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Title:

New diabetes questionnaire to add patients' perspectives to diabetes care for adults with type 1 and type 2 diabetes – Nationwide cross-sectional study of construct validity assessing associations with generic health-related quality of life and clinical variables

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Abstract

Objectives: To study evidence for construct validity, the aim was to describe the outcome from the recently developed Diabetes Questionnaire, assess the associations of that outcome with clinical variables and generic health-related quality of life, and study the sensitivity to differences between clinically relevant groups of glycaemic control in adults with type 1 and type 2 diabetes in a nationwide setting.

Design: Cross-sectional survey.

Setting, participants, and outcome measures: From the Swedish National Diabetes Register, 2,479 adults with type 1 diabetes and 2,469 adults with type 2 diabetes were selected at random among those 18-80 years of age with at least one registered test of glycated haemoglobin (HbA_{1c}) during the last 12 months. The Diabetes Questionnaire and the generic 36-item Short Form version 2 (SF-36v2) health survey were completed by 1373 (55.4%) adults with type 1 diabetes and 1353 (54.8%) with type 2 diabetes.

Results: Related to the pre-specified assumptions, supporting evidence for construct validity for the Diabetes Questionnaire was found. The statistically significant correlations with the clinical variables were few and weak. In relation to the SF-36v2, the strongest correlations were seen in the Diabetes Questionnaire scales General Well-being and Mood and Energy. In those scales, machine learning analyses showed that about 40-45% of the variance was explained by the SF-36v2 results and clinical variables. In multiple regression analyses among three groups with differing levels of HbA_{1c} adjusted for demographics, other risk factors, and diabetes complications, the high-risk group had statistically significant lower scores than the well-controlled group in most Diabetes Questionnaire scales.

Conclusions: This nation-wide study shows that the Diabetes Questionnaire captures some generic health-related quality-of-life dimensions, in addition to adding diabetes-specific information not covered by the SF-36v2 and clinical variables. The Diabetes Questionnaire is also sensitive to differences between clinically relevant groups of glycaemic control.

Keywords: Diabetes Mellitus, Type 1; Diabetes Mellitus, Type 2; Patient-reported outcome; Cross-Sectional Study; Construct validity

Article Summary

Strengths and limitations of this study

- The cross-sectional study used a large, heterogeneous nationwide sample of adults with type 1 diabetes and adults with type 2 diabetes selected at random.
- Respondents were representative of the 2015 population in the Swedish National Diabetes Register.
- The Diabetes Questionnaire scales scores were related to relevant clinical variables and a well-known and often recommended measure of generic health-related quality of life.
- The analyses were limited to the respondents and might reflect a group with greater motivation for participation.
- The questionnaires were only offered in Swedish.

Main text:

INTRODUCTION

Everyday life with diabetes as an adult is a complex challenge. Diabetes makes individuals responsible for self-management to avoid serious short-term and long-term complications, while balancing self-perceived health and well-being in the present as well as in the future.[1-6] To support skills for self-management is a central task of diabetes care, and the individual patient's prerequisites, wishes, and available evidence must be taken into account.[1, 4-6] An important step for the Swedish National Diabetes Register (NDR) has therefore been to broaden health-care provider perspectives and enable a systematic collection of adults' perspectives of living with diabetes and their experiences of whether they are offered adequate support from diabetes care.[7-10] The newly developed Diabetes Questionnaire is intended to support meetings with individuals and provide a means for quality improvement at the local, regional, and national levels.[7-9]

The Diabetes Questionnaire has a sound basis and was developed from interviews with adults with type 1 or type 2 diabetes that identified a broad range of aspects important to the target group, such as well-being, impact on daily life, capabilities to manage diabetes, and support from diabetes care.[9] In line with Sen's capability approach,[11, 12] the Diabetes Questionnaire focuses on the individual's opportunities, prerequisites, and possible barriers to live a good life with diabetes.[7-9] Supporting evidence for content validity, face validity, and ease of items understandability and answerability has been presented.[8, 9] In addition, supporting evidence for test-retest reliability and that the scales can be used for comparison between men and women, between different age groups, and, for most scales, between type 1 and type 2 diabetes have been provided.[7, 8] Furthermore, the scales can detect differences between clinically relevant subgroups, such as diabetes type, diabetes treatment, age group, and gender.[7] We have also begun to study the associations with clinical variables by showing low individual-level correlations with glycated haemoglobin (HbA_{1c}), systolic blood pressure (SBP), and LDL cholesterol.[7]

This study reports on an extended analysis of the evidence for construct validity by studying pre-specified assumptions of relationships to other measures and differences between relevant groups.[13] For this work, we chose to focus on differences between subgroups of glycaemic control and the relations to clinical variables relevant for diabetes care and an often-recommended generic measure of health-related quality of life, the 36-item Short Form

(SF-36v2) health survey. To study evidence for construct validity, the aim was to describe the outcome from the Diabetes Questionnaire, to assess the associations of that outcome with clinical variables and generic health-related quality of life, and to study the sensitivity to differences between clinically relevant groups of glycaemic control in adults with type 1 and type 2 diabetes in a nationwide setting.

METHODS

Sample and data-collection

In this cross-sectional survey, 2,479 adults with type 1 diabetes and 2,469 with type 2 diabetes were selected at random without replacement from the Swedish NDR. Eligibility criteria were being alive, 18-80 years of age, and recorded in the NDR during the period from September 30th 2014 to October 1st 2015 with at least one recorded test of HbA_{1c} level during the previous 12 months. With these criteria, 29,245 adults with type 1 diabetes at hospital out-patient clinics and 208,852 adults with type 2 diabetes at primary health care centres were eligible for recruitment. The sample size was estimated to enable subgroup analyses. No formal sample size-calculation was conducted as there was a lack of data on the variation in standard deviations for the Diabetes Questionnaire prior to this data-collection effort.

The Diabetes Questionnaire, the SF-36v2 survey, and a prepaid return envelope were sent by mail in October 2015 to survey selectees and again to non-respondents after 30 days.[7, 14] Both questionnaires were answered by 1,373 (55.4%) individuals with type 1 diabetes and 1,353 (54.8%) with type 2 diabetes[14]. With small differences in response rate depending on the questionnaires in question, the sample has been described as previously focusing on the scale development of the Diabetes Questionnaire[7] and separate analyses of the SF-36v2 data[14]. Age, sex, and clinical variables (diabetes type defined by clinical diagnosis, diabetes duration, HbA_{1c} level, cardiovascular risk factors, complications, physical activity level, and receipt of medical treatment) recorded because of their relevance to high-quality diabetes care were collected from the NDR.

