1.45)	6.05(1.44)	804	6.05(1.55)	1.0

Data are Mean ± SD or n(%). P-value based on paired t-tests; independent t-tests or Chi-square tests. BMI: body mass index.
* Two random samples created using random split for purposes of conducting exploratory and confirmatory factor analyses.

Table 2 – Exploratory factor analysis of baseline sample A (n = 746): unforced loadings of 20-item PAID and unforced loadings and communalities of 11-item PAID when re-analysed, ranked by mean importance.

Item	Mean (SD)	Mode	Initial analysis of PAID-20			Re-analysis of PAID-11	
			Factor 1	Factor 2	Factor 3	Factor 1	Communalities
Worrying about the future and the possibility of serious complications (PAID_12)	2.11 (1.25)	2	0.741			0.782	0.611
Feelings of guilt or anxiety when you get off track with your diabetes management (PAID_13)	1.76 (1.23)	1	0.728			0.745	0.555
Not knowing if your mood or feelings are related to your diabetes (PAID_7)	1.47 (1.17)	1	0.748			0.752	0.565
Worrying about low blood sugar reactions (PAID_9)	1.47 (1.17)	1	0.573			0.591	0.350
Not having clear and concrete goals for your diabetes care (PAID_1)	1.38 (1.15)	2	0.606	0.502			
Coping with complications of diabetes (PAID_19)	1.26 (1.24)	0	0.687			0.702	0.493
Feeling discouraged with your diabetes treatment plan (PAID_2)	1.23 (1.13)	0	0.624	0.534			
Feeling constantly concerned about food and eating (PAID_11)	1.22 (1.17)	0	0.738			0.738	0.544
Feeling “burned out” by the constant effort needed to manage diabetes (PAID_20)	1.19 (1.20)	0	0.791			0.796	0.634
Feeling scared when you think about living with diabetes (PAID_3)	1.17 (1.16)	0	0.774			0.769	0.591
Feeling depressed when you think about living with diabetes (PAID_6)	1.15 (1.19)	0	0.829			0.820	0.673
Feeling overwhelmed by your diabetes (PAID_8)	1.03 (1.12)	0	0.823			0.822	0.675
Feeling angry when you think about living with diabetes (PAID_10)	0.99 (1.21)	0	0.795				
Uncomfortable social situations related to your diabetes (e.g., people telling you what to eat) (PAID_4)	0.96 (1.10)	0	0.566				
Feeling alone with your diabetes (PAID_17)	0.95 (1.21)	0	0.766		0.385		
Feeling of deprivation regarding food and meals (PAID_5)	0.82 (0.99)	0	0.635				
Not “accepting” your diabetes (PAID_14)	0.79 (1.21)	0	0.685				
Feeling unsatisfied with your diabetes physician (PAID_15)	0.56 (1.01)	0	0.401	0.305			
Feeling that your friends and family are not supportive of your diabetes management efforts (PAID_18)	0.51 (0.92)	0	0.544		0.403		
Eigenvalue			10.17	1.26	1.06	6.65	
Total scale variance			50.84	6.28	5.30	60.49	
Internal consistency reliability (Cronbach’s alpha)			0.934	0.756	0.764	0.934	

Factor loadings <0.30 are suppressed for clarity of presentation. The Eigenvalues in the initial analysis for the second and third factor were 1.26, and 1.06, respectively. The Eigenvalue in the re-analysis for the second factor was 0.68. An 11-item PAID was derived by excluding: one item loading <0.50 (item 15), two items with high double loadings (item 1 and 2) and six items with mean score <1.0 (item 4, 5, 10, 14, 17, and 18), suggesting they are least important to understanding the experience of diabetes distress.

