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# The psychometric properties of the Norwegian version of the short form of The Problem Areas in Diabetes scale (PAID-5) – a validation study

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## ABSTRACT

**Objectives:** To assess the psychometric properties of the short form of the Problem Areas in Diabetes scale in Norwegian adult patients with type 1 or type 2 diabetes.

**Design:** Cross-sectional survey design.

**Methods:** Participants (n=143) were included consecutively from three Western-Norway endocrinology outpatient clinics. Demographic and clinical data was collected in addition to questionnaires concerning diabetes-related distress, fear of hypoglycemia, symptoms of depression, emotional well-being and perception of general health. Psychometric evaluation of the PAID-5 included confirming its postulated one-factor structure using confirmatory factor analysis; and assessing convergent validity, discriminant validity, internal consistency and test-retest reliability.

**Results:** The confirmatory factor analysis for the PAID-5 scale showed excellent one-factor structure, and there was high internal consistency (α=0.89) and good test-retest reliability (ICC=0.81). The PAID-5 correlated positively with fear of hypoglycemia (r=0.598) and depression (r=0.380) and negatively with emotional well-being (r=-0.363) and perception of general health (r=-0.420), thus satisfying convergent validity. Patients who had experienced episodes of serious hypoglycemia in the past 6 months had a significantly higher PAID-5 mean score (7.5, SD= 4.95) versus those who had not had these episodes (5.0, SD=4.2, (p=0.043)). However, its ability to discriminate between groups needs to be tested further in a larger sample.

**Conclusion:** The Norwegian PAID-5 was shown to be a reliable and valid short questionnaire for assessing diabetes-related distress among people with type 1 or type 2 diabetes. The PAID-5 scale can be a particularly valuable screening instrument in outpatient clinics, as its brevity makes it easy to use as a tool for health care professionals in one-on-one consultations. When used in national registries or population health databases it will enable increased knowledge on the prevalence of diabetes-related distress and thus inform guidelines and future interventions.

**Key words:** Diabetes, distress, psychometric properties, Problem Areas in Diabetes

**Strengths and limitations of this study:**

- The psychometric findings provide evidence for a one-factor structure for the PAID-5 scale, enabling the assessment of diabetes-related emotional distress.
- The PAID-5 demonstrated good internal consistency and a stable test-retest reliability among patients with type 1 and type 2 diabetes across three different clinics in Norway.
- The PAID-5 demonstrated positive associations with worry about hypoglycemia and symptoms of depression, as variants of the same construct, and a negative association with the perception of general health and emotional well-being.
- Further testing of the PAID-5's ability to discriminate between different subgroups is required in a larger sample.

## INTRODUCTION

The International Diabetes Federation [1] states that diabetes is one of the largest global health emergencies of the 21st century and that by the year 2045 an estimated 628.6 million people will have diabetes, which is 9.9 % of the total world population. This eruption of diabetes has grown into a health crisis, with a substantial amount of patients not achieving satisfactory metabolic control [2]. The Diabetes Control and Complications Trial showed that inadequate quality of diabetes care contributes to an increased risk for developing a number of serious and disabling health problems among people with type 1 diabetes [3]. The United Kingdom Prospective Diabetes Study showed similar results among people with type 2 diabetes [4].

The daily demands of diabetes, as a chronic disease, have a negative impact not only on physical health, but also on psychological health [5]. The complex nature of diabetes itself, acute fluctuations in blood glucose levels, and the fear of long-term complications lead to high levels of sub-clinical diabetes-specific distress [6]. Diabetes distress is part of the experience of diabetes for many patients over time [7, 8]. Furthermore, even at low levels, diabetes distress has been shown to be related to glycemic control and behavioral management [7, 9]. People with diabetes make far more health management decisions compared to health-care personnel, and the needs of the person with diabetes including attention to emotional distress must be addressed in the clinical setting [2] .

The cross-national Diabetes Attitudes, Wishes and Needs (DAWN) study showed that almost half of the study population had a high level of diabetes-related distress [5]. High levels of diabetes-related distress have been linked to medication non-adherence, higher HbA1c, lower self-efficacy and poor dietary and exercise behaviors that lead to poor health outcomes [10]. Diabetes-specific distress should not be confused with general emotional distress and it is also conceptually distinct from major depressive disorder [11].

Screening for diabetes specific distress is important in a clinical setting and has been recommended at key time points in the care pathway such as: diagnosis, annual medical appointments, inpatient episodes, when complications arise and when issues of glycemic control or self-management arise [12]. Therefore, health care personnel need to have validated tools, which can capture the patient's perceived diabetes specific distress. Patient Reported Outcomes (PRO) are directly reported by the patient without any interpretation of the patient's response by health care professionals [13, 14]. Patient reported outcome measures

(PROMs) are important tools to measure the effect of interventions in everyday clinical practice, and to measure if these interventions are appropriate for the patient′s needs [15].

**Background**

Short and validated measures are needed in clinical care situations. The most commonly used PRO instruments for identifying problematic areas in diabetes and measuring diabetes-related emotional distress are the Problem Areas in Diabetes Scale (PAID-20) and the Diabetes Distress Scale (DDS) [16]. The PAID-20 scale covers a greater variety of emotional concerns, while the Diabetes Distress Scale (DDS) seems to reflect more of distress regarding physician involvement in diabetes treatment [17]. Such questionnaires can be used by health care providers to identify problematic areas in diabetes care and at the same time facilitate the relationship with the health care provider, by creating a two-way discussion and information sharing. The PAID-20 is a valid 20-item scale to measure the overall level of diabetes-related emotional distress, where each item represents a unique area of diabetes-related psychological stress. Higher scores indicate greater emotional diabetes-related distress [18]. The validation study of the PAID-20 questionnaire conducted in Norway showed sufficient reliability and validity among adults with type 1 and type 2 diabetes [19].

A shorter version of the PAID, which has 5 items (PAID-5), was developed as a tool that can be used for rapid screening of diabetes-related distress both in a clinical setting and in research studies [20]. The brevity of the PAID-5 may impose a lower burden on patients with diabetes and represents efforts to increase the clinical usefulness of the original scale [16] as the length and unclear factor structure of the PAID-20 have been identified as shortcomings [11, 16]. The PAID-5 has been validated among people with type 2 diabetes in Korea [21] and among people with type 1 and type 2 diabetes in the multicultural DAWN study [20]. In both studies, the PAID-5 showed good reliability and validity [20, 21]. Research concerning diabetes and its psychological burden has received more focus among researchers, health care providers, and patients in the recent years. The availability of sound instruments is important not only for screening, but in order to compare different cultures and populations on a global basis. The PAID-5 has recently become more widely used in research, because of its brevity. However, there is still limited knowledge of the psychometric properties of the PAID-5 scale, in particular the factor structure of the PAID-5 [16, 20, 21], therefore this needs to be

explored.

### Aim

The aim of this study was to examine the psychometric properties of the PAID-5 scale. We hypothesized that PAID-5 scores would be positively associated with worry about hypoglycemia and symptoms of depression, as variants of the same construct, and negatively associated with the perception of general health and emotional well-being. The associations between PAID-5 scores and demographic (age, gender) and clinical variables (HbA1c, duration of diabetes, insulin therapy, diabetes-related complications, and episodes of serious hypoglycemia) were examined and we hypothesized that the PAID-5 scores would discriminate between diabetes-related emotional distress at a group level for gender, insulin regimen and presence of diabetes long-term complications. The reliability of the PAID-5 scale was examined by its internal consistency and test-retest reliability. We also tested the uni-dimensionality of the PAID-5 questionnaire.

## METHODS

### Design, sample and setting

A test-retest survey design was used to collect data from three Western-Norway endocrinology outpatient clinics between October 2016 and March 2017 by using a consecutive sampling strategy. To investigate the one-dimensional structure scale with a confirmatory factor analysis (CFA), a sample size of 140 participants was required with standard factor loadings on 0.50 [22]. In total, 341 patients who met the inclusion criteria were invited to participate in the study. We included more participants than needed based on the power analysis, because of the possibility for a low response rate. Patients were considered eligible for participation if they were diagnosed with type 1 or type 2 diabetes more than one year ago, were between 18 and 65 years old, had the mental capacity to participate, and were able to read and write in Norwegian language. Patients with gestational diabetes, short life expectancy or terminal illness, and patients who were not able to give informed consent due to some serious mental illness or cognitive disorder were excluded.

### Data collection procedure

Patients meeting the inclusion criteria received a paper questionnaire by mail, an information letter, a consent form to accept a repeat (re-test) questionnaire, and two pre-paid envelopes and

stamps. To examine the stability of the PAID-5 measurement, the repeat questionnaire was sent out 35 ± 15 days after the first assessment to those who agreed (n=117).

**Measures**

The questionnaire included questions on demographic- and clinical characteristics: age, gender, duration of diabetes, diabetes treatment (using insulin and/or oral glucose-lowering agents), episodes of serious hypoglycemia (needing help from others) in the last 6 months, and the presence of diabetes long-term complications (cardiovascular diseases, retinopathy and foot ulcers). The most recent $HbA_{1c}$, taken in close connection to the data collection was obtained from medical records, as a measure of metabolic control. HbAc1 values older than 8 weeks prior and more than 12 weeks after filling out the survey were excluded.

In this study, the overall question of the RAND-36 scale was used to assess perceptions of general health ("In general, how would you say your health is?"). Responses were rated on a Likert scale from 1 (excellent) to 5 (poor). Higher scores indicate poorer health [23].

The HAD-scale is a measure for screening symptoms of anxiety and depression [24]. In the current study, we used only the HADS-D scale with 7 self-report items measuring general symptoms of depression. Responses are rated on a 4 – point Likert scale from 0 (not a problem) to 3 (a serious problem). Higher scores indicate higher levels of depressive symptoms. According to Bjelland et al. [25] the validity of the HAD scale generally has been good to very good. The Norwegian version of the HAD-scale has shown good psychometric properties in terms of its two-factor structure, intercorrelation of the subscales (variance of 24-36%) and internal consistency (α= 0.73 – 0.85) [26].

The WHO-5 questionnaire monitors a person's level of emotional well-being. This generic unidimensional instrument includes five positively worded items, rated on a 6 – point Likert scale. Higher scores indicating better well-being. The WHO-5 questionnaire has shown to be a psychometrically sound instrument among patients with type 1 and type 2 diabetes in terms of its one-factor structure, inter-item correlations (0.71 to 0.84), and internal consistency (α= 0.91 and 0.93) [27].

The Hypoglycemia Fear Survey II (HFS-II) has two subscales (33 items), one measuring worry about hypoglycemia and its negative effects (HFS-W) and the other one behavior to avoid hypoglycemia (HFS-B) [28]. In this study only the HFS-W (18 items) was used, as the HFS-B has shown a questionable structure [30]. The responses are rated on a 5 – point Likert

scale from 0 (never) to 4 (always), with higher scores indicating higher levels of fear related to hypoglycemia. Internal consistency for the worry scale was satisfactory with a Cronbach´s α of 0.87 [29].