Diabetes Questionnaire

The Diabetes Questionnaire is a 33-item self-reporting questionnaire having a total of 12 scales divided into 2 main parts.[7, 8] Part 1 has 22 items on 8 scales and acts as a patient-reported outcome measure (PROM). These scales are General Wellbeing (GenW), Mood and Energy (MoE), Free of Worries about blood sugar (FreW), Capabilities to Manage your

Diabetes (ManD), Diet and Exercise (DiEx), Not Limited by Diabetes (NLD), Not Limited by Blood Sugar (NLBS), and Support from Others (SuO). Part 2 is an 11-item patient-reported experience measure (PREM) with 4 scales. Those scales are Support from Diabetes Care (SuDC), Access to Diabetes Care (AcDC), Continuity in Diabetes Care (CoDC), and Medical Devices and Medical Treatment (MDMT). All scales are scored from 0 to 100, with higher scores representing the more desirable outcome. The scales ManD, NLBS, and MDMT are specific to diabetes type.[7]

SF-36v2 survey

The SF-36v2 survey is a self-reporting questionnaire for generic health-related quality of life with support for its validity and reliability in overall populations, such as people with diabetes.[3, 15-19] We used the self-administered standard form in Swedish and software from QualityMetric Inc. The eight domains produced are physical functioning (PF); role-physical (RP), that is role limitations due to physical health problems; bodily pain (BP); general health (GH); vitality (VT); social functioning (SF); role-emotional (RE), that is role limitations due to mental health problems; and mental health (MH). The domains are scored from 0 to 100. Higher scores indicate a better general health-related quality of life.[15, 16]

Pre-specified assumptions

As the Diabetes Questionnaire is intended to measure patient perspectives on how they feel, how their diabetes treatment is going, and their experiences of support from diabetes care, the pre-specified assumptions for correlations with clinical variables and the SF-36v2 were as follows:

- A small number of negative and weak correlations would be found between the Diabetes Questionnaire scales and the clinical variables, mostly related to the HbA_{1c} level. There would be no correlations with SBP and LDL cholesterol.
- The Diabetes Questionnaire PROM scales GenW, MoE, FreW, ManD, DiEx, NLD, and NLBS would have more and stronger correlations to the SF-36v2 domains, as compared to the PROM scale SuO and the PREM scales (SuDC, AcDC, CoDC, and MDMT). Observed correlations would be positive, with the strongest in GenW and MoE. Across the other scales, strong correlations were not expected. Correlations ≥0.60 were considered as very strong, 0.50 to <0.60 as strong, 0.40 to <0.50 as moderate, and <0.40 as weak.

Statistical Analysis

The data for participants with type 1 and type 2 diabetes were analysed separately. The descriptive statistics for each variable are based on non-missing observations. The continuous variables are given as means and standard deviations for normal distributions and as medians and interquartile ranges for skewed distributions. The categorical variables are presented as numbers and percentages. The generation of scale scores from the Diabetes Questionnaire is described in detail elsewhere.[7] The SF-36v2 domain scores were generated using the manual and licensed software from QualityMetric.[16]

Spearman's rank correlation was used to study the associations between the Diabetes Questionnaire scale scores and the clinical variables age, diabetes duration, HbA_{1c} level, body mass index (BMI), LDL cholesterol, and SBP, as well as between the scores from the Diabetes Questionnaire scales and the SF-36v2 domains. With machine learning using random forests, non-linear associations were investigated between the Diabetes Questionnaire scales and the SF-36v2 domains together with clinical variables (age, sex, diabetes duration, HbA_{1c} level, BMI, LDL cholesterol, and SBP). First, the variance in all Diabetes Questionnaire scales was examined in relation to the SF-36v2 domains and the clinical variables together. Next, the variable importance of the SF-36v2 domains and the clinical variables as predictors of the PROM scales GenW and MoE were examined. We also examined the percent variance in HbA_{1c} explained by another clinical variable, the Diabetes Questionnaire scales, and the SF-36v2 domains together. The results are given as percent of the total variance. Each model contained 1000 trees.

To study group-level associations between the Diabetes Questionnaire scales and glycaemic control as measured by HbA_{1c}, unadjusted and adjusted multiple regression analyses were conducted in the same manner as previously described for the SF-36v2 data[14]. HbA_{1c} was considered as a categorical variable divided into three clinically relevant groups corresponding to differing levels of glycaemic control and consequently differing levels of the risk of diabetes complications according to international and Swedish treatment guidelines. The three groups were well-controlled (<52 mmol/mol), sub-optimal (52-69 mmol/mol), and high-risk (≥70 mmol/mol). For the three HbA_{1c} groups, the least square mean estimates and 95% confidence intervals were calculated for each scale. The scale observations were modelled with a linear model with fixed effects for the HbA_{1c} group (exposure), age, sex, diabetes duration, BMI, SBP, LDL-cholesterol, micro- and macro-albuminuria, estimated

glomerular filtration rate, retinopathy, smoking status, physical activity level, previous coronary heart disease, previous stroke, and receipt of antihypertensive and lipid lowering treatments. The analyses were performed separately for each imputed data set, and the results were subsequently combined using Rubin's rules. The results are presented as least square mean estimates with 95% confidence intervals.

The extent of missing data was 0% for age and sex, 7.2% for clinical variables (range 0-36.5%), 1.7% for the SF-36v2 domains (range 0-3.3% for individual dimensions), and 4.8% for the Diabetes Questionnaire scales (range 0.3-34.7% for individual scales). For the Diabetes Questionnaire, the higher extent of missing data is likely related to having "not applicable" as a response alternative in some scales, which at this stage was treated as missing data. For scales without "not applicable" as a response alternative, the range for missing data was 0.3-2.8%. Missing data were imputed 10 times, using multiple chained equations.

The standardized mean difference was used to examine the data balance between the HbA_{1c} groups and the deviation from the means in the clinical and demographic data. A significance level of 5% was used throughout; no allowance was made for multiplicity of statistical tests. The analyses were conducted using SAS 9.4 and R 3.4.4.

Patient and public involvement statement

The Diabetes Questionnaire was based on qualitative interviews with adults living with diabetes.[8, 9] Adults with diabetes and representatives from patient organizations participated in expert reviews during the development and initial testing.[8] Adults with diabetes were involved in the pre-testing phase by participating in cognitive interviews and being consulted to comment on questionnaire revisions.[8] The analyses presented here as the previous scale development and evaluation of reliability and validity relied on the contributions from those adults with diabetes who responded to the questionnaires.[7, 8] The Swedish Diabetes Foundation, the national patient organization, has expressed their support for the project.

Ethical considerations

The study conforms to the Declaration of Helsinki and was approved by the Regional Ethical Review Board in Gothenburg, Sweden (No. 029-15, T600-15). Participants gave their informed consent. The letter to the participants contained information about the study's

purpose, the voluntary nature of their participation, and their right to end participation. The letter also disclosed information about the NDR, methods of handling personal data, confidentiality measures, and contact details.

RESULTS

Among respondents with type 1 diabetes, 50.3% were men. The averages of key statistics were 48.6 years for age, 24.7 years for diabetes duration, and 62 mmol/mol for HbA_{1c} level. Among respondents with type 2 diabetes, 60.8% were men. Corresponding averages were 66.6 years for age, 9.4 years for diabetes duration, and 53 mmol/mol for HbA_{1c} level (Table 1). The crude means and standard deviations for the Diabetes Questionnaire scales are given in Table S1. The clinical characteristics of non-respondents are given in Table S2.

Linear correlations between the Diabetes Questionnaire scale scores and the clinical variables

In line with the assumptions, there were few statistically significant linear correlations between the Diabetes Questionnaire scales and the clinical variables. Observed correlations were weak, and most were negative. The results are shown as heat maps in Figs. S1-S2 with details provided in Tables S3-S4.

As assumed, the HbA_{1c} level was the variable with most statistically significant correlations across the Diabetes Questionnaire scales. Statistically significant but weak correlations between having a lower and better HbA_{1c} level and higher and better scores were seen in several Diabetes Questionnaire scales. For participants with type 1 diabetes, significant weak negative correlations (-0.12 to -0.25) were seen in the five Diabetes Questionnaire PROM scales GenW, FreW, ManD, DiEx, and NLBS. The strongest correlations were seen in ManD and DiEx. Among participants with type 2 diabetes, statistically significant but weak negative correlations (-0.13 to -0.24) were seen in the seven Diabetes Questionnaire PROM scales GenW, MoE, FreW, ManD, DiEx, NLD, and NLBS and in the two PREM scales SuDC and AcDC. The strongest correlations were seen in MoE, FreW, and ManD, with generally stronger correlations in the PROM scales than in the PREM scales (Figs. S1-S2, Tables S3-S4).