that EQ5D, as a measure of general health status, would show low correlation with PAID ($r < 0.40$), and that HADS, as a measure of emotional distress (albeit generic), would show higher correlations with PAID ($r > 0.40$, optimally $r > 0.60$). To examine known groups validity, we used an independent groups *t*-test to determine the differences in diabetes distress by gender, hypothesising that women would score higher than men, as in previous reports [23]. To analyse change in the 20-item PAID score (i.e. from baseline to one-year follow-up), that is, to see whether there was an impact of time (pre/post intervention) on PAID score, a repeated measures ANOVA was conducted with time and PAID item number (i.e., to avoid multiple comparisons if not needed) as within-subject factors and PAID score as dependent variable. As the sphericity test for ANOVA was significant, indicating that the variances between pairs of scores were not equal, a Greenhouse-Geisser correction (a standard statistical procedure) was applied. Subsequently each PAID item was compared at pre and post-intervention with the use of paired *t*-test (with Bonferroni correction; see Table 3). Each PAID item was analysed separately, as this could provide useful information about item responsiveness and clinical utility, which the scale total alone cannot provide. The pre-post difference data were normally distributed, satisfying the requirements of the *t*-test. Finally, we examined the predictive validity of the PAID short-form by analysing its specificity and sensitivity (using ROC curve analysis and Youden index), against the original 20-item scale. We ascribed the same weights to both sensitiv-

Table 3 – Responsiveness of the PAID items for participants who completed both baseline and follow-up assessments (n = 846).

PAID item number and wording	Baseline		Year 1		
	Mean	SD	Mean	SD	Test statistic
1: Not having clear and concrete goals for your diabetes care	1.28	1.11	0.73	1.01	t = 12.64, p < .0001
2: Feeling discouraged with your diabetes treatment plan	1.15	1.11	0.75	1.03	t = 9.31, p < .0001
3: Feeling scared when you think about living with diabetes	1.13	1.14	0.88	1.02	t = 6.84, p < .0001
4: Uncomfortable social situations related to your diabetes (e.g., people telling you what to eat)	0.90	1.02	0.62	0.87	t = 7.77, p < .0001
5: Feelings of deprivation regarding food and meals	0.77	0.98	0.39	0.71	t = 11.32, p < .0001
6: Feeling depressed when you think about living with diabetes	1.08	1.17	0.88	1.05	t = 5.65, p < .0001
7: Not knowing if your mood or feelings are related to your diabetes	1.39	1.20	1.12	1.13	t = 6.79, p < .0001
8: Feeling overwhelmed by your diabetes	0.96	1.10	0.72	0.97	t = 6.66, p < .0001
9: Worrying about low blood sugar reactions	1.46	1.16	1.05	1.06	t = 10.79, p < .0001
10: Feeling angry when you think about living with diabetes	0.90	1.16	0.71	1.02	t = 5.61, p < .0001
11: Feeling constantly concerned about food and eating	1.12	1.09	0.77	0.95	t = 9.66, p < .0001
12: Worrying about the future and the possibility of serious complications	2.07	1.23	1.72	1.19	t = 8.96, p < .0001
13: Feelings of guilt or anxiety when you get off track with your diabetes management	1.66	1.16	1.47	1.18	t = 4.67, p < .0001
14: Not accepting your diabetes	0.70	1.14	0.48	0.95	t = 6.66, p < .0001
15: Feeling unsatisfied with your diabetes physician	0.48	0.88	0.29	0.70	t = 6.13, p < .0001
16: Feeling that diabetes is taking up too much of your mental and physical energy every day	1.06	1.09	0.89	1.03	t = 4.75, p < .0001
17: Feeling alone with your diabetes	0.86	1.12	0.63	0.96	t = 6.22, p < .0001
18: Feeling that your friends and family are not supportive of your diabetes management efforts	0.44	0.82	0.37	0.75	t = 2.48, p = .013*
19: Coping with complications of diabetes	1.17	1.20	0.93	1.12	t = 6.03, p < .0001
20: Feeling "burned out" by the constant effort needed to manage diabetes	1.07	1.15	0.85	1.08	t = 5.95, p < .0001

* Difference between baseline and one-year follow-up for item 18 exceeds the Bonferroni correction for multiple comparisons (p < .003) and is not considered significant.

ity and specificity, and used Youden index (J) to determine the best cut-off point, as recommended by Kumar and Indrayan [35].

3. Results

3.1. *Participants' characteristics*

The characteristics of those participants with PAID data at both baseline and follow-up are detailed in Table 1. The 644 participants (43% female; $p < .02$) who had complete PAID baseline data but did not complete one-year follow-up were, at baseline, significantly younger (42.36 (13.50) years, $p < .001$), had higher HbAlc (9.11% (1.78), 76.01 mmol/mol (19.41), $p < .001$), and significantly higher scores on PAID-20 (31.18 (20.99), $p < .001$), HADS anxiety symptoms (6.77 (4.46), $p = .025$) and shorter time since diagnosis (21.88 (12.37) years, $p = .03$) than those with baseline and follow up data (n = 903 at baseline, but then reduced to 846 due to pregnancies and using pumps at follow-up). There were no significant differences between these groups in their levels of HADS depression symptoms (4.08 (3.72), $p = .27$), BMI (26.38 (5.26), $p = .70$) and EQ5D health status (6.14 (1.53), $p = .32$).