The PAID-20 questionnaire provides a total score from 0 – 100, by summing the 0 – 4 responses given for each of the 20 items and multiplying this sum by 1.25 [30]. The PAID-5 contains questions 3, 6, 12, 16 and 19 from the full PAID-20 scale. The scale gives a total score from 0 to 20. A score of 8 and above indicates a high level of diabetes-related distress [20] (Table 1).

**Patient and Public Involvement**

Patients and or public were not involved in this work.

**Data analysis**

Descriptive statistics were conducted to describe the sample. A CFA was used to investigate the factor structure of the PAID-5 scale. Missing data for PAID-5 and PAID-20 scales was handled by listwise deletion. Model fit was evaluated by inspection of various goodness-of-fit measures, including model Chi-square ($\chi^2$), degrees of freedom (df) and its associated p-value. In addition, a goodness-of-fit index (GFI), comparative fit index (CFI), root mean squared error of approximation (RMSEA) and standardized root mean square residual (SRMR), ratio of chi square value to the degrees of freedom (CMIN/DF) and normed fit index (NFI) were assessed [31, 32]. The model was considered to fit the data when the following criteria were satisfied: RMSEA < 0.08, CFI > 0.95, GFI > 0.90, SRMR < 0.08, CMIN/DF <3, NFI > 0.95 [31, 32].

Convergent validity was assessed by Pearson's correlations [33] to examine the relationships between diabetes-related emotional distress (PAID-5 scores) and perceived overall health, emotional well-being (WHO-5), depression (HADS-D), and worry about hypoglycemia (HFS-W). We also investigated how the PAID-5 scale correlated with the total PAID-20 score. Discriminant validity assessed whether the PAID-5 scale can differentiate between groups. Independent samples t-tests were used to compare the mean scores on the PAID-5 for people with and without diabetes long-term complications, and between type 1 and type 2 diabetes. Relationships between the PAID-5 score and age, diabetes duration, treatment regimen and metabolic control (HbA1c) were explored using Pearson correlations.

The reliability of the PAID-5 scale was estimated by calculating the internal consistency and the test-retest reliability. Cronbach´s α was used to determine internal consistency for the PAID-5 scale total scores and PAID-20 total scores. Test-retest reliability for the PAID-5 scale was examined by intra-class correlation coefficient [34].

Missing substitution with the mean was used for the HAD depression scale when at least 5 items of 7 were answered [35]. For the other questionnaires, when less than 50% was missing, missing data were replaced with the case mean [36]. Statistical Package for the Social Sciences (SPSS) version 23.0 and AMOS version 23.0 for Windows were used to analyze the data. A significance level of 0.05 was used in all analyses.

### Ethical considerations

The National Committee for Medical and Health Research Ethics assessed the application (2016/1104/REK vest) and approval was obtained from the Norwegian Center for Research Data (ref.nr. 49383). In addition, approval was obtained from the clinics where the study was conducted. Informed consent was obtained from the participants.

## RESULTS

### Demographic and clinical data

The questionnaire was returned by 143 patients of 342 yielding a response rate of 42%. Clinical and demographic characteristics are presented in Table 2. The mean age of the participants was 48.9 years (SD 11.9) (range 19- 65). The mean HbA1c for the participants was 7.6 % (SD=1.2). The mean duration of diabetes was 17.9 years (SD 12.9) (range 1 – 54 years). In total, 117 patients (82%) agreed to the second assessment. The non-participants (n=197) were younger than the participants (mean age 45.15 vs. 48.9, p=0.006), and a larger proportion was male compared to the participants.

### Validity

### Construct validity

A CFA for PAID-5 was carried out for 141 patients (Table 3). We hypothesized a one-factor model for PAID-5. After allowing the correlation between error terms between item 3 and 16, the overall $\chi^2 = 6.0$, df = 4 with a p-value of 0.195, showed a good model fit. Additional

indices resulted as following: RMSEA = 0.061, CFI = 0.995, GFI = 0.984 and SRMR = 0.024, NFI= 0.984, CMIN/DF=1.51 showing excellent fit.

**Convergent and discriminant validity**

There was a significant moderate correlation between PAID-5 total score and HFS worry scale (r=0.598, $p < 0.001$). There was also a weak positive correlation between PAID-5 scale and HAD depression scale (r=0.380, $p < 0.001$). The convergent validity was also confirmed by a negative correlation between PAID-5 and WHO-5 scale (r=-0.363, $p < 0.001$) and the perception of general health (r=-0.420, $p < 0.001$). The PAID-5 total score also correlated significantly with the PAID-20 total score (r=0.923, $p < 0.001$) (Table 4).

There was no significant difference in PAID-5 scores between persons with type 1 diabetes (mean=5.59, SD=4.58) and persons with type 2 diabetes (mean=4.95, SD=3.93, p=0.38). There was also no significant difference in PAID-5 mean scores between those who reported having diabetes long-term complications (mean=5.75, SD=0.7) and those not having these complications (mean=5.2, SD=4.4, t (140) =0.61, p=0.54). Diabetes-related distress mean scores nearly reached statistical significance when comparing patients who reported having retinopathy (7.2, SD=4.0) versus those without retinopathy (mean=5.1, SD=4.2, p=0.06). Although women scored higher on PAID-5 (mean=5.9, SD=4.6) than men (mean=4.86, SD=4.01), the difference was not significant (p=0.15).

Patients who had experienced episodes of serious hypoglycemia in the past 6 months had a significantly higher PAID-5 mean score (7.5 (SD= 4.95) versus those who had not had these episodes (5.0, SD=4.2, (p=0.043). There were no significant differences between the mean scores of PAID-5 for the three different treatment groups: insulin (n=87), oral medication (n=28) or both (n=27) (p=0.90). There were no significant correlations with higher age and longer duration of diabetes. Higher HbA1c was positively correlated with PAID-5 mean scores, but the correlation was weak (r=0.14) and not significant (p=0.16).

**Reliability**

**Internal consistency and test-retest reliability**

The Cronbach's α for the PAID-5 scale was 0.89. Inter-item correlations for the PAID-5 scale reached from 0.49 to 0.74. The test-retest of the PAID-5 was conducted for 92 participants, who returned the repeat questionnaire, and resulted in an ICC of 0.81 (95% CI=0.70– 0.87, p

< 0.001).

## DISCUSSION

The results of the current study showed satisfactory psychometric properties of the short form of the Problem Areas in Diabetes scale in Norwegian adult patients with type 1 and type 2 diabetes. Our findings provide evidence for a one-factor structure for the PAID-5 scale, enabling the assessment of diabetes-related emotional distress. The convergent validity was demonstrated by statistically significant moderate correlations with other concept-related PROMs. The PAID-5 scale showed good internal consistency and a stable test-retest reliability among patients with type 1 and type 2 diabetes across three different clinics in Norway. The instrument might be considered as a supplement to guide consultations, or as a screening instrument in registries and/or population health databases enabling increased knowledge on the prevalence of diabetes-related emotional distress and thus inform guidelines for health care professionals and future interventions.

The Norwegian version of the PAID-5 clearly demonstrated a one-factor structure as postulated. The psychometric results in the current study lend support to findings from two previous validation studies on the PAID-5 scale [20, 21]. In Asia, the Korean version of the PAID-5 enabled a one factor model and demonstrated excellent goodness-of-fit indices after the modification with the error of terms between items 3 and 6 [21]. Our CFA among Norwegians showed excellent goodness-of-fit indices after model modification with the covariance of error terms between items 3 and 16. Therefore, it seems that the instrument enables the assessment of diabetes-related emotional distress, although one data driven modification was needed, that may have inflated the model fit.

The present study showed that diabetes-distress (PAID-5) correlated positively with fear of hypoglycemia (HFS) and symptoms of depression (HADS-D), and negatively with emotional well-being (WHO-5) and ones' general health perception (RAND-36), which emphasizes good convergent validity. When diabetes-related stress increases, emotional well-being and perception of ones´ general health decreases, as expected [20, 27]. Previously, McGuire et al. [20] demonstrated the relationship between the PAID-5 scale and the WHO-5 scale. However, there is limited evidence showing relationships with concepts of fear of hypoglycemia and

symptoms of depression. We demonstrated this in the current study, emphasizing the usefulness of this brief questionnaire.

The PAID-5 scale discriminates well among those who had experienced episodes of serious hypoglycemia in the past 6 months compared to those who had not had hypoglycemia. The study population in general experienced a low level of diabetes-related emotional distress, as the mean score for PAID-5 for the study population was 5.3 (SD=4.3). However, individual scores ranged from 0–19, indicating that there were patients with a high level of diabetes-related emotional distress. Relationships between the PAID-5 scale and other subgroups were weak and non-significant. For example, women scored higher on the PAID-5 scale just as expected, but this difference was not significant, probably due to the relative small sample size similar to the previous study conducted in Iceland [38].

In the current study, the mean diabetes duration of the study population was 17.1 years and metabolic control was generally close to the treatment goals, as 50 % of the participants in the subgroup had a HbA1c value lower than ≤ 7.3 % (163 mg/dl). In the current study, the PAID-5 scale did not discriminate between groups, such as patients with and without diabetes-related long-term complications. This might be a consequence of the relative low number of people with complications. Nevertheless, the proportion of diabetes long-term complications seems reasonable for this patient group and is in line with previous research in Norway [19, 39].

Metabolic control (HbA1c measurements) was positively, but only weakly correlated with PAID-5. This is consistent with results from PAID-20 validation studies, where diabetes-related emotional distress and glycemic control have shown to be positively correlated - as diabetes distress increases, HbA1c level also increases [19, 40-42]. Although higher HbA1c values have been associated with high diabetes-related emotional distress, it should not be taken as self-evident that patients who are able to maintain an optimum blood sugar feel less distressed.

The short-form of the PAID-20, the PAID-5, showed a good internal consistency and test-retest reliability. This confirms the assumption previous validation studies made, that the number of items in the PAID-20 could be reduced [19]. Our findings, and findings in previous studies of the PAID-5 scale showed good to excellent internal consistency reliability, with

Cronbach's α varying from 0.83 – 0.93 [5, 20, 21, 43] supporting that all items measured the same construct, diabetes distress.

Diabetes, which is a chronic disease, not only involves making health choices in one's everyday life, but one must also have the ability to see diabetes and its psychological aspects as a larger and more complex picture with many different challenges throughout life. Diabetes self-management training is closely connected to how patients understand the nature of the disease and its management, thus reducing different fears (e.g., fear of hypoglycemia), guilt and frustration, and at the same time increasing skills in managing diabetes self-care and medication adherence [6]. When screening patients for diabetes specific distress, it is also important that health care providers have clear communication strategies and guidelines emphasizing how to help their patients depending on their level of distress [2]. Goal setting should be collaborative and support should be team based and interdisciplinary.