Table 1. Clinical and demographic characteristics of the respondents separated by diabetes type and glycated haemoglobin (HbA_{1c}) level

Variable	Type 1 diabetes					Type 2 diabetes				
	All	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	Standardized mean difference, SMD	All	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	Standardized mean difference, SMD
Number (%)	1373	284 (20.7%)	781 (56.9%)	308 (22.4%)		1353	725 (53.6%)	503 (37.2%)	125 (9.2%)	
Men, n (%)	690 (50.3)	152 (53.5)	391 (50.1)	147 (47.7)	0.077	822 (60.8)	444 (61.2)	302 (60.0)	76 (60.8)	0.016
Age, years (SD)	48.6 (16.4)	46.9 (17.0)	49.6 (16.1)	47.8 (16.3)	0.113	66.6 (9.1)	66.5 (9.1)	66.9 (9.0)	65.5 (9.7)	0.103
Diabetes duration, years (IQR)	22.0 (12.0-36.0)	19.0 (7.0-32.0)	23.0 (13.0-37.0)	24.0 (13.0-37.0)	0.150	8.0 (4.0-14.0)	6.0 (3.0-11.0)	10.0 (6.0-16.0)	13.0 (6.0-17.0)	0.443
HbA_{1c} mmol/mol (SD)	62 (12.7)					53 (12.5)				
BMI, kg/m^2 (SD)	26.0 (4.2)	25.2 (3.8)	26.0 (4.2)	26.7 (4.6)	0.239	29.9 (5.3)	29.3 (5.2)	30.3 (5.4)	32.0 (5.5)	0.332
Systolic blood pressure, mmHg (SD)	127.0 (14.0)	124.8 (14.0)	127.5 (13.8)	127.8 (14.2)	0.145	134.3 (14.3)	134.0 (14.4)	134.5 (13.7)	135.1 (16.5)	0.046
Antihypertensive medication, n (%)	589 (44.7)	99 (36.9)	341 (45.3)	149 (50.2)	0.179	1070 (80.1)	572 (79.6)	404 (81.9)	94 (76.4)	0.091
LDL-cholesterol, mmol/L (SD)	2.4 (0.8)	2.5 (0.8)	2.4 (0.8)	2.5 (0.8)	0.077	2.5 (0.9)	2.5 (0.9)	2.4 (0.9)	2.5 (1.0)	0.026
Lipid-lowering medication, n (%)	642 (48.4)	94 (34.6)	378 (49.8)	170 (57.6)	0.315	900 (68.1)	472 (66.6)	344 (70.1)	84 (69.4)	0.050
Micro-albuminuria, n (%)	132 (10.3)	12 (4.6)	70 (9.5)	50 (17.6)	0.285	194 (18.0)	80 (13.9)	83 (20.1)	31 (34.1)	0.323
Macro-albuminuria, n (%)	31 (2.6)	5 (2.1)	12 (1.8)	14 (5.2)	0.126	52 (5.0)	27 (4.8)	20 (5.1)	5 (6.1)	0.037
Estimated Glomerular Filtration Rate,	90.0 (23.5)	90.6 (20.7)	89.1 (22.6)	91.6 (27.7)	0.071	82.3 (23.5)	82.5 (22.3)	81.9 (24.0)	83.4 (27.9)	0.038

Variable	Type 1 diabetes					Type 2 diabetes				
	All	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	Standardized mean difference, SMD	All	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	Standardized mean difference, SMD
eGFR, mL/min (SD)										
Retinopathy, n (%)	875 (65.9)	137 (50.6)	520 (68.2)	218 (74.1)	0.333	327 (29.4)	128 (21.7)	153 (36.3)	46 (47.0)	0.366
Coronary heart disease, n (%)	83 (6.3)	9 (3.3)	53 (7.0)	21 (7.1)	0.113	279 (22.4)	136 (20.2)	111 (24.0)	32 (28.6)	0.130
Stroke, n (%)	48 (3.6)	5 (1.9)	32 (4.2)	11 (3.7)	0.093	96 (7.8)	48 (7.2)	40 (8.9)	8 (7.1)	0.043
Smoker, n (%)	135 (10.1)	14 (5.1)	78 (10.2)	43 (14.4)	0.214	162 (12.9)	79 (11.7)	58 (12.3)	25 (23.1)	0.203
Physical activity, daily, n (%)	359 (27.6)	90 (33.5)	203 (27.2)	66 (23.2)	0.334	426 (34.9)	251 (38.7)	157 (33.9)	18 (16.7)	0.410
Diabetes treatment					0.136					0.813
Diet alone, n (%)						195 (14.4)	172 (23.7)	19 (3.8)	4 (3.3)	
Oral hypoglycaemic agent alone, n (%)						718 (53.1)	419 (57.8)	261 (52.0)	38 (30.9)	
Insulin alone, n (%)	1335 (97.2)	271 (95.4)	764 (97.8)	300 (97.4)		130 (9.6)	46 (6.3)	63 (12.5)	21 (17.1)	
Insulin and oral agent, n (%)	32 (2.3)	9 (3.2)	15 (1.9)	8 (2.6)		266 (19.7)	76 (10.5)	140 (27.9)	50 (40.7)	
Insulin pump users, n (%)	356 (26.2)	66 (23.8)	221 (28.5)	69 (22.5)	0.091	2 (0.5)	1 (0.9)	1 (0.5)	0 (0.0)	0.093

The descriptive statistics are presented as the means and standard deviations (SD) for normally distributed continuous variables, the median and interquartile range (IQR) for skewed distributions, or number and percentages for categorical variables.

For age, statistically significant positive correlations showed that a higher age was weakly associated with higher and better scores in several Diabetes Questionnaire scales. For participants with type 1 diabetes, statistically significant weak positive correlations (0.11 to 0.19) were seen in the four PROM scales MoE, FreW, ManD, and DiEx, and in the two PREM scales AcDC and MDMT. The highest correlations were seen in MoE, FreW, and MDMT. Among participants with type 2 diabetes, statistically significant weak positive correlations (0.12 to 0.16) were seen in the six PROM scales GenW, MoE, FreW, ManD, and DiEx. The highest correlations were seen in MoE, FreW, and DiEx. For LDL cholesterol and SBP, the results came up to the expectations of no statistically significant correlations. However, for participants with type 1 diabetes, a statistically significant negative correlation showed that a lower SBP was weakly associated with better scores in MoE. A lower BMI showed statistically significant weak negative correlations with higher scores in DiEx in both diabetes types as with GenW and MoE in type 2 diabetes. For diabetes duration, statistically significant positive correlations showed that a longer duration was weakly associated with higher scores in FreW and ManD for participants with type 1 diabetes. For those with type 2 diabetes, statistically significant negative correlations showed that a longer duration was associated with lower scores in FreW and NLBS (Figs. S1-S2, Tables S3-S4).

Linear correlations between scores in the Diabetes Questionnaire scales and the SF-36v2 domains

In line with the assumptions, the statistically significant linear correlations between the Diabetes Questionnaire scales and the SF-36v2 domains were stronger in seven of the PROM scales as compared to the PROM scale SuO and the PREM scales. As expected, the observed statistically significant correlations were all positive, showing an association between higher scores in both questionnaires. The results are shown in Figs. 1-2 and Tables S5-S6.