When comparing the characteristics of sample A (n = 746) and B (n = 801), that we derived at by randomly splitting baseline data, with approximately 50% per sample, there were no significant differences found (see Table 1), supporting the appropriateness of the random split.

3.2. *Exploratory factor analysis (EFA), scale reduction and internal consistency reliability – baseline sample A*

Based on Eigenvalues >1, the initial solution determined three factors, explaining 62.42% of the variance. The scree plot and factor loadings suggested that a one-factor solution (Eigenvalue for first factor = 10.17), with few items cross-loading, provided a better fit. The single factor solution explained 50.84% of the variance. All items apart from one (i.e. item 15) loaded >0.50 (see Table 2), suggesting satisfactory construct validity. Thus, we excluded this item. After applying

other criteria specified in methods section, we derived at 11 final items (see Appendix A).

A second EFA was conducted using only the selected 11 items (KMO = 0.94). This demonstrated a one-factor solution (Eigenvalue for first factor = 6.65), explaining 60.49% of the variance. The internal consistency of the PAID-11 in sample A was excellent (α = 0.93).

3.3. Confirmatory factor analysis (CFA) and internal consistency reliability – Baseline sample B and one-year follow-up

Using data from baseline sample B (n = 801), a CFA showed all 11 items were assigned to a single factor, and following modification indices (values >20), covariates between the error terms were established (see Fig. 1a). The specified model presented the following model fit indices: $X^2(36) = 132.13$, $p < .0001$, Cmin/df = 3.67, CFI = 0.982, NFI = 0.975, RMSEA = 0.058. The large sample size affected the X^2, but model fit indices indicated a good fit of the data to the model.

Using data from the one-year follow-up (n = 846), the second confirmatory factor analysis showed all 11 items were assigned to single factor, and following modification indices (values > 20), covariates between the error terms were established (see Fig. 1b). The final model with PAID-11 (Fig. 1b) showed a good fit to the data, with the model fit indices being: $X^2(39) = 183.31$, $p < .0001$, Cmin/df = 4.70, CFI = 0.976, NFI = 0.970, RMSEA = 0.066. Again, the large sample size affected the X^2, but model fit indices signified a good fit of the data to the model. The internal consistency of the PAID-11 was excellent (sample B: α = 0.925; follow-up: α = 0.931).

The mean total score for PAID-11 was M = 15.01(SD = 10.18) in sample A, M = 15.01 (SD = 9.84) in sample B, and M = 11.26 (SD = 9.08) at follow-up.

3.4. Construct validity of PAID-11 – all samples

The convergent validity of the PAID-11 in sample A was demonstrated by its strong positive correlations with the HADS anxiety symptoms (sample A: $r = 0.66$; sample B: $r = 0.63$; follow up: $r = 0.67$; all $p < .001$) and HADS depression symptoms (sample A: $r = 0.54$; sample B: $r = 0.56$; follow-up: $r = 0.56$; all $p < .001$), indicating that anxiety and depression symptoms increase alongside increases in diabetes distress,