**Limitations**

Although the scale has demonstrated good psychometric properties, this study has limitations. Type of diabetes, and metabolic control ($HbA_{1c}$) were received from the patient's medical record. However, patients self-reported other clinical characteristics such as diabetes complications, which may cause inaccuracies [33]. However, patients with diabetes have a chronic disease, which needs health management decisions every day. Therefore, it is not unlikely that they are aware of the presence of diabetes complications. Second, the non-responders were younger than the participants, which calls for caution when interpreting the results for younger adults with diabetes. Third, the information about the study and the request for participation was sent by mail. The distribution method in this study has probably contributed to a relatively low response rate. However, we had enough power to investigate the one-dimensional structure scale with a CFA. Nevertheless, the sample size restricted us in determining if the PAID-5 scale has the ability to discriminate between different subgroups. This needs further research in a larger sample. In spite of these limitations, this cross-sectional study should provide a valid assessment of the psychometric properties of the short form of the PAID scale in Norwegian adult patients with type 1 and type 2 diabetes.

**Conclusions**

In conclusion, the findings from this study provide evidence that the Norwegian version of PAID-5 scale is a reliable and valid instrument for assessing diabetes-related emotional

distress among patients with type 1 and type 2 diabetes in Norway, although its ability to discriminate between groups needs to be tested further in a larger sample. The scale has only five items and has the potential to guide communication in one-on-one consultations. Although this validation study was conducted among patients visiting their doctor or a diabetes nurse in specialist health care, the PAID-5 questionnaire is also relevant to use in primary health care.

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**Patient consent**

Obtained.

**Conflict of interest**

None declared

**Contributor ship statement**

MV contributed to the study concept, project planning and management, recruitment of participants, data analysis, manuscript preparation, drafting the manuscript and approved the final manuscript. AB contributed to the study concept, project planning, manuscript preparation, drafting the manuscript and approved the final manuscript. JI contributed to data analysis, manuscript preparation, drafting the manuscript and approved the final manuscript. AV contributed to the study concept, manuscript preparation, drafting the manuscript, and approved the final manuscript. MMI contributed to the study concept, project planning and management, data analysis, manuscript preparation, drafting the manuscript and approved the final manuscript.

**Data sharing statement**

No additional data available.

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**Table 1.** Questions included in the PAID-5 questionnaire

| Questions | |
|---|---|
| 3 | "Feeling scared when you think about living with diabetes?" |
| 6 | "Feeling depressed when you think about living with diabetes?" |
| 12 | "Worrying about the future and the possibility of serious complications?" |
| 16 | "Feeling that diabetes is taking up too much of your mental and physical energy every day?" |
| 19 | "Coping with complications of diabetes?" |

**Table 2.** Demographic and clinical characteristics of the study population

| **Characteristics** | Total sample |
|---|---|
| *Demographic variables* | (n = 143) |
| Age (years) | 48.9 (11.9) |
| Male sex n (%) | 78 (54.5) |
| *Clinical variables* | |
| Type of diabetes | |
| Type 1 | 87 (60.8) |
| Type 2 | 56 (39.2) |
| $HbA_{1c}$ (%)[a, b] | 7.6 (1.2) |
| $HbA_{1c}$ (mmol/L)[a, b] | 60 (13) |
| Diabetes duration (years) | 17.1(12.9) |
| Type of treatment | |
| Insulin | 88 (61.5) |
| Oral medication | 28 (19.6) |
| Insulin and oral medication | 27 (18.9) |
| Episodes of serious hypoglycemia | |
| 1-3 times in the past 6 months | 16 (11.2) |
| Self-reported complications n (%) | |
| Presence of one or more late complications[c] | 32 (22.4) |

Data are shown as *n* (%). Percent of patients with valid values for categorical variables and mean ± SD (Standard Deviation) for continuous variables.

[a] $HbA_{1c}$ (glycated hemoglobin) measurements were reported using the International Federation of Clinical Chemistry units (mmol/mol) in addition to the derived NGSP units (%)

[b] n = 100, $HbA_{1c}$ values older than 8 weeks a prior and more than 12 weeks after filling out the survey were excluded.

[c] Retinopathy, cardiovascular diseases or foot ulcers

**Table 3.** Goodness-of-fit indices for the PAID-5 one-factor solutions before and after modification fit

| ***One-factor model*** | ***$\chi^2$ (p)*** | ***Df*** | ***CFI*** | ***GFI*** | ***SRMR*** | ***RMSEA*** | ***CMIN/DF*** | ***NFI*** |
|---|---|---|---|---|---|---|---|---|
| PAID-5 | 14.85 (0.11) | 5 | 0.974 | 0.961 | 0.035 | 0.119 | 2.971 | 0.962 |
| PAID-5 [a, b] | 6.0 (0.195) | 4 | 0.995 | 0.984 | 0.024 | 0.061 | 1.51 | 0.984 |

$\chi^2$ (p): Model Chi-Square, Df: degrees of freedom; CFI: comparative fit index (good fit > 0.95). GFI: goodness of fit index (good fit > 0.90); SRMR: standardized root mean square residual (good fit <0.08). RMSEA: root mean square error of approximation (acceptable fit <0.08); CMIN/DF: ratio of chi square value to the degrees of freedom (<3); NFI: normed fit index (good fit > 0.95);

[a] after modification with the covariance of error terms between item 3 and 16.

[b] With standardized factor loadings 0.72 – 0.83.

**Table 4.** Correlations between different standardized questionnaires and PAID-5 (Pearson´s bivariate correlation coefficient).

| | Overall health | WHO-5 | HADS-D | HSF-W | PAID-20 |
|---|---|---|---|---|---|
| PAID-5 | r=-0.420* | r=-0.363* | r=0.380* | r=0.598* | r=0.923* |

* Correlation is significant at the 0.001 level (two tailed)

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# The psychometric properties of the Norwegian version of the short form of The Problem Areas in Diabetes scale (PAID-5) – a validation study

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| | |

# The psychometric properties of the Norwegian version of the short form of The Problem Areas in Diabetes scale (PAID-5) – a validation study

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## ABSTRACT

**Objectives:** To assess the psychometric properties of the short form of the Problem Areas in Diabetes scale in Norwegian adult patients with type 1 or type 2 diabetes.

**Design:** Cross-sectional survey design.

**Methods:** Participants (n=143) were included consecutively from three Western-Norway endocrinology outpatient clinics. Demographic and clinical data was collected in addition to questionnaires concerning diabetes-related distress, fear of hypoglycemia, symptoms of depression, emotional well-being and perception of general health. Psychometric evaluation of the PAID-5 included confirming its postulated one-factor structure using confirmatory factor analysis; and assessing convergent validity, discriminant validity, internal consistency and test-retest reliability. The retest questionnaire was sent out 35 ± 15 days after the initial assessment to those who agreed (n=117).

**Results:** The confirmatory factor analysis for the PAID-5 scale showed excellent one-factor structure, and there was high internal consistency (α=0.89) and good test-retest reliability (ICC=0.81). The PAID-5 correlated positively with fear of hypoglycemia (r=0.598) and depression (r=0.380) and negatively with emotional well-being (r=-0.363) and perception of general health (r=-0.420), thus satisfying convergent validity. Patients who had experienced episodes of serious hypoglycemia in the past 6 months had a significantly higher PAID-5 mean score (7.5, SD= 4.95) versus those who had not had these episodes (5.0, SD=4.2, (p=0.043)). However, its ability to discriminate between groups needs to be tested further in a larger sample.

**Conclusion:** The Norwegian PAID-5 was shown to be a reliable and valid short questionnaire for assessing diabetes-related distress among people with type 1 or type 2 diabetes. However, its ability to discriminate between groups needs to be tested further in larger samples. The PAID-5 scale can be a particularly valuable screening instrument in outpatient clinics, as its brevity makes it easy to use as a tool for health care professionals in one-on-one consultations. This short questionnaire is useful in the national diabetes registry or population cohort studies as it enables increased knowledge on the prevalence of diabetes-related distress.

**Key words:** Diabetes, distress, psychometric properties, Problem Areas in Diabetes

**Strengths and limitations of this study:**

- The Norwegian PAID-5 scale demonstrated good psychometric properties, enabling the assessment of diabetes-related emotional distress.
- The non-responders were younger than the participants, which calls for caution when interpreting the results for younger adults with diabetes.
- The sample size restricted us in determining if the PAID-5 scale has the ability to discriminate between different subgroups.
- Further testing in a larger sample is required.

## INTRODUCTION

The International Diabetes Federation [1] states that diabetes is one of the largest global health emergencies of the 21st century and that by the year 2045 an estimated 628.6 million people will have diabetes, which is 9.9 % of the total world population. In Norway, the prevalence of type 2 diabetes increased from 4.9% to 6.1% between 2009-2014 [2]. After Finland and Sweden, Norway is among the countries with the highest incidence of childhood-onset type 1 diabetes in the world and the average incidence rate was 32.7 per 100,000 person-years from 2004–2012 [3]. The Diabetes Control and Complications Trial showed that inadequate quality of diabetes care contributes to an increased risk for developing a number of serious and disabling health problems among people with type 1 diabetes [4]. The United Kingdom Prospective Diabetes Study showed similar results among people with type 2 diabetes [5].

The daily demands of diabetes, as a chronic disease, have a negative impact not only on physical health, but also on psychological health [6]. The complex nature of diabetes itself, acute fluctuations in blood glucose levels, and the fear of long-term complications lead to high levels of sub-clinical diabetes-specific distress [7]. Diabetes distress is part of the experience of diabetes for many patients over time [8, 9]. Even at low levels, diabetes distress has been shown to be related to glycemic control and behavioral management [8, 10]. People with diabetes make far more health management decisions compared to health-care personnel, and the needs of the person with diabetes including attention to emotional distress must be addressed in the clinical setting [11] .

The cross-national Diabetes Attitudes, Wishes and Needs (DAWN) study showed that almost half of the study population had a high level of diabetes-related distress [6]. High levels of diabetes-related distress have been linked to medication non-adherence, higher HbA1c, lower self-efficacy and poor dietary and exercise behaviors that lead to poor health outcomes [12]. Screening for diabetes specific distress is important in a clinical setting and has been recommended at key time points in the care pathway such as: diagnosis, annual medical appointments, inpatient episodes, when complications arise and when issues of glycemic control or self-management arise [13]. Therefore, health care personnel need to have validated tools, which can capture the patient's perceived diabetes specific distress.