As assumed, the strongest correlations were seen in the Diabetes Questionnaire PROM scales GenW and MoE. Statistically significant positive correlations showed that higher scores in GenW and MoE were strongly associated with higher scores in about half of the SF-36v2 domains. In GenW, statistically significant positive correlations were seen with the SF-36v2 domains PF, GH, VT, and MH. The correlations were very strong with VT (0.60), strong with GH and MH (0.51 to 0.56), and weak with PF. Among those with type 2 diabetes, there were also statistically significant strong positive correlations between GenW and SF (0.51). In MoE, statistically significant positive correlations were seen with the SF-36v2 domains GH,

VT, SF, and MH. The correlations were very strong with MH (0.60) and strong with GH, VT, and SF (0.51 to 0.58). Among those with type 2 diabetes, statistically significant strong positive correlations were also seen between MoE and RF (0.51). For both diabetes types, statistically significant strong positive correlations were also seen between the PROM scale DiEx and the VT domain (0.51). Statistically significant moderate positive correlations were also seen between the PROM scales and SF-36v2 domains. In NLD and NLBS, statistically significant moderate positive correlations were more common in type 2 diabetes than in type 1 diabetes. In the PROM scale SuO and the PREM scales, statistically significant correlations were weak (0.11 to 0.32) or absent (Figs. 1-2, Tables S5-S6).

Non-linear associations

The results from the machine learning analysis are shown in Figs. 3 and S3. Similar results were seen for type 1 and type 2 diabetes. Among the PROM scales, the variance was explained by the SF-36v2 domains and the clinical variables to almost 40% in GenW and to around 45% in MoE. In FreW, ManD, DiEx, NLD, and NLBS, the variance was explained to about 25-30% and in SuO to about 10%. Among the PREM scales, SuDC, AcDC, and MDMT were explained to about 10% or below. In CoDC, almost no variance was explained (Fig. 3). As predictors of the Diabetes Questionnaire PROM scales GenW and MoE, the variables with the highest importance were the SF-36v2 domains GH, VT, and MH. LDL cholesterol and SBP had low variable importance (Fig. S3). The percent variance in HbA_{1c} explained by other clinical variables, the SF-36v2 domains, and the Diabetes Questionnaire scales together was low, around 5% in type 1 diabetes and around 10% in type 2 diabetes. Consequently, the importance of the other clinical variables, the SF-36v2 domains, and the Diabetes Questionnaire scales as predictors of HbA_{1c} was not examined.

Regression analyses of the Diabetes Questionnaire scales by HbA_{1c} level

The results from the adjusted regression analyses of the Diabetes Questionnaire scales and the HbA_{1c} groups are presented separately for participants with type 1 and type 2 diabetes in Fig. 4. The least square mean estimates and confidence intervals from the unadjusted and adjusted analyses are given in detail in Table S7.

Among those with type 1 diabetes, the adjusted analysis of the HbA_{1c} groups showed significantly lower scores for the high-risk group than the well-controlled group in the eight PROM scales GenW, MoE, FreW, ManD, DiEx, NLD, NLBS, and SuO as in the PREM scale

SuDC. The largest between-group differences were seen in the PROM scales ManD and DiEx, where the well-controlled group had the significantly highest means, followed by the sub-optimal group and the high-risk group. Among those with type 2 diabetes, the adjusted analysis showed that the high-risk group had significantly lower scores than the well-controlled group in all scales but CoDC. In the five PROM scales MoE, FreW, ManD, NLD, and NLBS, the well-controlled group had the significantly highest means, followed by the sub-optimal and high-risk groups. The largest between-group differences were seen in MoE, FreW, NLD, and NLBS (Fig. 4, Table S7).

DISCUSSION

From a nationwide setting with a large sample of adults with type 1 and type 2 diabetes selected at random, we present the outcome from the Diabetes Questionnaire. To study construct validity, we assess the associations of that outcome with clinical variables and generic health-related quality of life, as measured by the SF-36v2 and assess the sensitivity to differences between clinically relevant groups of glycaemic control. We found supporting evidence for construct validity in both type 1 and type 2 diabetes. As expected, there were few statistically significant correlations with the clinical variables. The observed correlations were weak, and most were negative. Also as expected, the correlations with the SF-36v2 domains were positive; the strongest correlations were found in the Diabetes Questionnaire PROM scales GenW and MoE. Furthermore, either weak or no correlations were seen in the PREM scales. In machine learning analyses, the SF-36v2 domains and the clinical variables together explained the variance in the PROM scales GenW and MoE to about 40-45%. In the other scales, the variance explained was low. In regression analyses among three groups with differing levels of HbA_{1c} adjusted for demographics, other risk factors, and diabetes complications, the high-risk group had statistically significantly lower scores than the well-controlled group in most Diabetes Questionnaire scales for participants with type 1 diabetes and in almost all scales for those with type 2 diabetes. Statistically significant differences between all three groups of glycaemic control were seen in two scales for type 1 diabetes and in five scales for type 2 diabetes.

Findings and implications

Evaluating the measurement qualities of a questionnaire is a complex and cumulative effort.[13, 20] In this study, we continue the evaluation of the Diabetes Questionnaire by addressing its construct validity. The results show supporting evidence that the Diabetes

Questionnaire targets different concepts than the clinical variables for diabetes care traditionally covered by the NDR. Thus, the central aspects covered by the Diabetes Questionnaire including patient perspectives on how they feel, how their diabetes treatment is going, or their experiences of support from diabetes care cannot be measured by HbA_{1c} or other tested clinical variables. Nor can the clinical variables be estimated through the Diabetes Questionnaire. We need the combination. There is a growing emphasis that the perspectives of those living with diabetes should be part of clinical meetings and be given priority among outcomes in diabetes care assessments.[1, 5, 6, 21-23] Supplementing decision-making by adding the patient's perspective is suggested to increase the focus on these aspects in clinical meetings[2, 24] and to enhance the quality of care.[24-26] In Sweden, the Patient Act strengthens the patient's position and possibilities for shared decision-making and states that the individual patient's prerequisites and wishes should be taken into account.[27] There is also a growing movement towards person-centred care aiming for partnership that is centred on the patient's experience and individual prerequisites, resources, and barriers. An important basis is the patient's story.[28] We hope that the Diabetes Questionnaire can support the patient story if used in the clinical meetings together with the clinical variables.

The Diabetes Questionnaire is unique in being developed to support clinical meetings with individuals and to be used as a means for quality improvement through longitudinal assessment at a local, regional, and national levels within the frame of a nationwide healthcare quality register.[7-9] Many other questionnaires for diabetes were developed to target a specific aspect within intervention studies.[3, 17, 18] The Diabetes Questionnaire has a broad approach with aspects identified as important to adults with diabetes.[8, 9] The Diabetes Questionnaire is also developed using the vocabulary and phrasing of people with diabetes,[8] unlike many other questionnaires that often use academic or professional jargon. In this study, we found supporting evidence that the Diabetes Questionnaire is sensitive to statistically significant differences between clinically relevant subgroups with differing levels of glycaemic control. The Diabetes Questionnaire was also found to capture some aspects of generic health-related quality of life, while also adding aspects that are not covered by the often-recommended SF-36v2. For routine use within clinical diabetes care, the Diabetes Questionnaire is likely more relevant than the generic SF-36v2. A limitation of the Diabetes Questionnaire is, however, the currently limited opportunity for international comparisons. The opportunities and barriers related to clinical use of the Diabetes Questionnaire are currently being studied from the perspectives of professionals and adults with diabetes.