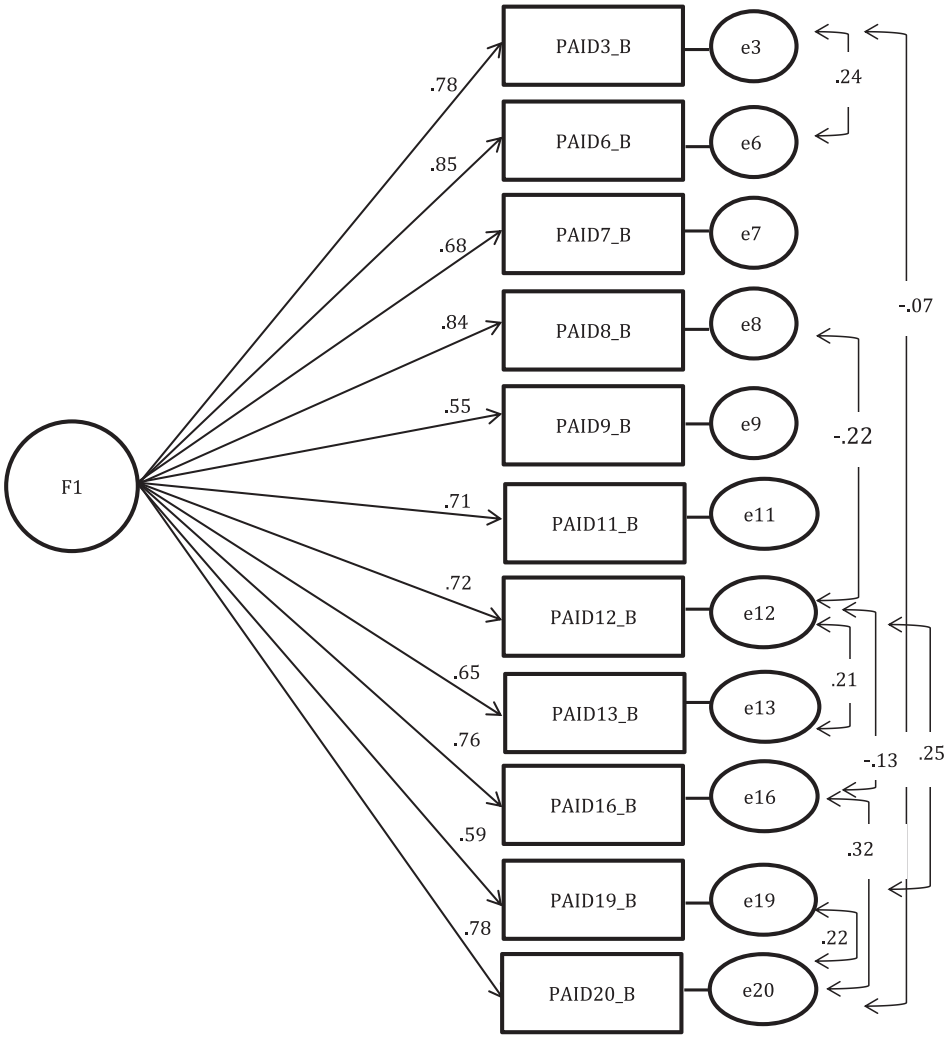

Fig. 1a – Confirmatory factor analysis of PAID-11 using baseline sample B (n = 801).