The PAID-20 is a valid 20-item scale to measure the overall level of diabetes-related emotional distress, developed in the US [14]. Each item represents a unique area of diabetes-

related psychological stress and higher scores indicate greater emotional diabetes-related distress. The validation study of the PAID-20 questionnaire conducted in Norway showed sufficient reliability and validity among adults with type 1 and type 2 diabetes [15]. A shorter version of the PAID, which has 5 items (PAID-5), was developed as a tool that can be used for rapid screening of diabetes-related distress both in a clinical setting and in research studies [16]. The brevity of the PAID-5 may impose a lower burden on patients with diabetes and represents efforts to increase the clinical usefulness of the original scale [17] as the length and unclear factor structure of the PAID-20 have been identified as shortcomings [17, 18]. The PAID-5 has been validated among people with type 2 diabetes in Korea [19] and among people with type 1 and type 2 diabetes in the multicultural DAWN study [16]. In both studies, the PAID-5 showed good reliability and validity [16, 19]. As research concerning diabetes and the associated psychological burden continues to receive more attention from researchers, health care providers, and patients, the availability of sound instruments is important for screening, and to compare different cultures and populations on a global basis. However, a questionnaire that is not properly translated and culturally adapted will be a threat to validity and reliability. Empirical testing of validity and reliability should follow the translation and cultural adaptation phase [20]. There is still limited knowledge of the psychometric properties of the PAID-5 scale in Europe, in particular the factor structure of the PAID-5 [16, 17, 19]. As there is a need for a short diabetes distress questionnaire in the Norwegian Diabetes Registry for Adults, as well as in population based cohort studies, this needs to be explored.

**Aim**

The aim of this study was to examine the psychometric properties of the PAID-5 scale. We hypothesized that PAID-5 scores would be positively associated with worry about hypoglycemia and symptoms of depression, as variants of the same construct, and negatively associated with the perception of general health and emotional well-being. The associations between PAID-5 scores and demographic (age, gender) and clinical variables (HbA1c, duration of diabetes, insulin therapy, diabetes-related complications, and episodes of serious hypoglycemia) were examined and we hypothesized that the PAID-5 scores would discriminate between diabetes-related emotional distress at a group level for gender, insulin regimen and presence of diabetes long-term complications. The reliability of the PAID-5 scale was examined by its internal consistency and test-retest reliability. We also tested the uni-dimensionality of the PAID-5 questionnaire.

## METHODS

### Design, sample and setting

A cross-sectional survey design was used to collect data from three Western-Norway endocrinology outpatient clinics between October 2016 and March 2017 by using a consecutive sampling strategy. According to a Monte-Carlo simulation study on estimation of sample size for confirmatory factor analysis (CFA), 190 cases are required for a one-factor model with four items and standardized loadings equal to 0.5, while a model with six items and the same loadings requires a sample size of 90 [21]. Given that the PAID-5 has five items, the minimum required sample size in our study was determined to be between 90 and 190. We included more participants than needed based on the power analysis, because of the possibility for a low response rate. Therefore, 341 patients who met the inclusion criteria were invited to participate in the study. We included more participants than needed based on the power analysis, because of the possibility for a low response rate. Patients were considered eligible for participation if they were diagnosed with type 1 or type 2 diabetes more than one year ago, were between 18 and 65 years old, had the mental capacity to participate, and were able to read and write in Norwegian language. We included only patients diagnosed with type 1 or type 2 diabetes more than one year ago, as patients may have more diabetes distress adapting to living with diabetes in the first year. Patients with gestational diabetes, short life expectancy or terminal illness, and patients who were not able to give informed consent due to some serious mental illness or cognitive disorder were excluded.

### Data collection procedure

Patients meeting the inclusion criteria received the questionnaire (in total 68 questions) by mail, an information letter, a consent form to accept, pre-paid envelopes and stamps. To examine the stability of the PAID-5 measurement, the re-test questionnaire was sent out 35 ± 15 days after the first assessment to those who agreed (n=117).

### Measures

The questionnaire included questions on demographic- and clinical characteristics: age, gender, duration of diabetes, diabetes treatment (using insulin and/or oral glucose-lowering agents), episodes of serious hypoglycemia (needing help from others) in the last 6 months, and the presence of diabetes long-term complications (cardiovascular diseases, retinopathy and foot ulcers). The most recent $HbA_{1c}$, taken in close connection to the data collection was

obtained from medical records, as a measure of metabolic control. HbAc1 values older than 8 weeks prior and more than 12 weeks after filling out the survey were excluded.

The questionnaire included the overall question of the RAND-36 scale was used to assess perceptions of general health ("In general, how would you say your health is?"). Responses were rated on a Likert scale from 1 (excellent) to 5 (poor). Higher scores indicate poorer health [22].

The HAD-scale is a measure for screening symptoms of anxiety and depression [23]. In the current study, we used only the HADS-D scale with 7 self-report items measuring general symptoms of depression. Responses are rated on a 4 – point Likert scale from 0 (not a problem) to 3 (a serious problem). Higher scores indicate higher levels of depressive symptoms. According to Bjelland et al. [24] the validity of the HAD scale generally has been good to very good. The Norwegian version of the HAD-scale has shown good psychometric properties in terms of its two-factor structure, intercorrelation of the subscales (variance of 24-36%) and internal consistency (α= 0.73 – 0.85) [25].

The WHO-5 questionnaire monitors a person's level of emotional well-being. This generic unidimensional instrument includes five positively worded items, rated on a 6 – point Likert scale. Higher scores indicating better well-being. The WHO-5 questionnaire has shown to be a psychometrically sound instrument among patients with type 1 and type 2 diabetes in terms of its one-factor structure, inter-item correlations (0.71 to 0.84), and internal consistency (α= 0.91 and 0.93) [26, 27].

The Hypoglycemia Fear Survey II (HFS-II) has two subscales (33 items), one measuring worry about hypoglycemia and its negative effects (HFS-W) and the other one behavior to avoid hypoglycemia (HFS-B) [28]. In this study only the HFS-W (18 items) was used, as the HFS-B has shown a questionable structure [29]. The responses are rated on a 5 – point Likert scale from 0 (never) to 4 (always), with higher scores indicating higher levels of fear related to hypoglycemia. Internal consistency for the worry scale was satisfactory with a Cronbach´s α of 0.87 [30].

The PAID-20 questionnaire provides a total score from 0 – 100, by summing the 0 – 4 responses given for each of the 20 items and multiplying this sum by 1.25 [29]. The PAID-5 contains questions 3, 6, 12, 16 and 19 from the full PAID-20 scale. The scale gives a total

score from 0 to 20. A score of 8 and above indicates a high level of diabetes-related distress [16] (Table S1).

**Data analysis**

Descriptive statistics were conducted to describe the sample. A CFA with maximum likelihood estimation was used to investigate the factor structure of the PAID-5 scale. Missing data for PAID-5 was handled by listwise deletion in CFA-models, however only two persons had missing data on at least one item. Model fit was evaluated by inspection of various goodness-of-fit measures, including model Chi-square ($\chi^2$), degrees of freedom (df) and its associated p-value. In addition, a goodness-of-fit index (GFI), comparative fit index (CFI), root mean squared error of approximation (RMSEA) and standardized root mean square residual (SRMR), ratio of chi square value to the degrees of freedom (CMIN/DF) and normed fit index (NFI) were assessed [30, 31]. The model was considered to fit the data when the following criteria were satisfied: RMSEA < 0.08, CFI > 0.95, GFI > 0.90, SRMR < 0.08, CMIN/DF <3, NFI > 0.95 [31, 32].

Convergent validity was assessed by Pearson's correlations [33] to examine the relationships between diabetes-related emotional distress (PAID-5 scores) and perceived overall health, emotional well-being (WHO-5), depression (HADS-D), and worry about hypoglycemia (HFS-W). We also investigated how the PAID-5 scale correlated with the total PAID-20 score. Coefficients in the range 0-0.19 were regarded as very weak, 0.2-0.39 as weak, 0.40-0.59 as moderate, 0.6-0.79 as strong and 0.8-1 as very strong correlation [33]. Discriminant validity assessed whether the PAID-5 scale can differentiate between groups. Independent samples t-tests were used to compare the mean scores on the PAID-5 for people with and without diabetes long-term complications, and between type 1 and type 2 diabetes. Relationships between the PAID-5 score and age, diabetes duration, treatment regimen and metabolic control (HbA1c) were explored using Pearson correlations.

The reliability of the PAID-5 scale was estimated by calculating the internal consistency and the test-retest reliability. Cronbach´s α was used to determine internal consistency for the PAID-5 scale total scores. Test-retest reliability for the PAID-5 scale was examined by intra-class correlation coefficient [34].

Missing substitution with the mean was used for the HAD depression scale when at least 5 items of 7 were answered [35]. For the other questionnaires, when less than 50% was missing, missing data were replaced with the case mean [36]. Statistical Package for the Social Sciences (SPSS) version 23.0 and AMOS version 23.0 for Windows were used to analyze the data. A significance level of 0.05 was used in all analyses.

### Ethical considerations

The National Committee for Medical and Health Research Ethics assessed the application (2016/1104/REK vest) and approval was obtained from the Norwegian Center for Research Data (ref.nr. 49383). In addition, approval was obtained from the clinics where the study was conducted. Informed consent was obtained from the participants.

## RESULTS

### Demographic and clinical data

The questionnaire was returned by 143 patients of 342 yielding a response rate of 42%. Clinical and demographic characteristics are presented in Table 1. The mean age of the participants was 48.9 years (SD 11.9) (range 19- 65). The mean HbA1c for the participants was 7.6 % (60 mmol/mol) (SD=1.2). The mean duration of diabetes was 17.9 years (SD 12.9) (range 1 – 54 years). In total, 117 patients (82%) agreed to the second assessment. The non-participants (n=197) were younger than the participants (mean age 45.15 vs. 48.9, p=0.006), and a larger proportion was male compared to the participants. The mean score for the PAID-5 in this study sample was 5.3 (SD=4.3) and individual scores ranged from 0–19.

### Validity

### Construct validity

A CFA for PAID-5 was carried out for 141 patients (Table 2). We hypothesized a one-factor model for PAID-5. After allowing the correlation between error terms between item 3 and 16, the overall $\chi^2 = 6.0$, df = 4 with a p-value of 0.195, showed a good model fit. Additional indices resulted as following: RMSEA = 0.061, CFI = 0.995, GFI = 0.984 and SRMR = 0.024, NFI= 0.984, CMIN/DF=1.51 showing excellent fit.

### Convergent and discriminant validity

There was a significant moderate correlation between PAID-5 total score and HFS worry scale (r=0.598, p < 0.001). There was also a weak positive correlation between PAID-5 scale and HAD depression scale (r=0.380, p < 0.001). The convergent validity was also confirmed by a negative correlation between PAID-5 and WHO-5 scale (r=-0.363, p < 0.001) and the perception of general health (r=-0.420, p < 0.001). The PAID-5 total score also correlated significantly with the PAID-20 total score (r=0.923, p < 0.001).

There was no significant difference in PAID-5 scores between persons with type 1 diabetes (mean=5.59, SD=4.58) and persons with type 2 diabetes (mean=4.95, SD=3.93, p=0.38). There was also no significant difference in PAID-5 mean scores between those who reported having diabetes long-term complications (mean=5.75, SD=0.7) and those not having these complications (mean=5.2, SD=4.4, t (140) =0.61, p=0.54). Diabetes-related distress mean scores nearly reached statistical significance when comparing patients who reported having retinopathy (7.2, SD=4.0) versus those without retinopathy (mean=5.1, SD=4.2, p=0.06). Although women scored higher on PAID-5 (mean=5.9, SD=4.6) than men (mean=4.86, SD=4.01), the difference was not significant (p=0.15).