Strengths and weaknesses

Among the strengths of this study are the large and heterogeneous sample of adults with type 1 and type 2 diabetes selected at random from the nationwide NDR. The respondents were representative of the 2015 population in the NDR (data on file). The results can be considered representative of the Swedish adult population with diabetes related to the coverage rate of about 90% in 2015 when around 40,000 adults with type 1 diabetes and 347,000 with type 2 diabetes were registered in the NDR. Through the NDR, we had access to clinical variables relevant for diabetes care and background data for the non-respondents. Another strength is the use of a well-known measure of health-related quality of life. As there is a lack of agreed-upon benchmarks for how strong positive correlations between questionnaires addressing subjective aspects should be to support convergent construct validity,[29, 30] this study based the division of the correlation strength on reports that such correlations generally are low,[30, 31] often within the range 0.20-0.40[31] or 0.40-0.60[30]. A correlation of 0.60 has been suggested to be extremely strong, as the random error of measurement of the two questionnaires impede perfect correlations.[30] As the Diabetes Questionnaire and the SF-36v2 do not measure the exact same construct, there were no prerequisites for broad strong correlations.[13, 30, 31]

Our study also has limitations. The analyses were limited to the respondents and might reflect a group that is more motivated to participate. Another limitation is that the questionnaires were only offered in Swedish, potentially resulting in a higher proportion of foreign-born individuals among the non-responders than among the respondents. Furthermore, the cross-sectional design means that it is not possible to make causal conclusions.

Future perspectives

The evaluation of construct validity is a work of putting the pieces together.[13, 20] Consequently, more studies are needed to relate the Diabetes Questionnaire to different concepts and measures. An important task for diabetes care is to identify suitable interventions that adequately can support individuals with diabetes. The Diabetes Questionnaire can be an important contribution to identify the need and focus for targeted interventions, especially for adults with low scores. In future studies, it is important to evaluate the potential of using scores from the Diabetes Questionnaire scales as the primary selection base or in combination with, for example, HbA_{1c} levels or BMI. It is also essential to

evaluate whether the Diabetes Questionnaire scales are responsive to actual changes and can be used as an evaluative tool adding patient perspectives to both nursing and medical interventions, longitudinal assessments, and quality improvement. The NDR is established as a clinical and a national assessment tool in Swedish diabetes care.[4, 32-34] By now, the Diabetes Questionnaire is digitally and freely available for use by all clinics in Sweden connected to the NDR. The Diabetes Questionnaire is also included as the basis for developmental quality indicators in the Swedish national guidelines for diabetes care.[4] In the future, the Diabetes Questionnaire can be amongst the established quality indicators bringing patient perspectives to the fore for diabetes care.

Conclusion

This nationwide study shows that the Diabetes Questionnaire captures some generic health-related quality of life dimensions as well as adds diabetes-specific information not covered by the SF-36v2 and clinical variables. The Diabetes Questionnaire is also sensitive to differences between clinically relevant groups of glycaemic control.

List of abbreviations

Abbreviations related to the Diabetes Questionnaire

GenW: General Well-being

MoE: Mood and Energy

FreW: Free of Worries about blood sugar

ManD: Capabilities to Manage your Diabetes

DiEx: Diet and Exercise

NLD: Not Limited by Diabetes

NLBS: Not Limited by Blood Sugar

SuO: Support from Others

SuDC: Support from Diabetes Care

AcDC: Access to Diabetes Care

CoDC: Continuity in Diabetes Care

MDMT: Medical Devices and Medical Treatment

PREM: Patient-reported experience measure

PROM: Patient-reported outcome measure

Abbreviations related to the SF-36v2 survey

PF: Physical functioning

RP: Role-physical

BP: Bodily pain

GH: General health

VT: Vitality

SF: Social functioning

RE: Role-emotional

MH: Mental health

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Competing interests

Dr. Eeg-Olofsson reports grants from the ALF agreement (ALFGBG 698991), during the conduct of the study; personal fees from Abbott, personal fees from Lilly, personal fees from Novo Nordisk, personal fees from Bayer, outside the submitted work; Dr. Gudbjörnsdottir reports grants from the ALF-agreement (ALFGBG 725311), during the conduct of the study; grants and personal fees from AstraZeneca, grants and personal fees from Boehringer Ingelheim, grants and personal fees from Eli Lilly, grants and personal fees from Merck Sharp & Dohme, grants and personal fees from Novo Nordisk, grants and personal fees from Sanofi, outside the submitted work; the other authors declare that they have nothing to disclose.

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ALFGBG-698991). None of the funding providers have influenced the design of the study; the collection, analysis, or interpretation of data; the writing of the manuscript, or any publication decision at any stage.

Author Contributions

MSE made substantial contributions to the design of the work, applying for ethical approval and funding, interpreting the data, and drafting and revising the manuscript (major contributor). JL and UBJ supervised and made substantial contributions to the design of the work, applied for funding, made intellectual contributions in the interpretation of the data, critically revised the manuscript for important intellectual content, and contributed experience and knowledge from diabetes care and research in diabetes and health-related quality of life. SB made substantial contributions to the design of the work, made intellectual contributions in the interpretation of the data, and critically revised the manuscript for important intellectual content. BP made substantial contributions to the design of the work; performed the selection of the random sample; made intellectual contributions in the interpretation of the data; critically revised the manuscript for important intellectual content, and contributed statistical advice, experience, and knowledge in the research of generic health-related quality of life and patient-reported outcome. SF made substantial contributions to the design of the work, contributed substantial statistical advice, was the major contributor in analysing the data, made substantial intellectual contributions in the interpretation of the data, and critically revised the manuscript for important intellectual content. SG supervised and made substantial contributions to the design of the work; applied for ethical approval and funding; made intellectual contributions in interpretation of the data; critically revised the manuscript for important intellectual content, and contributed medical experience and knowledge from diabetes care, diabetes research, and research using health-care quality registers. KEO supervised and made substantial contributions to the design of the work; applied for ethical approval and funding; generated the SF-36v2 data; interpreted the data; critically revised the manuscript for important intellectual content, and contributed medical experience and knowledge from diabetes care, diabetes research, and research using health-care quality registers. All authors read and approved the final manuscript as well as consented to be on the author list.

Data sharing statement

The data that support the findings of this study are not publicly available. The study presented here has been subject to review by an ethical board and approved for publication related to the specific aim of our research project. With reference to the European General Data Protection Regulation, the data are personal and therefore confidential.

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Figure Legends

Fig. 1. Spearman's rank correlation between the Diabetes Questionnaire scales and the SF-36v2 domains in type 1 diabetes

Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment. SF-36v2 domains: PF: physical functioning; RP: role-physical; BP: bodily pain; GH: general health.

Fig. 2. Spearman's rank correlation between the Diabetes Questionnaire scales and the SF-36v2 domains in type 2 diabetes

Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment. SF-36v2 domains: PF: physical functioning; RP: role-physical; BP: bodily pain; GH: general health.

Fig. 3. Percent variance in the Diabetes Questionnaire scales explained by the SF-36v2 domains and clinical variables in type 1 (A) and type 2 diabetes (B)

GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.

Fig. 4. Adjusted least square mean estimates with 95% confidence intervals for the Diabetes Questionnaire scales in type 1 diabetes (A) and type 2 diabetes (B) separated by glycated haemoglobin (HbA_{1c}) level

Adjusted for age, sex, diabetes duration, body mass index, systolic blood pressure, LDL cholesterol level, micro- and macro-albuminuria, estimated glomerular filtration rate, retinopathy, smoking status, physical activity level, receipt of antihypertensive and lipid lowering treatments, previous coronary heart disease and previous stroke.

GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.

Supplementary material

Supplementary figures

Fig. S1. Spearman's rank correlation between the Diabetes Questionnaire scales and clinical variables in type 1 diabetes

Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.

Clinical variables: BMI: body mass index, SBP: systolic blood pressure, LDL: LDL cholesterol, HbA_{1c}: glycated haemoglobin level.

Fig. S2. Spearman's rank correlation between the Diabetes Questionnaire scales and clinical variables in type 2 diabetes

Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.
Clinical variables: BMI: body mass index, SBP: systolic blood pressure, LDL: LDL cholesterol, HbA_{1c}: glycated haemoglobin level.