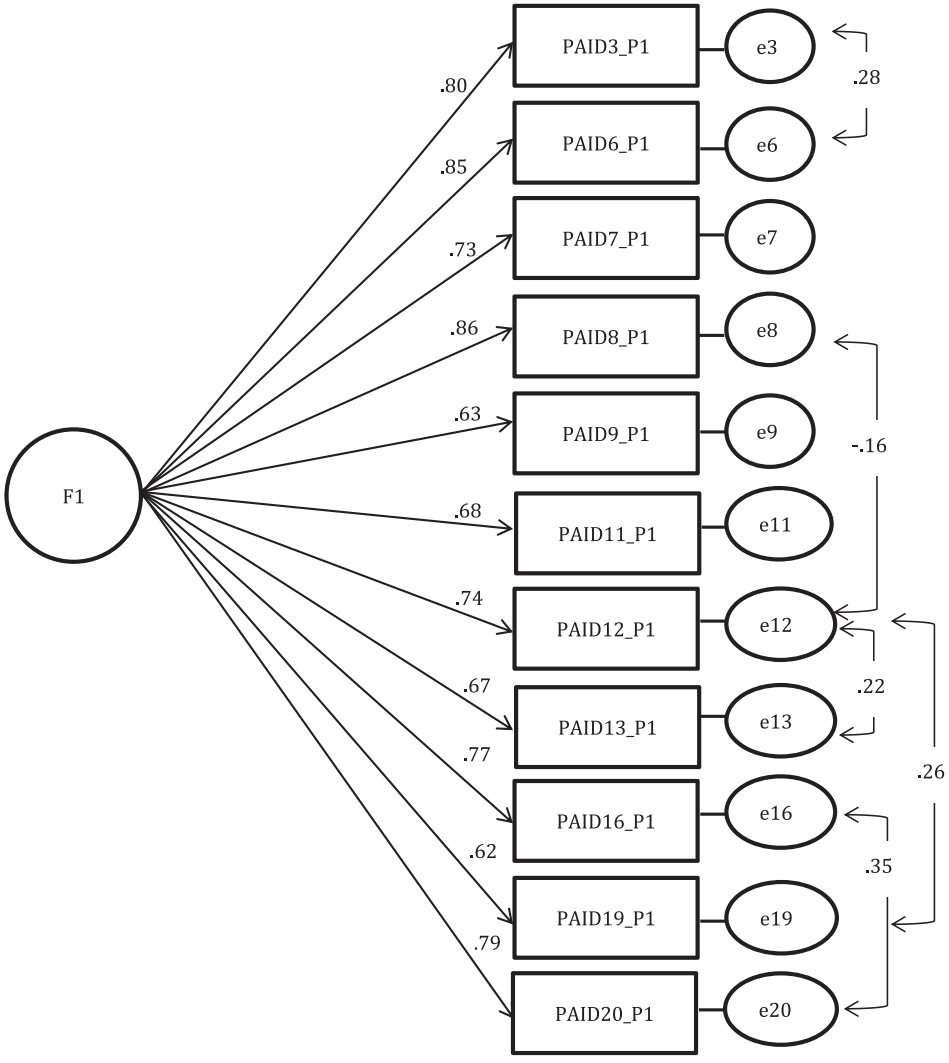

Fig. 1b – Confirmatory factor analysis of PAID-11 using one-year follow up data (n = 846).

and are closely related generic and diabetes-specific versions of an emotional well-being construct.

The divergent validity of PAID-11 was demonstrated, as expected, by its weaker correlation with EQ5D scores (sample A: $r = 0.32$; sample B: $r = 0.40$; follow-up: $r = 0.39$; all $p < .001$), demonstrating that self-reported general health worsens as diabetes distress increases but that the two are distinct constructs.

With respect to known groups validity, we observed that women in sample A (M = 16.40, SD = 10.18, n = 352) scored on average significantly higher ($t(743) = -2.68$, $p < .0001$; Mean difference = −2.68, 95% CI = −4.13, −1.22) than men (M = 13.73, SD = 10.01, n = 393) on the new PAID-11, with an effect size of Cohen's $d = -0.27$ (95% CI = −0.41;−0.12). Essentially similar results were observed in sample B and in the follow-up sample. The mean score on PAID-11 for females (sample B: M = 17.06, SD = 10.11, n = 367; follow up: M = 12.22, SD = 8.90, n = 406) and males (sample B: M = 13.30, SD = 9.29, n = 433; follow up: M = 10.38, SD = 9.18, n = 439) differed significantly: at baseline (Mean difference = −3.76, 95% CI = −5.11, −2.41) ($t(7\,9\,8) = -5.48$, $p < .0001$) and at follow up (Mean difference = −1.84, 95% CI = −3.06, −0.61; $t(8\,4\,3) = -2.95$, $p = .003$). The effect size for this difference was equal to Cohen's $d = -0.39$ (95% CI = −0.53;−0.25) in sample B, and Cohen's $d = -0.20$ (95% CI = −0.33; −0.07) at follow up.

3.5. *Criterion and predictive validity of PAID-11 – baseline samples A and B*

Criterion validity was demonstrated with the 11-item scale correlating highly with the original 20-item scale (sample A: $r = 0.974$, $p < .001$, n = 746; sample B: $r = 0.973$, n = 801; follow up: $r = 0.978$, $p < .001$, n = 846). Lastly, we evaluated the ability of the PAID-11 to predict severe diabetes distress on the PAID-20 using two cut-off scores, as used in previous studies.

Using a PAID-20 cut-off score of 33, consistent with the approach used by McGuire at el. [23], the area under the curve analysis for PAID-11 showed that C = 0.990 (SE = 0.002; 95% CI = 0.987, 0.994) demonstrating high diagnostic accuracy of PAID-11. Using the Youden Index (J), the best cut-off score for PAID-11 was determined to be a score of 17.5 (J = 0.905 for this point, in comparison J for score of 18.50 = 0.879, and J for score of 16.50 = 0.895). This cut-off had 95% sensitivity and 96% specificity in the PAID-11. This cut-off classified

36.4% (n = 563) of the full baseline sample as experiencing severe diabetes distress, and 22.7% (n = 192) as experiencing severe diabetes distress at one-year post-intervention.