Patients who had experienced episodes of serious hypoglycemia in the past 6 months had a significantly higher PAID-5 mean score (7.5 (SD= 4.95) versus those who had not had these episodes (5.0, SD=4.2, (p=0.043). There were no significant differences between the mean scores of PAID-5 for the three different treatment groups: insulin (n=87), oral medication (n=28) or both (n=27) (p=0.90). There were no significant correlations with higher age and longer duration of diabetes. Higher HbA1c was positively correlated with PAID-5 mean scores, but the correlation was weak (r=0.14) and not significant (p=0.16).

**Reliability**

**Internal consistency and test-retest reliability**

The Cronbach's α for the PAID-5 scale was 0.89. Inter-item correlations for the PAID-5 scale reached from 0.49 to 0.74. The test-retest of the PAID-5 was conducted for 92 participants, who returned the repeat questionnaire, and resulted in an ICC of 0.81 (95% CI=0.70– 0.87, p < 0.001).

## DISCUSSION

The results of the current study showed satisfactory psychometric properties of the short form of the PAID-5 in Norwegian adult patients with type 1 and type 2 diabetes. Our findings provide evidence for a one-factor structure for the PAID-5 scale, enabling the assessment of diabetes-related emotional distress. The convergent validity was demonstrated by statistically significant moderate correlations with other concept-related PROMs. The PAID-5 scale showed good internal consistency and a stable test-retest reliability among patients with type 1 and type 2 diabetes across three different clinics in Norway. The instrument might be considered as a supplement to guide consultations, or as a screening instrument in registries and/or population health databases enabling increased knowledge on the prevalence of diabetes-related emotional distress and thus inform guidelines for health care professionals and future interventions.

The Norwegian version of the PAID-5 clearly demonstrated a one-factor structure as postulated. The psychometric results in the current study lend support to findings from two previous validation studies on the PAID-5 scale [16, 19]. In Asia, the Korean version of the PAID-5 enabled a one factor model and demonstrated excellent goodness-of-fit indices after the modification with the error of terms between items 3 and 6 [17]. Our CFA among Norwegians showed excellent goodness-of-fit indices after model modification with the covariance of error terms between items 3 and 16. Therefore, it seems that the instrument enables the assessment of diabetes-related emotional distress, although one data driven modification was needed, that may have inflated the model fit.

The present study showed that PAID-5 correlated positively with fear of hypoglycemia (HFS) and symptoms of depression (HADS-D), and negatively with emotional well-being (WHO-5) and ones' general health perception (RAND-36), which emphasizes good convergent validity. When diabetes-related stress increases, emotional well-being and perception of ones´ general health decreases, as expected [16, 26, 27]. Previously, McGuire et al. [16] demonstrated the relationship between the PAID-5 scale and the WHO-5 scale. However, there is limited evidence showing relationships with concepts of fear of hypoglycemia and symptoms of depression. We demonstrated this in the current study, emphasizing the usefulness of this brief questionnaire.

The PAID-5 scale discriminates well among those who had experienced episodes of serious hypoglycemia in the past 6 months compared to those who had not had hypoglycemia. The

study population in general experienced a low level of diabetes-related emotional distress, as the mean score for PAID-5 for the study population was 5.3 (SD=4.3). However, individual scores ranged from 0–19, indicating that there were patients with a high level of diabetes-related emotional distress. Relationships between the PAID-5 scale and other subgroups were weak and non-significant. For example, women scored higher on the PAID-5 scale just as expected, but this difference was not significant, probably due to the relative small sample size similar to the previous study conducted in Iceland [37]. There were no significant differences between the mean scores of PAID-5 for the three different treatment groups (insulin, oral medication or both) (p=0.90). Our relatively small sample size might be the reason, but it is also possible that type of treatment is not the main reason for a higher burden of diabetes distress. On the other hand, a higher HbA1c (as a measure of metabolic control), might be a better marker as higher HbA1c was positively correlated with PAID-5 mean scores in this study (NS) as well as in previous research [15]. However, future studies specifically designed to answer these questions (e.g., by use of stratified sampling or by using latent class analyses) with large sample sizes are needed to test for discrimination between different subgroups.

In the current study, the mean diabetes duration of the study population was 17.1 years and metabolic control was generally close to the treatment goals, as 50 % of the participants in the subgroup had a HbA1c value lower than ≤ 7.3 % (56 mmol/mol). In the current study, the PAID-5 scale did not discriminate between groups, such as patients with and without diabetes-related long-term complications. This might be a consequence of the relative low number of people with complications. Nevertheless, the proportion of diabetes long-term complications seems reasonable for this patient group and is in line with previous research in Norway [15, 38].

Metabolic control (HbA1c measurements) was positively, but only weakly correlated with PAID-5. This is consistent with results from PAID-20 validation studies, where diabetes-related emotional distress and glycemic control have shown to be positively correlated - as diabetes distress increases, HbA1c level also increases [15, 39-41]. Although higher HbA1c values have been associated with high diabetes-related emotional distress, it should not be taken as self-evident that patients who are able to maintain an optimum blood sugar feel less distressed.

The short-form of the PAID-20, the PAID-5, showed a good internal consistency and test-retest reliability. This confirms the assumption previous validation studies made, that the number of items in the PAID-20 could be reduced [15]. Our findings, and findings in previous studies of the PAID-5 scale showed good to excellent internal consistency reliability, with Cronbach's α varying from 0.83 – 0.93 [6, 16, 19, 42] supporting that all items measured the same construct, diabetes distress.

Diabetes, which is a chronic disease, not only involves making health choices in one's everyday life, but one must also have the ability to see diabetes and its psychological aspects as a larger and more complex picture with many different challenges throughout life. Diabetes self-management training is closely connected to how patients understand the nature of the disease and its management, thus reducing different fears (e.g., fear of hypoglycemia), guilt and frustration, and at the same time increasing skills in managing diabetes self-care and medication adherence [7].

**Strengths and limitations**

In this well-defined sample of patients across three clinics, the Norwegian PAID-5 was shown to be a reliable and valid short questionnaire for assessing diabetes-related distress among people with type 1 or type 2 diabetes. Although the scale has demonstrated good psychometric properties, this study has limitations. Type of diabetes, and metabolic control ($HbA_{1c}$) were received from the patient's medical record. However, other clinical characteristics such as diabetes complications were self-reported by the patient,, which may cause inaccuracies [33]. Second, the non-responders were younger than the participants, which calls for caution when interpreting the results for younger adults with diabetes. Third, the information about the study and the request for participation was sent by mail. The distribution method in this study has probably contributed to a relatively low response rate. However, we had enough power to investigate the one-dimensional structure scale with a CFA. Nevertheless, the sample size restricted us in determining if the PAID-5 scale has the ability to discriminate between different subgroups. This needs further research in a larger sample. In spite of these limitations, this cross-sectional study should provide a valid assessment of the psychometric properties of the short form of the PAID scale in Norwegian adult patients with type 1 and type 2 diabetes.

**Conclusions**

In conclusion, the findings from this study provide evidence that the Norwegian version of PAID-5 scale is a reliable and valid instrument for assessing diabetes-related emotional distress among patients with type 1 and type 2 diabetes in Norway, although its ability to discriminate between groups needs to be tested further in a larger sample. The scale has only five items and has the potential to guide communication in one-on-one consultations. Although this validation study was conducted among patients visiting their doctor or a diabetes nurse in specialist health care, the PAID-5 questionnaire is also relevant to use in primary health care.

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**Patient consent**

Obtained.

**Conflict of interest**

None declared

**Contributor ship statement**

MV contributed to the study concept, project planning and management, recruitment of participants, data analysis, manuscript preparation, drafting the manuscript and approved the final manuscript. AB contributed to the study concept, project planning, manuscript preparation, drafting the manuscript and approved the final manuscript. JI contributed to data analysis, manuscript preparation, drafting the manuscript and approved the final manuscript. AV contributed to the study concept, manuscript preparation, drafting the manuscript, and approved the final manuscript. MMI contributed to the study concept, project planning and management, data analysis, manuscript preparation, drafting the manuscript and approved the final manuscript.

**Data sharing statement**

No additional data available.

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**Table 1.** Demographic and clinical characteristics of the study population

| **Characteristics** | Total sample |
|---|---|
| *Demographic variables* | (n = 143) |
| Age (years) | 48.9 (11.9) |
| Male sex n | 78 (54.5) |
| *Clinical variables* | |
| Type of diabetes | |
| Type 1 | 87 (60.8) |
| Type 2 | 56 (39.2) |
| $HbA_{1c}$ (%)[a, b] | 7.6 (1.2) |
| $HbA_{1c}$ (mmol/mol)[a, b] | 60 (13) |
| Diabetes duration (years) | 17.1(12.9) |
| Type of treatment | |
| Insulin | 88 (61.5) |
| Oral medication | 28 (19.6) |
| Insulin and oral medication | 27 (18.9) |
| Episodes of serious hypoglycemia | |
| 1-3 times in the past 6 months | 16 (11.2) |
| Self-reported complications | |
| Presence of one or more late complications[c] | 32 (22.4) |

Data are shown as *n* (%). Percent of patients with valid values for categorical variables and mean ± SD (Standard Deviation) for continuous variables.

[a] $HbA_{1c}$ (glycated hemoglobin) measurements were reported using the International Federation of Clinical Chemistry units (mmol/mol) in addition to the derived NGSP units (%)

[b] n = 100, $HbA_{1c}$ values older than 8 weeks a prior and more than 12 weeks after filling out the survey were excluded.