Fig. S3. Variable importance of clinical variables and the SF-36v2 domains as predictors of the Diabetes Questionnaire scales GenW (General Wellbeing) and MoE (Mood and Energy) in type 1 (A and B) and type 2 diabetes (C and D)

Clinical variables: BMI: body mass index, SBP: systolic blood pressure, LDL: LDL cholesterol, HbA_{1c}: glycated haemoglobin level.
SF-36v2 domains: PF: physical functioning; RP: role-physical; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning; RE: role-emotional; MH: mental health.

Supplementary tables

Table S1. Crude means and standard deviations for the Diabetes Questionnaire scales and the SF-36v2 domains for participants with type 1 diabetes and those with type 2 diabetes

Table S2. Clinical and demographic characteristics for non-respondents separated for type 1 and type 2 diabetes

Table S3. Spearman's rank correlations with p-values between the Diabetes Questionnaire scale scores and clinical variables in type 1 diabetes

Table S4. Spearman's rank correlations with p-values between the Diabetes Questionnaire scale scores and clinical variables in type 2 diabetes

Table S5. Spearman's rank correlations with p-values between the Diabetes Questionnaire scales and the SF-36v2 domains in type 1 diabetes

Table S6. Spearman's rank correlations with p-values between the Diabetes Questionnaire scales and the SF-36v2 domains in type 2 diabetes

Table S7. Least square mean estimates and 95% confidence intervals for the Diabetes Questionnaire scales in three glycated haemoglobin (HbA_{1c}) groups for type 1 and type 2 diabetes

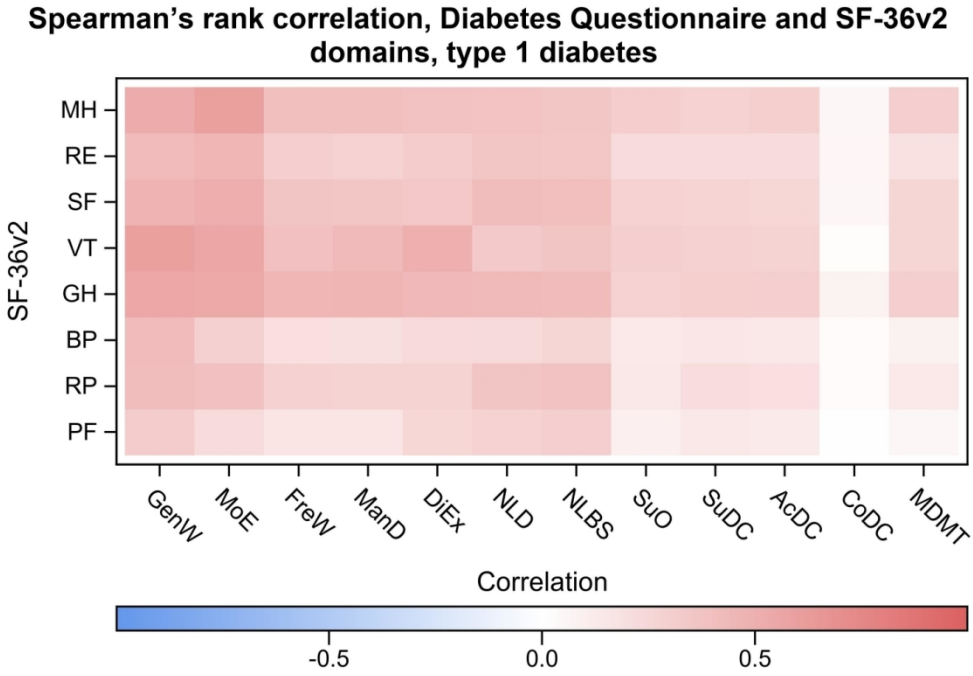

Fig. 1. Spearman's rank correlation between the Diabetes Questionnaire scales and the SF 36v2 domains in type 1 diabetes

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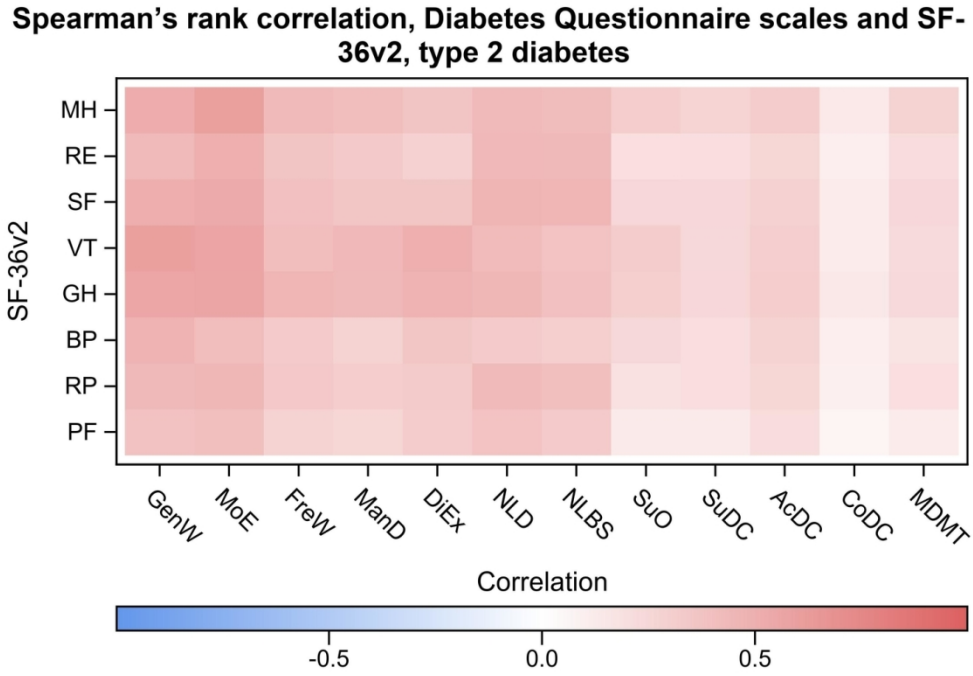

Fig. 2. Spearman's rank correlation between the Diabetes Questionnaire scales and the SF 36v2 domains in type 2 diabetes

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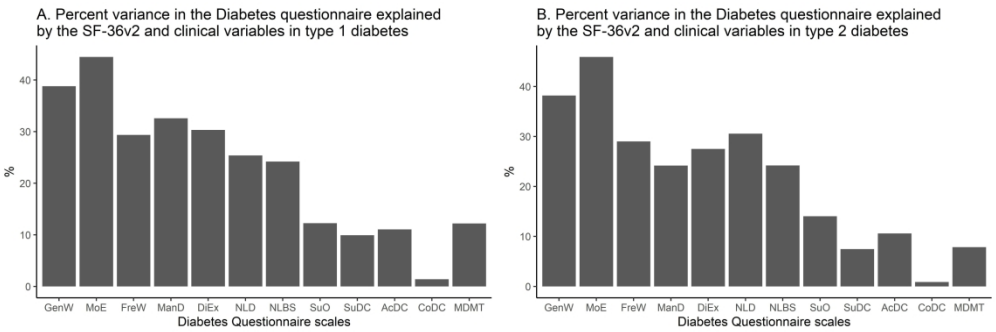


Fig. 3. Percent variance in the Diabetes Questionnaire scales explained by the SF 36v2 domains and clinical variables in type 1 (A) and type 2 diabetes (B)

304x101mm (300 x 300 DPI)