Using a PAID-20 cut-off score of 40 [36], the area under the curve analysis for PAID-11 showed, very similarly, that C = 0.990 (SE = 0.002; 95% CI = 0.987, 0.993) demonstrating high diagnostic accuracy of PAID-11. Following the Youden Index method, the best cut-off score for PAID-11 was determined to be a score of 19.5 (J = 0.903 for this point, in comparison J for score of 18.50 = 0.885, and J for score of 20.50 = 0.880). This cut-off was linked to 96% sensitivity and 94% specificity of PAID-11. This cut-off classified 31.2% (n = 483) of the full baseline sample as experiencing severe diabetes distress, and 18.6% (n = 157) as experiencing severe diabetes distress at one-year post-intervention.

However, as the cut-off of 17.5 shows high sensitivity and marginally higher specificity, we recommend that a PAID-11 score of 18 or more (out of a maximum of 44) is used to identify severe diabetes distress.

3.6. *Responsiveness and stability*

Lastly, we examined whether the PAID-11 is able to detect *change* in diabetes distress following a structured type 1 diabetes education intervention (n = 846). Change scores were normally distributed. For the PAID-20, there was a main effect of time ($F(1, 845) = 146.09$, $p < .001$; $\eta^2 = 0.15$) and item number ($F(13.39, 11313.50) = 270.48$, $p < .001$, $\eta^2 = 0.24$), together with a significant interaction ($F(15.93, 13458.99) = 12.61$, $p < .001$, $\eta^2 = 0.02$).

Adjusting for multiple comparisons, all item scores (apart from item 18) showed a statistically significant reduction from baseline to one-year follow-up.

For the PAID-11, there was a significant decrease in diabetes distress between baseline (M = 14.16, SD = 9.71) and one-year post-intervention (M = 11.26, SD = 9.08) with a mean difference of 2.90 points (SD = 8.10; 95% CI = 2.36, 3.45; $t(845) = 10.42$, $p < .001$). This change corresponds to small effect size (Cohen's d = −0.36; 95% CI = −0.44, −0.25) with a 20.48% reduction in PAID-11 score, and thus demonstrated that PAID-11 is sensitive for observing change in diabetes distress.

4. Discussion

This study indicates that a brief version of the PAID questionnaire requiring just 11 responses is valid and reliable for assessing diabetes distress in adults with type 1 diabetes. The PAID-11 questionnaire has high predictive validity (95% sensitivity and 96% specificity) and a suggested cut-off point of ≥ 18 is recommended for identifying those experiencing severe diabetes distress.

Using data from a large UK sample of adults with type 1 diabetes, we demonstrated that the original 20-item PAID [4] was best described as a scale with a one-factor solution with few double-loading items. While several previous studies have found the PAID-20 to be uni-dimensional, i.e. assessing one underlying latent construct of diabetes distress (e.g., [15,16]), several have identified multi-dimensional structures, i.e. two- (e.g., [37]) three- (e.g., [21]) or even four-factors [14]. The PAID-11 seems to present a much clearer one-factor solution, and therefore supports the use of a single total score better than the full PAID-20 scale. The PAID-11 offers a high level of internal consistency reliability (but with less evidence of redundancy), with the considerable advantage of comprising almost half the items (and therefore half the time required for completion) as the original PAID-20 scale. Further, the psychometric properties of PAID-11 have been tested in a larger sample compared with prior short versions of PAID (5-item and single item). In comparison to McGuire et al. [23] who obtained only 10 items loading >0.50 when conducting EFA, all our items apart from one (item 15) loaded >0.50. Interestingly, the same item has been found to possess the highest item misfit in another study in which Rasch analysis was applied to the PAID-20 [16]. Importantly, PAID-11 offers better screening utility (95% sensitivity and 96% specificity) than that offered by PAID-5 (i.e., 94% and 89% respectively; [23]).