[c] Retinopathy, cardiovascular diseases or foot ulcers

**Table 2.** Factor loadings and goodness-of-fit indices for the PAID-5 one-factor solutions

| | Model 1 | Model 2 |
|---|---|---|
| Standardized loadings | | |
| Item 3 | 0.83 | 0.85 |
| Item 6 | 0.86 | 0.85 |
| Item 12 | 0.82 | 0.80 |
| Item 16 | 0.68 | 0.72 |
| Item 19 | 0.73 | 0.72 |
| AVE | 0.62 | 0,63 |
| Composite reliability | 0.76 | 0,76 |
| Df | 5 | 4 |
| $\chi$2 (p) | 14.85 (0.11) | 6.0 (0.195) |
| CFI | 0.974 | 0.995 |
| GFI | 0.961 | 0.984 |
| SRMR | 0.035 | 0.024 |
| RMSEA | 0.119 | 0.061 |
| CMIN/DF | 2.971 | 1.51 |
| NFI | 0.962 | 0.984 |

Model 1: One-factor CFA, Model 2: One-factor CFA with covariance of error terms between item 3 and 16
$\chi^2$ (p): Model Chi-Square, Df: degrees of freedom; CFI: comparative fit index (good fit > 0.95). GFI: goodness of fit index (good fit > 0.90); SRMR: standardized root mean square residual (good fit <0.08). RMSEA: root mean square error of approximation (acceptable fit <0.08); CMIN/DF: ratio of chi square value to the degrees of freedom (<3); NFI: normed fit index (good fit > 0.95);

**Table S1.** Questions included in the PAID-5 questionnaire

| Questions | |
|---|---|
| 3 | "Feeling scared when you think about living with diabetes?" |
| 6 | "Feeling depressed when you think about living with diabetes?" |
| 12 | "Worrying about the future and the possibility of serious complications?" |
| 16 | "Feeling that diabetes is taking up too much of your mental and physical energy every day?" |
| 19 | "Coping with complications of diabetes?" |

STROBE Statement—checklist of items that should be included in reports of observational studies

| | Item No | Recommendation | Page No |
|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract | 1 |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 2 |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 4-5 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 5 |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | 5 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 6-7 |
| Participants | 6 | (*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up<br>*Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls<br>***Cross-sectional study***—Give the eligibility criteria, and the sources and methods of selection of participants | 6 |
| | | (*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed<br>*Case-control study*—For matched studies, give matching criteria and the number of controls per case | |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 6-7 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 6-7 |
| Bias | 9 | Describe any efforts to address potential sources of bias | 6-7 |
| Study size | 10 | Explain how the study size was arrived at | 6 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 8 |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | |
| | | (*b*) Describe any methods used to examine subgroups and interactions | 8 |
| | | (*c*) Explain how missing data were addressed | 8 |
| | | (*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed<br>*Case-control study*—If applicable, explain how matching of cases and controls was addressed<br>***Cross-sectional study***—If applicable, describe analytical methods taking account of sampling strategy | 6 |
| | | (*e*) Describe any sensitivity analyses | |

| | | | |
|---|---|---|---|
| **Results** | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 9 |
| | | (b) Give reasons for non-participation at each stage | |
| | | (c) Consider use of a flow diagram | |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 9 |
| | | (b) Indicate number of participants with missing data for each variable of interest | |
| | | (c) *Cohort study*—Summarise follow-up time (eg, average and total amount) | |
| Outcome data | 15* | *Cohort study*—Report numbers of outcome events or summary measures over time | |
| | | *Case-control study*—Report numbers in each exposure category, or summary measures of exposure | |
| | | *Cross-sectional study*—Report numbers of outcome events or summary measures | 9-10 |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | 9-10 |
| | | (*b*) Report category boundaries when continuous variables were categorized | |
| | | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | |
| **Discussion** | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 10-11 |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 13 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 13 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 12-13 |
| **Other information** | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 14 |

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

# The psychometric properties of the Norwegian version of the short form of The Problem Areas in Diabetes scale (PAID-5) – a validation study

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| Keywords: | diabetes, distress, psychometric properties, problem areas in diabetes, validation study |
| | |

# The psychometric properties of the Norwegian version of the short form of The Problem Areas in Diabetes scale (PAID-5) – a validation study

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## ABSTRACT

**Objectives:** To assess the psychometric properties of the short form of the Problem Areas in Diabetes scale in Norwegian adult patients with type 1 or type 2 diabetes.

**Design:** Cross-sectional survey design.

**Methods:** Participants (n=143) were included from three Western-Norway endocrinology outpatient clinics. Demographic and clinical data were collected in addition to questionnaires concerning diabetes-related distress, fear of hypoglycemia, symptoms of depression, emotional well-being and perception of general health. Psychometric evaluation of the PAID-5 included confirming its postulated one-factor structure using confirmatory factor analysis; and assessing convergent validity, discriminant validity, internal consistency and test-retest reliability. The retest questionnaire was sent out 35 ± 15 days after the initial assessment to those who agreed (n=117).

**Results:** The confirmatory factor analysis for the PAID-5 scale showed excellent one-factor structure, and there was high internal consistency (α=0.89) and good test-retest reliability (ICC=0.81). The PAID-5 correlated positively with fear of hypoglycemia (r=0.598) and depression (r=0.380) and negatively with emotional well-being (r=-0.363) and perception of general health (r=-0.420), thus satisfying convergent validity. Patients who had experienced episodes of serious hypoglycemia in the past 6 months had a significantly higher PAID-5 mean score (7.5, SD= 4.95) than those who had not had these episodes (5.0, SD=4.2, (p=0.043)). However, its ability to discriminate between groups needs to be tested further in a larger sample.

**Conclusion:** The Norwegian PAID-5 was shown to be a reliable and valid short questionnaire for assessing diabetes-related distress among people with type 1 or type 2 diabetes. However, its ability to discriminate between groups needs to be tested further in larger samples. The PAID-5 scale can be a particularly valuable screening instrument in outpatient clinics, as its brevity makes it easy to use as a tool in patient-provider encounters. This short questionnaire is useful in the national diabetes registry or population cohort studies as

it enables increased knowledge regarding the prevalence of diabetes-related distress.

**Key words:** Diabetes, distress, psychometric properties, Problem Areas in Diabetes

**Strengths and limitations of this study:**

- The Norwegian PAID-5 scale demonstrated good psychometric properties, enabling the assessment of diabetes-related emotional distress.
- The non-responders were younger than the participants, which calls for caution when interpreting the results for younger adults with diabetes.
- The sample size restricted us in determining if the PAID-5 scale has the ability to discriminate between different subgroups.
- Further testing in a larger sample is required.

## INTRODUCTION

The International Diabetes Federation [1] states that diabetes is one of the largest global health emergencies of the 21st century and that by the year 2045 an estimated 628.6 million people will have diabetes, which is 9.9 % of the total world population. In Norway, the prevalence of type 2 diabetes increased from 4.9% to 6.1% between 2009-2014 [2]. After Finland and Sweden, Norway is among the countries with the highest incidence of childhood-onset type 1 diabetes in the world and the average incidence rate was 32.7 per 100,000 person-years from 2004–2012 [3]. The Diabetes Control and Complications Trial showed that inadequate quality of diabetes care contributes to an increased risk for developing a number of serious and disabling health problems among people with type 1 diabetes [4]. The United Kingdom Prospective Diabetes Study showed similar results among people with type 2 diabetes [5].

The daily demands of diabetes, as a chronic disease, have a negative impact not only on physical health, but also on psychological health [6]. The complex nature of diabetes itself, acute fluctuations in blood glucose levels, and the fear of long-term complications lead to high levels of sub-clinical diabetes-specific distress [7]. Diabetes distress is part of the experience of diabetes for many patients over time [8, 9]. Even at low levels, diabetes distress has been shown to be related to glycemic control and behavioral management [8, 10]. People with diabetes make far more health management decisions compared to healthcare personnel, and the needs of the person with diabetes including attention to emotional distress must be addressed in the clinical setting [11] .

The cross-national Diabetes Attitudes, Wishes and Needs (DAWN) study showed that almost half of the study population had a high level of diabetes-related distress [6]. High levels of diabetes-related distress have been linked to medication non-adherence, higher HbA1c, lower self-efficacy and poor dietary and exercise behaviors that lead to poor health outcomes [12]. Screening for diabetes specific distress is important in a clinical setting and has been recommended at key time points in the care pathway such as: diagnosis, annual medical appointments, inpatient episodes, when complications arise and when issues of glycemic control or self-management arise [13]. Therefore, health care personnel need to have validated tools to assess patients' perceived diabetes specific distress.

The PAID-20 is a valid 20-item scale to measure the overall level of diabetes-related emotional distress, developed in the US [14]. Each item represents a unique area of diabetes-related psychological stress and higher scores indicate greater emotional diabetes-related distress. The

validation study of the PAID-20 questionnaire conducted in Norway showed sufficient reliability and validity among adults with type 1 and type 2 diabetes [15]. A shorter version of the PAID, which has 5 items (PAID-5), was developed as a tool that can be used for rapid screening of diabetes-related distress both in a clinical setting and in research studies [16]. The brevity of the PAID-5 may impose a lower burden on patients with diabetes and represents efforts to increase the clinical usefulness of the original scale [17] as the length and unclear factor structure of the PAID-20 have been identified as shortcomings [17, 18]. The PAID-5 has been validated among people with type 2 diabetes in Korea [19] and among people with type 1 and type 2 diabetes in the multicultural DAWN study [16]. In both studies, the PAID-5 showed good reliability and validity [16, 19]. As research concerning diabetes and the associated psychological burden continues to receive more attention from researchers, health care providers, and patients, the availability of sound instruments is important for screening, and to compare different cultures and populations on a global basis. However, a questionnaire that is not properly translated and culturally adapted will be a threat to validity and reliability. Empirical testing of validity and reliability should follow the translation and cultural adaptation phase [20]. There is still limited knowledge of the psychometric properties of the PAID-5 scale in Europe, in particular the factor structure of the PAID-5 [16, 17, 19]. As there is a need for a short diabetes distress questionnaire in the Norwegian Diabetes Registry for Adults, as well as in population based cohort studies, this needs to be explored.

**Aim**

The aim of this study was to examine the psychometric properties of the PAID-5 scale. We hypothesized that PAID-5 scores would be positively associated with worry about hypoglycemia and symptoms of depression, as variants of the same construct, and negatively associated with the perception of general health and emotional well-being. The associations between PAID-5 scores and demographic (age, gender) and clinical variables (HbA1c, duration of diabetes, insulin therapy, diabetes-related complications, and episodes of serious hypoglycemia) were examined. We hypothesized that the PAID-5 scores would discriminate between diabetes-related emotional distress at a group level for gender, insulin regimen and presence of diabetes long-term complications. The reliability of the PAID-5 scale was examined by its internal consistency and test-retest reliability. We also tested the uni-dimensionality of the PAID-5 questionnaire.

## METHODS

### Design, sample and setting

A cross-sectional survey design was used to collect data from three Western-Norway endocrinology outpatient clinics between October 2016 and March 2017 by using a consecutive sampling strategy. According to a Monte-Carlo simulation study on estimation of sample size for confirmatory factor analysis (CFA), 190 cases are required for a one-factor model with four items and standardized loadings equal to 0.5, while a model with six items and the same loadings requires a sample size of 90 [21]. Given that the PAID-5 has five items, the minimum required sample size in our study was determined to be between 90 and 190. We included more participants than needed based on the power analysis, because of the possibility for a low response rate. Therefore, 341 patients who met the inclusion criteria were invited to participate in the study. Patients were considered eligible for participation if they were diagnosed with type 1 or type 2 diabetes more than one year ago, were between 18 and 65 years old, had the mental capacity to participate, and were able to read and write in Norwegian language. We included only patients diagnosed with type 1 or type 2 diabetes more than one year ago, as patients may have more diabetes distress adapting to living with diabetes in the first year. Patients with gestational diabetes, short life expectancy or terminal illness, and patients who were not able to give informed consent due to some serious mental illness or cognitive disorder were excluded.