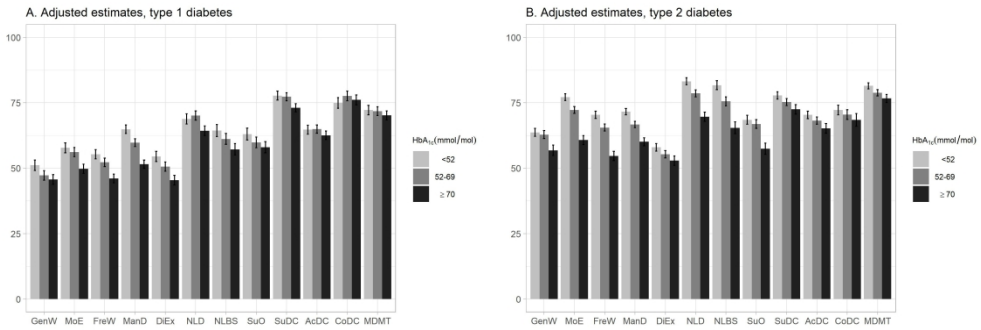


Fig. 4. Adjusted least square mean estimates with 95% confidence intervals for the Diabetes Questionnaire scales in type 1 diabetes (A) and type 2 diabetes (B) separated by glycated haemoglobin (HbA1c) level

349x119mm (300 x 300 DPI)

SUPPLEMENTARY MATERIAL

To the article titled

New diabetes questionnaire to add patients' perspectives to diabetes care for adults with type 1 and type 2 diabetes – Nationwide cross-sectional study of construct validity assessing associations with generic health-related quality of life and clinical variables

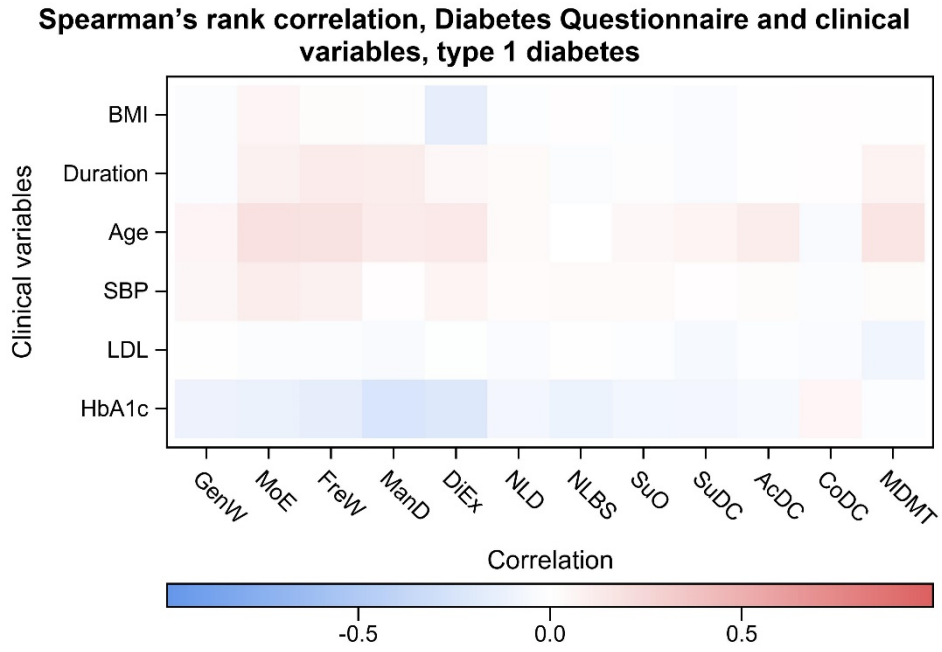
By

Maria Svedbo Engström; Janeth Leksell; Unn-Britt Johansson; Sixten Borg, Bo Palaszewski; Stefan Franzén; Soffia Gudbjörnsdottir; Katarina Eeg-Olofsson

Submitted to BMJ Open

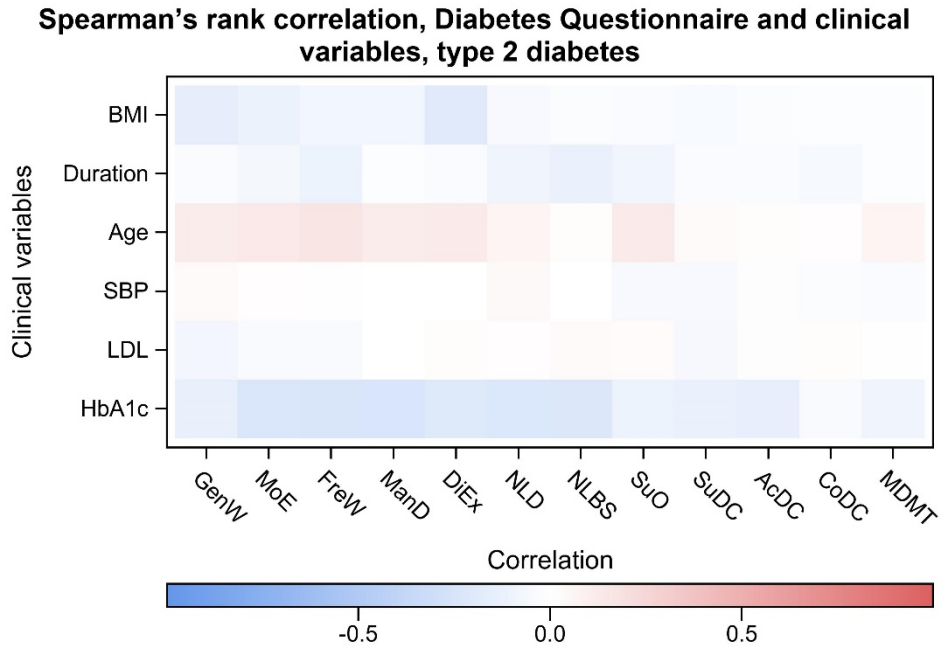
Supplementary figures

Fig. S1. Spearman's rank correlation between the Diabetes Questionnaire scales and clinical variables in type 1 diabetes



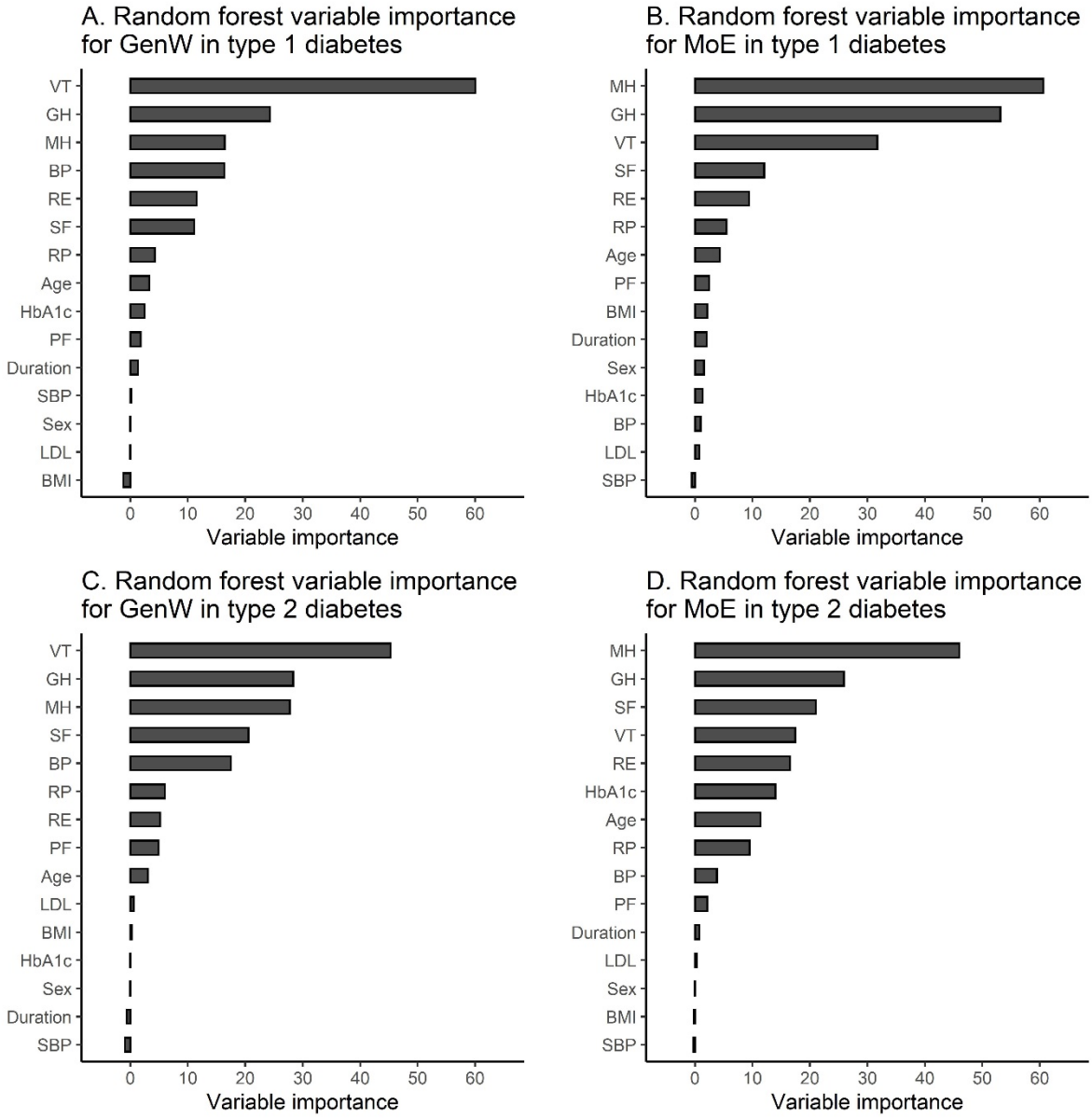
Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.
Clinical variables: BMI: body mass index, SBP: systolic blood pressure, LDL: LDL cholesterol, HbA_{1c}: glycated haemoglobin level.