The availability of a large, longitudinal dataset has enabled us to demonstrate that PAID-11 is sensitive to capturing change in diabetes distress following an intervention. The comparison of the effect size for change in diabetes distress observed with PAID-11 (Cohen's d = −0.36) was in line with previous literature, suggesting intervention effectiveness for diabetes distress ranging from small (Cohen's d = 0.31) to moderate (Cohen's d = 0.65) [38]. The obtained reduction in diabetes distress (20.48%) was highly comparable with other work demonstrating a 22.5% reduction [39] using a smaller sample.

The consistent correlations with other measures of emotional distress, such as HADS anxiety and depressive symptoms, and with the EQ5D measure of generic health status, lend support to the convergent and divergent validity of PAID-11. Adjusted analyses for multiple statistical tests suggest the findings are unlikely to have arisen spuriously. Although PAID-11 correlated positively with EQ5D scores as a measure of health status (average $r = 0.37$), this correlation was slightly lower than that reported by McGuire et al. [23] who used the WHO-5 ($r = 0.47$), potentially suggesting a more specific measure that was arrived at. However, it has been demonstrated that the EQ5D suffers from ceiling effects with type 1 diabetes samples. For example, Peasgood and colleagues [40] identified that approximately 50% of respondents in each time period reported a health state that was valued at 1.

Some indirect support for the items chosen to create PAID-11 stems from a previous study [36] that examined each item's score for those with clinical depression. When comparing the items that create PAID-11 with the results reported by Hermanns et al. [36], it can be observed that nine of our PAID-11 items score highest in that sample. Whereas the remaining two items of PAID-11 (item 8 and 11) in the above study still score higher than the majority of the excluded items. Similar observations can be made when comparing chosen PAID-11 items with the highest scoring items in another sample that underwent a structured education [19]. Here, nine of the chosen PAID-11 items were among 11 highest scored items, while all 11 items from the PAID-11 were included within the 13 top-scored items. These similar results from different samples seem to support the importance of the selected items for assessing diabetes distress.

We propose that PAID-11 has greater content validity and clinical utility than shorter versions of this scale (e.g., PAID-5, PAID-1) due to the breadth of issues retained in the measure. Harsh reduction of a full scale and failure to include a sufficient number of aspects that are known to contribute to the construct being measured may serve to reduce validity of the scale and its utility [41]. Although the main concerns related to diabetes might be similar for many patients and their families, there is likely to be some level of variation that would be challenging to identify through single item or 5-item measures.

The abbreviated PAID-11 questionnaire is likely to be useful for clinicians seeking to incorporate a measure of psychological distress related to diabetes into their routine clinical consultations, given that almost halving the items from the full scale should equate to a considerable reduction in the time required for completion, with retention of excellent psychometric characteristics. This scale might also represent a good choice for research projects in which multiple measures are used, necessitating brevity as one of the criteria for selecting scales. It should be noted, however, that this is the first study introducing the PAID-11, and thus further validation efforts are required to replicate these findings in other populations and fully ascertain its psychometric validity and utility.

4.1. *Study Limitations*

Our sample included only UK adults with type 1 diabetes using basal-bolus insulin therapy attending a structured type 1 diabetes education course. The fact that our sample had participated in structured education might be seen as a limitation. However, it is important to note that: (a) the DAFNE inclusion criteria are broad and do not exclude many people with type 1 diabetes; (b) structured education has been a standard care recommendation for adults with diabetes in the UK since 2001 [25]. Thus, it could be argued that the vast majority of individuals with diabetes in the UK should receive similar education and our sample is likely to be fairly representative of the broader population with type 1 diabetes. Nevertheless, not everyone attends structured education programmes, and it is known that those who do not attend are often less affluent, have logistical or other medical issues, or do not perceive the value of such education [42]. Thus, the psychometric properties of the PAID-11 need to be confirmed in other care settings, populations (including type 2 diabetes) and countries (especially ones where structured education is not a part of routine care). Using other methodological approaches (e.g., Rasch analysis), as well as conducting prospective studies, would be valuable, although it would be a major undertaking to study a population as large as the one in the current study.

The sample size was also influenced by a relatively substantial drop-out between baseline and year 1 assessment, although this is a common occurrence in longitudinal studies. Nevertheless, as the analyses focused on intragroup rather than intergroup comparisons that issue should have a limited effect on the results presented [43]; as such, we do not expect that such a drop-out has affected our results significantly. Nevertheless, in our study, those who dropped out did have elevated diabetes distress and also higher anxiety level, which may have contributed to their attrition. Indeed, there is evidence to suggest that anxiety in particular may affect expectations about treatments and be associated with drop-out [44]. It would be valuable, therefore, for future studies to investigate whether diabetes distress is related to intervention attrition through comparison of diabetes distress levels in those who continue applying the principles of DAFNE post-course with those who do not.