### Data collection procedure

Patients meeting the inclusion criteria received the questionnaire (68 questions in total) by mail, an information letter, a consent form to accept, pre-paid envelopes and stamps. To examine the stability of the PAID-5 measurement, the re-test questionnaire was sent out 35 ± 15 days after the first assessment to those who agreed (n=117).

### Measures

The questionnaire included questions on demographic- and clinical characteristics: age, gender, duration of diabetes, diabetes treatment (using insulin and/or oral glucose-lowering agents), episodes of serious hypoglycemia (needing help from others) in the last 6 months,

and the presence of diabetes long-term complications (cardiovascular diseases, retinopathy and foot ulcers). The most recent $HbA_{1c}$, taken in close connection to the data collection was obtained from medical records, as a measure of metabolic control. $HbA_{1c}$ values older than 8 weeks prior and more than 12 weeks after filling out the survey were excluded.

The questionnaire included the overall question of the RAND-36 scale to assess perceptions of general health ("In general, how would you say your health is?"). Responses were rated on a Likert scale from 1 (excellent) to 5 (poor). Higher scores indicate poorer health [22].

The HAD-scale is a measure for screening symptoms of anxiety and depression [23]. In the current study, we used only the HADS-D scale with 7 self-report items measuring general symptoms of depression. Responses are rated on a 4 – point Likert scale from 0 (not a problem) to 3 (a serious problem). Higher scores indicate higher levels of depressive symptoms. According to Bjelland et al. [24] the validity of the HAD scale generally has been good to very good. The Norwegian version of the HAD-scale has shown good psychometric properties in terms of its two-factor structure, intercorrelation of the subscales (variance of 24-36%) and internal consistency ($\alpha$= 0.73 – 0.85) [25].

The WHO-5 questionnaire monitors a person's level of emotional well-being. This generic unidimensional instrument includes five positively worded items, rated on a 6 – point Likert scale. Higher scores indicate better well-being. The WHO-5 questionnaire has been shown to be a psychometrically sound instrument among patients with type 1 and type 2 diabetes in terms of its one-factor structure, inter-item correlations (0.71 to 0.84), and internal consistency ($\alpha$= 0.91 and 0.93) [26, 27].

The Hypoglycemia Fear Survey II (HFS-II) has two subscales (33 items), one measuring worry about hypoglycemia and its negative effects (HFS-W) and the other one behavior to avoid hypoglycemia (HFS-B) [28]. In this study only the HFS-W (18 items) was used, as the HFS-B has shown a questionable structure [29]. The responses are rated on a 5 – point Likert scale from 0 (never) to 4 (always), with higher scores indicating higher levels of fear related to hypoglycemia. Internal consistency for the worry scale was satisfactory with a Cronbach´s $\alpha$ of 0.87 [30].

The PAID-20 questionnaire provides a total score from 0 – 100, by summing the 0 – 4 responses given for each of the 20 items and multiplying this sum by 1.25 [29]. The PAID-5 contains

questions 3, 6, 12, 16 and 19 from the full PAID-20 scale. The scale gives a total score from 0 to 20. A score of 8 and above indicates a high level of diabetes-related distress [16] (Table S1).

**Data analysis**

Descriptive statistics were conducted to describe the sample. A CFA with maximum likelihood estimation was used to investigate the factor structure of the PAID-5 scale. Missing data for PAID-5 was handled by listwise deletion in CFA-models, however only two persons had missing data on at least one item. Model fit was evaluated by inspection of various goodness-of-fit measures, including model Chi-square ($\chi^2$), degrees of freedom (df) and associated p-values. In addition, a goodness-of-fit index (GFI), comparative fit index (CFI), root mean squared error of approximation (RMSEA) and standardized root mean square residual (SRMR), ratio of chi square value to the degrees of freedom (CMIN/DF) and normed fit index (NFI) were assessed [30, 31]. The model was considered to fit the data when the following criteria were satisfied: RMSEA < 0.08, CFI > 0.95, GFI > 0.90, SRMR < 0.08, CMIN/DF <3, NFI > 0.95 [31, 32].

Convergent validity was assessed by Pearson's correlations [33] to examine the relationships between diabetes-related emotional distress (PAID-5 scores) and perceived overall health, emotional well-being (WHO-5), depression (HADS-D), and worry about hypoglycemia (HFS-W). We also investigated how the PAID-5 scale correlated with the total PAID-20 score. Coefficients in the range of 0-0.19 were regarded as very weak, 0.2-0.39 as weak, 0.40-0.59 as moderate, 0.6-0.79 as strong and 0.8-1 as very strong correlation [33]. Discriminant validity assessed whether the PAID-5 scale can differentiate between groups. Independent samples t-tests were used to compare the mean scores on the PAID-5 for people with and without diabetes long-term complications, and between type 1 and type 2 diabetes. Relationships between the PAID-5 score and age, diabetes duration, treatment regimen and metabolic control (HbA1c) were explored using Pearson correlations.

The reliability of the PAID-5 scale was estimated by calculating the internal consistency and the test-retest reliability. Cronbach´s α was used to determine internal consistency for the PAID-5 scale total scores. Test-retest reliability for the PAID-5 scale was examined by intra-class correlation coefficient [34].

Missing substitution with the mean was used for the HAD depression scale when at least 5 items of 7 were answered [35]. For all other questionnaires, when less than 50% was missing, missing

data were replaced with the case mean [36]. Statistical Package for the Social Sciences (SPSS) version 23.0 and AMOS version 23.0 for Windows were used to analyze the data. A significance level of 0.05 was used in all analyses.

### Ethical considerations

The National Committee for Medical and Health Research Ethics assessed the application (2016/1104/REK vest) and approval was obtained from the Norwegian Center for Research Data (ref.nr. 49383). In addition, approval was obtained from the clinics where the study was conducted. Informed consent was obtained from the participants.

### Patient and Public Involvement

Patients and or public were not involved in setting the research questions or planning the study. Outcomes were self-reported by patients based on predefined questions. The study had no patient advisers. Due to the nature of this validation study, feedback regarding the results was not planned for those involved.

## RESULTS

### Demographic and clinical data

The questionnaire was returned by 143 patients of 342 yielding a response rate of 42%. Clinical and demographic characteristics are presented in Table 1. The mean age of the participants was 48.9 years (SD 11.9) (range 19-65). The mean HbA1c for the participants was 7.6% (60 mmol/mol) (SD 1.2). The mean duration of diabetes was 17.9 years (SD 12.9) (range 1 – 54 years). In total, 117 patients (82%) agreed to the second assessment. The non-participants (n=197) were younger than the participants (mean age 45.15 vs. 48.9, p=0.006), and a larger proportion was male compared to the participants. The mean score for the PAID-5 in this study sample was 5.3 (SD=4.3) and individual scores ranged from 0–19.

### Validity

### Construct validity

A CFA for PAID-5 was carried out for 141 patients (Table 2). We hypothesized a one-factor model for PAID-5. After allowing the correlation between error terms between items 3 and 16, the overall $\chi^2 = 6.0$, df = 4 (p-value of 0.195), showed a good model fit. Additional indices resulted as follows: RMSEA = 0.061, CFI = 0.995, GFI = 0.984 and SRMR = 0.024, NFI= 0.984, CMIN/DF=1.51, showing excellent fit.

**Convergent and discriminant validity**

There was a significant moderate correlation between the PAID-5 total score and HFS worry scale (r=0.598, p < 0.001). There was also a weak positive correlation between the PAID-5 scale and HAD depression scale (r=0.380, p < 0.001). Convergent validity was also confirmed by a negative correlation between the PAID-5 and WHO-5 scale (r=-0.363, p < 0.001) and the perception of general health (r=-0.420, p < 0.001). The PAID-5 total score also correlated significantly with the PAID-20 total score (r=0.923, p < 0.001).

There was no significant difference in PAID-5 scores between persons with type 1 diabetes (mean=5.59, SD=4.58) and persons with type 2 diabetes (mean=4.95, SD=3.93, p=0.38). There was also no significant difference in PAID-5 mean scores between those who reported having diabetes long-term complications (mean=5.75, SD=0.7) and those not having these complications (mean=5.2, SD=4.4, t (140) =0.61, p=0.54). Diabetes-related distress mean scores approached statistical significance when comparing patients who reported having retinopathy (7.2, SD=4.0) versus those without retinopathy (mean=5.1, SD=4.2, p=0.06). Although women scored higher on the PAID-5 (mean=5.9, SD=4.6) than men (mean=4.86, SD=4.01), the difference was not significant (p=0.15).

Patients who had experienced episodes of serious hypoglycemia in the past 6 months had a significantly higher PAID-5 mean score (7.5 (SD= 4.95) versus those who had not had these episodes (5.0, SD=4.2, (p=0.043). There were no significant differences in the PAID-5 mean scores for the three different treatment groups: insulin (n=87), oral medication (n=28) or both (n=27) (p=0.90). There were no significant correlations with higher age and longer duration of diabetes. Higher HbA1c was positively correlated with higher PAID-5 mean scores, but the correlation was weak (r=0.14) and not significant (p=0.16).

**Reliability**

**Internal consistency and test-retest reliability**

The Cronbach's α for the PAID-5 scale was 0.89. Inter-item correlations for the PAID-5 scale ranged from 0.49 to 0.74. The test-retest reliability of the PAID-5 was assessed in 92 participants who returned the repeat questionnaire, and resulted in an ICC of 0.81 (95% CI=0.70– 0.87, p < 0.001).

## DISCUSSION

The results of the current study demonstrate satisfactory psychometric properties of the short form of the PAID-5 in Norwegian adult patients with type 1 and type 2 diabetes. Our findings provide evidence for a one-factor structure for the PAID-5 scale, enabling the assessment of diabetes-related emotional distress. Convergent validity was demonstrated by statistically significant moderate correlations with other concept-related PROMs. The PAID-5 scale showed good internal consistency and a stable test-retest reliability among patients with type 1 and type 2 diabetes across three different clinics in Norway. The instrument might be considered as a supplement to guide consultations, or as a screening instrument in registries and/or population health databases. Use of this tool may increase knowledge on the prevalence of diabetes-related emotional distress, and thus inform guidelines for health care professionals and future interventions.

The Norwegian version of the PAID-5 clearly demonstrated a one-factor structure as postulated. The psychometric results in the current study lend support to findings from two previous validation studies on the PAID-5 scale [16, 19]. In Asia, the Korean version of the PAID-5 enabled a one factor model and demonstrated excellent goodness-of-fit indices after the modification with the error of terms between items 3 and 6 [17]. Our CFA among Norwegians showed excellent goodness-of-fit indices after model modification with the covariance of error terms between items 3 and 16. Therefore, it seems that the instrument enables the assessment of diabetes-related emotional distress, although one data driven modification was needed that may have inflated the model fit.