Notwithstanding these study limitations, psychometric testing of PAID-11 has been conducted in a large sample, and demonstrates that PAID-11 is responsive to intervention.

4.2. *Conclusion*

This study has introduced and validated the PAID-11, a brief measure of emotional distress related to living with and managing diabetes. The PAID-11 offers similar utility to the original 20-item measure [4] with the advantage of almost half the time required for administration and lower associated burden. It has greater sensitivity and specificity than the 5-item version [23]. We recommend that researchers consider the PAID-11 as an alternative to the PAID-20, to reduce participant burden in multi-measure studies. Clinicians may consider using the tool to enable quick and easy identification of diabetes distress in routine practice, although further validation studies are required to assure the utility of PAID-11 in other populations beyond the DAFNE population in which the PAID-11 was tested and analyzed in this study.

‘Research in context’ summary

What is already known about this subject?

- Elevated or severe diabetes distress is experienced by around one quarter of adults with diabetes living in the UK, at any one time.
- The Problem Areas In Diabetes (PAID) questionnaire is widely used to assess emotional distress related to living with diabetes, although it is lengthy for routine clinical use.
- Providing more time-efficient measures of diabetes distress can improve care for people with diabetes.

What is the key question?

- Can we identify a time-efficient, valid and reliable measure of diabetes distress?

What are the new findings?

- Brief version of the PAID questionnaire requiring just 11 responses is valid and reliable for assessing diabetes distress in adults with type 1 diabetes.
- The PAID-11 questionnaire has high predictive validity (95% sensitivity and 96% specificity) and a suggested cut-off point of $\geq$18 is recommended for identifying those experiencing severe diabetes distress.

How might this impact on clinical practice in the foreseeable future?

- Clinicians may consider using PAID-11 to enable quick and easy identification of diabetes distress in routine practice, although further validation studies are needed to ascertain the validity and utility of PAID-11 beyond the UK DAFNE population.

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Author contributions

NS, HB, PM, DC and DH developed the study concept. Data preparation, analysis and interpretation were performed by NS under supervision of HB. NS drafted the manuscript and is guarantor for the article contents. All authors provided critical revisions and approved the final version of the manuscript.

Declaration of interests

The authors confirm that there is no conflict of interest.

This study was presented at the 53rd Annual Meeting of the European Association for the Study of Diabetes as a poster presentation. Details below.

PM, NS, DH, DC, HB. Validation of a shortened 11-item version of the Problem Areas in Diabetes scale to measure distress in adults with type 1 diabetes. 53rd Annual Meeting of the European Association for the Study of Diabetes. 11-15th September 2017, Lisbon, Portugal.

Appendix A. PAID-11 measure

Instructions: Which of the following diabetes issues are currently a problem for you? Circle the number that gives the best answer for you. Please provide an answer for each question.

	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
Feeling scared when you think about living with diabetes?	0	1	2	3	4
Feeling depressed when you think about living with diabetes?	0	1	2	3	4
Not knowing if your mood or feelings are related to your diabetes?	0	1	2	3	4
Feeling overwhelmed by your diabetes?	0	1	2	3	4
Worrying about low blood sugar reactions?	0	1	2	3	4
Feeling constantly concerned about food and eating?	0	1	2	3	4
Worrying about the future and the possibility of serious complications?	0	1	2	3	4
Feelings of guilt or anxiety when you get off track with your diabetes management?	0	1	2	3	4
Feeling that diabetes is taking up too much of your mental and physical energy every day?	0	1	2	3	4
Coping with complications of diabetes?	0	1	2	3	4
Feeling "burned out" by the constant effort needed to manage diabetes?	0	1	2	3	4

Items are presented in the order of the original PAID-20 scale. To obtain a total score, sum all the scores together (items 3, 6, 7, 8, 9, 11, 12, 13, 16, 19, and 20 from original PAID-20). The total score ranges from 0 to 44, with higher scores indicating greater diabetes distress. Scores $\geq$18 indicate severe diabetes distress.

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