The present study showed that the PAID-5 correlated positively with fear of hypoglycemia (HFS) and symptoms of depression (HADS-D), and negatively with emotional well-being (WHO-5) and ones' general health perception (RAND-36), which emphasizes good convergent validity. When diabetes-related stress increases, emotional well-being and perception of ones´ general health decreases, as expected [16, 26, 27]. Previously, McGuire et al. [16] demonstrated the relationship between the PAID-5 scale and the WHO-5 scale. However, there is limited evidence showing relationships with concepts of fear of hypoglycemia and symptoms of depression. We demonstrated this in the current study, emphasizing the usefulness of this brief questionnaire.

The PAID-5 scale discriminates well among those who had experienced episodes of serious hypoglycemia in the past 6 months compared to those who had not had hypoglycemia. The study population in general experienced a low level of diabetes-related emotional distress, as the mean score on the PAID-5 for the study population was 5.3 (SD=4.3). However, individual scores ranged from 0–19, indicating that there were patients with a high level of diabetes-related emotional distress. Relationships between the PAID-5 scale and other subgroups were weak and non-significant. For example, women scored higher on the PAID-5 scale as expected, but this difference was not significant, probably due to the relatively small sample size as in the previous study conducted in Iceland [37]. There were no significant differences between the mean PAID-5 scores for the three different treatment groups (insulin, oral medication or both) (p=0.90). Our relatively small sample size might be the reason, but it is also possible that type of treatment is not the main reason for a higher burden of diabetes distress. On the other hand, a higher HbA1c (as a measure of metabolic control), might be a better marker as higher HbA1c was positively correlated with PAID-5 mean scores in this study (NS) as well as in previous research [15]. However, future studies specifically designed to answer these questions (e.g., by use of stratified sampling or by using latent class analyses) with large sample sizes are needed to test for discrimination between different subgroups.

In the current study, the mean diabetes duration of the study population was 17.1 years and metabolic control was generally close to the treatment goals, as 50 % of the participants in the subgroup had a HbA1c value of $\leq$ 7.3 % (56 mmol/mol). In the current study, the PAID-5 scale did not discriminate between groups, such as patients with and without diabetes-related long-term complications. This might be a consequence of the relatively low number of people with complications. Nevertheless, the proportion of diabetes long-term complications seems reasonable for this patient group and is in line with previous research in Norway [15, 38].

Metabolic control (HbA1c measurements) was positively, but only weakly correlated with PAID-5. This is consistent with results from PAID-20 validation studies, where diabetes-related emotional distress and glycemic control have shown to be positively correlated - as diabetes distress increases, HbA1c level also increases [15, 39-41]. Although higher HbA1c values have been associated with high diabetes-related emotional distress, it should not be taken as self-evident that patients who are able to maintain an optimum blood sugar feel less distressed.

The short-form of the PAID-20, the PAID-5, showed a good internal consistency and test-retest reliability. This confirms the assumption in previous validation studies that the number of items in the PAID-20 could be reduced [15]. Our findings and previous studies of the PAID-5 scale demonstrated good to excellent internal consistency reliability, with Cronbach's α varying from 0.83 – 0.93 [6, 16, 19, 42].

Diabetes, which is a chronic disease, not only involves making healthy choices in one's everyday life, but one must also have the ability to see diabetes and its psychological aspects as a larger and more complex picture with many different challenges throughout life. Diabetes self-management training is closely connected to how patients understand the nature of the disease and its management, thus reducing different fears (e.g., fear of hypoglycemia), guilt and frustration, and at the same time increasing skills in managing diabetes self-care and medication adherence [7].

**Strengths and limitations**

In this well-defined sample of patients across three clinics, the Norwegian PAID-5 was shown to be a reliable and valid short questionnaire for assessing diabetes-related distress among people with type 1 or type 2 diabetes. Although the scale has demonstrated good psychometric properties, this study has limitations. Type of diabetes and metabolic control ($HbA_{1c}$) were received from the patient's medical record. However, other clinical characteristics such as diabetes complications were self-reported by the patient, which may cause inaccuracies [33]. Second, the non-responders were younger than the participants, which calls for caution when interpreting the results for younger adults with diabetes. Third, the information about the study and the request for participation was sent by mail. The distribution method in this study has probably contributed to a relatively low response rate. However, we had enough power to investigate the one-dimensional scale structure with a CFA. Nevertheless, the sample size restricted us in determining if the PAID-5 scale has the ability to discriminate between different subgroups. This needs further research in a larger sample. In spite of these limitations, this cross-sectional study provides a valid assessment of the psychometric properties of the short form of the PAID scale in Norwegian adult patients with type 1 and type 2 diabetes.

**Conclusions**

In conclusion, the findings from this study provide evidence that the Norwegian version of the PAID-5 scale is a reliable and valid instrument for assessing diabetes-related emotional distress among patients with type 1 and type 2 diabetes in Norway, although its ability to discriminate between groups needs to be tested further in a larger sample. The scale has only five items and has the potential to guide communication in one-on-one consultations. Although this validation study was conducted among patients visiting their doctor or a diabetes nurse in specialty health care, the PAID-5 questionnaire is also relevant to use in primary health care.

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**Patient consent**

Obtained.

**Conflict of interest**

None declared

**Contributor ship statement**

MV contributed to the study concept, project planning and management, recruitment of participants, data analysis, manuscript preparation, drafting the manuscript and approved the final manuscript. AB contributed to the study concept, project planning, manuscript preparation, drafting the manuscript and approved the final manuscript. JI contributed to data analysis, manuscript preparation, drafting the manuscript and approved the final manuscript. AV contributed to the study concept, manuscript preparation, drafting the manuscript, and

approved the final manuscript. MMI contributed to the study concept, project planning and management, data analysis, manuscript preparation, drafting the manuscript and approved the final manuscript.

**Data sharing statement**

No additional data available.

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**Table 1.** Demographic and clinical characteristics of the study population

| **Characteristics** | Total sample |
|---|---|
| *Demographic variables* | (n = 143) |
| Age (years), mean ± SD | 48.9 ± 11.9 |
| Male sex | 78 (54.5) |
| *Clinical variables* | |
| Type of diabetes | |
| Type 1 | 87 (60.8) |
| Type 2 | 56 (39.2) |
| $HbA_{1c}$ (%), mean ± SD [a, b] | 7.6 ± 1.2 |
| $HbA_{1c}$ (mmol/mol), mean ± SD [a, b] | 60 ± 13 |
| Diabetes duration (years), mean ± SD | 17.1± 12.9 |
| Type of treatment | |
| Insulin | 88 (61.5) |
| Oral medication | 28 (19.6) |
| Insulin and oral medication | 27 (18.9) |
| Episodes of serious hypoglycemia | |
| 1-3 times in the past 6 months | 16 (11.2) |
| Self-reported complications | |
| Presence of one or more late complications[c] | 32 (22.4) |

Data are shown as *n* (%). Percent of patients with valid values for categorical variables and mean ± SD (Standard Deviation) for continuous variables.

[a] $HbA_{1c}$ (glycated hemoglobin) measurements were reported using the International Federation of Clinical Chemistry units (mmol/mol) in addition to the derived NGSP units (%)

[b] n = 100, $HbA_{1c}$ values older than 8 weeks a prior and more than 12 weeks after filling out the survey were excluded.

[c] Retinopathy, cardiovascular diseases or foot ulcers

**Table 2.** Factor loadings and goodness-of-fit indices for the PAID-5 one-factor solutions

| | Model 1 | Model 2 |
|---|---|---|
| Standardized loadings | | |
| Item 3 | 0.83 | 0.85 |
| Item 6 | 0.86 | 0.85 |
| Item 12 | 0.82 | 0.80 |
| Item 16 | 0.68 | 0.72 |
| Item 19 | 0.73 | 0.72 |
| AVE | 0.62 | 0,63 |
| Composite reliability | 0.76 | 0,76 |
| Df | 5 | 4 |
| $\chi 2$ (p) | 14.85 (0.11) | 6.0 (0.195) |
| CFI | 0.974 | 0.995 |
| GFI | 0.961 | 0.984 |
| SRMR | 0.035 | 0.024 |
| RMSEA | 0.119 | 0.061 |
| CMIN/DF | 2.971 | 1.51 |
| NFI | 0.962 | 0.984 |

Model 1: One-factor CFA, Model 2: One-factor CFA with covariance of error terms between item 3 and 16
$\chi^2$ (p): Model Chi-Square, Df: degrees of freedom; CFI: comparative fit index (good fit > 0.95). GFI: goodness of fit index (good fit > 0.90); SRMR: standardized root mean square residual (good fit <0.08). RMSEA: root mean square error of approximation (acceptable fit <0.08); CMIN/DF: ratio of chi square value to the degrees of freedom (<3); NFI: normed fit index (good fit > 0.95);

**Table S1.** Questions included in the PAID-5 questionnaire

| Questions | |
|---|---|
| 3 | "Feeling scared when you think about living with diabetes?" |
| 6 | "Feeling depressed when you think about living with diabetes?" |
| 12 | "Worrying about the future and the possibility of serious complications?" |
| 16 | "Feeling that diabetes is taking up too much of your mental and physical energy every day?" |
| 19 | "Coping with complications of diabetes?" |

STROBE Statement—checklist of items that should be included in reports of observational studies

| | Item No | Recommendation | Page No |
|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract | 1 |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 2 |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 4-5 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 5 |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | 5 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 6-7 |
| Participants | 6 | (*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up<br>*Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls<br>***Cross-sectional study***—Give the eligibility criteria, and the sources and methods of selection of participants | 6 |
| | | (*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed<br>*Case-control study*—For matched studies, give matching criteria and the number of controls per case | |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 6-7 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 6-7 |
| Bias | 9 | Describe any efforts to address potential sources of bias | 6-7 |
| Study size | 10 | Explain how the study size was arrived at | 6 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 8 |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | |
| | | (*b*) Describe any methods used to examine subgroups and interactions | 8 |
| | | (*c*) Explain how missing data were addressed | 8 |
| | | (*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed<br>*Case-control study*—If applicable, explain how matching of cases and controls was addressed<br>***Cross-sectional study***—If applicable, describe analytical methods taking account of sampling strategy | 6 |
| | | (*e*) Describe any sensitivity analyses | |

| | | | |
|---|---|---|---|
| **Results** | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 9 |
| | | (b) Give reasons for non-participation at each stage | |
| | | (c) Consider use of a flow diagram | |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 9 |
| | | (b) Indicate number of participants with missing data for each variable of interest | |
| | | (c) *Cohort study*—Summarise follow-up time (eg, average and total amount) | |
| Outcome data | 15* | *Cohort study*—Report numbers of outcome events or summary measures over time | |
| | | *Case-control study*—Report numbers in each exposure category, or summary measures of exposure | |
| | | *Cross-sectional study*—Report numbers of outcome events or summary measures | 9-10 |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | 9-10 |
| | | (*b*) Report category boundaries when continuous variables were categorized | |
| | | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | |
| **Discussion** | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 10-11 |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 13 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 13 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 12-13 |
| **Other information** | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 14 |

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.