Fig. S2. Spearman's rank correlation between the Diabetes Questionnaire scales and clinical variables in type 2 diabetes



Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.
Clinical variables: BMI: body mass index, SBP: systolic blood pressure, LDL: LDL cholesterol, HbA_{1c}: glycated haemoglobin level.

Fig. S3. Variable importance of clinical variables and the SF-36v2 domains as predictors of the Diabetes Questionnaire scales GenW (General Wellbeing) and MoE (Mood and Energy) in type 1 (A and B) and type 2 diabetes (C and D)



Clinical variables: BMI: body mass index, SBP: systolic blood pressure, LDL: LDL cholesterol, HbA_{1c}: glycated haemoglobin level.
SF-36v2 domains: PF: physical functioning; RP: role-physical; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning; RE: role-emotional; MH: mental health.

Supplementary tables

Table S1. Crude means and standard deviations for the Diabetes Questionnaire scales and the SF-36v2 domains for participants with type 1 diabetes and those with type 2 diabetes

Diabetes Questionnaire scale	Type 1 diabetes	Type 2 diabetes	p-value	Standardized mean difference, SMD
GenW	59.69 (23.81)	63.76 (24.71)	<0.001	0.168
MoE	64.07 (23.60)	75.19 (22.25)	<0.001	0.485
FreW	54.89 (21.91)	69.03 (22.29)	<0.001	0.640
ManD	63.20 (20.16)	70.48 (19.89)	<0.001	0.364
DiEx	56.66 (24.36)	58.88 (24.08)	0.018	0.092
NLD	75.33 (23.47)	84.14 (21.70)	<0.001	0.390
NLBS	69.97 (26.94)	80.94 (26.84)	<0.001	0.408
SuO	62.32 (23.46)	66.26 (23.71)	<0.001	0.167
SuDC	78.35 (20.29)	77.89 (22.61)	0.574	0.022
AcDC	67.80 (20.73)	71.31 (22.61)	<0.001	0.162
CoDC	80.04 (23.29)	71.42 (27.39)	<0.001	0.339
MDMT	75.40 (21.78)	80.47 (18.39)	<0.001	0.252

Diabetes questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.

Table S2. Clinical and demographic characteristics for non-responders separated for type 1 and type 2 diabetes

Variable	**Type 1 diabetes** (n=1106)	**Type 2 diabetes** (n=1116)
Men, %	60.7	58.1
Age, years (SD)	41.2 (15.5)	62.8 (10.9)
Diabetes duration, years (SD)	21.7 (14.0)	8.7 (7.0)
HbA_{1c}, mmol/mol (SD)	65.2 (15.1)	54.7 (14.3)
BMI, kg/m^2 (SD)	26.1 (4.6)	30.9 (5.9)
Systolic blood pressure, mmHg (SD)	126.1 (14.0)	134.7 (15.8)
Antihypertensive medication, %	34.6	77.5
LDL-cholesterol, mmol/L (SD)	2.53 (0.79)	2.64 (0.93)
Lipid-lowering medication, %	37.1	60.5
Micro-albuminuria, %	11.4	18.4
Macro-albuminuria, %	5.6	5.0
Retinopathy, %	66.2	30.5
Smoker, %	15.7	18.4
Physical activity, daily, %	20.3	27.1
Diabetes treatment		
Diet alone, %	-	20.1
Oral hypoglycaemic agent alone, %	-	52.5
Insulin alone, %	97.2	8.1
Insulin and oral agent, %	2.3	16.7
Insulin pump users, %	19.9	-

The descriptive statistics are presented as the means and standard deviations (SD) for continuous variables or number and percentages for categorical variables.

Table S3. Spearman's rank correlations with p-values between the Diabetes Questionnaire scale scores and clinical variables in type 1 diabetes

Clinical variable	GenW	MoE	FreW	ManD	DiEx	NLD	NLBS	SuO	SuDC	AcDC	CoDC	MDMT
Age	0.06 (0.0184)	0.19 (<.0001)	0.18 (<.0001)	0.13 (<.0001)	0.14 (<.0001)	0.03 (0.2050)	0.01 (0.8445)	0.05 (0.0875)	0.07 (0.0093)	0.11 (<.0001)	-0.04 (0.1635)	0.17 (<.0001)
Diabetes duration	-0.02 (0.4673)	0.09 (0.0006)	0.13 (<.0001)	0.11 (<.0001)	0.05 (0.0456)	0.04 (0.1981)	-0.02 (0.4678)	-0.01 (0.6936)	-0.03 (0.2024)	-0.00 (0.9883)	0.01 (0.6045)	0.08 (0.0027)
HbA_{1c}	-0.12 (<.0001)	-0.12 (<.0001)	-0.16 (<.0001)	-0.25 (<.0001)	-0.21 (<.0001)	-0.07 (0.0073)	-0.12 (<.0001)	-0.08 (0.0101)	-0.07 (0.0070)	-0.05 (0.0542)	0.06 (0.0356)	-0.02 (0.5485)
BMI	-0.02 (0.4601)	0.07 (0.0151)	0.03 (0.2763)	-0.01 (0.6738)	-0.15 (<.0001)	-0.01 (0.6239)	0.02 (0.5767)	-0.01 (0.6620)	-0.03 (0.2568)	-0.00 (0.9175)	0.02 (0.5998)	0.01 (0.7292)
SBP	0.06 (0.0231)	0.12 (<.0001)	0.09 (0.0005)	0.02 (0.5036)	0.07 (0.0072)	0.03 (0.3393)	0.03 (0.2152)	0.03 (0.3092)	0.01 (0.6002)	0.03 (0.2773)	-0.03 (0.3239)	0.03 (0.2610)
LDL	-0.00 (0.9452)	-0.02 (0.4805)	-0.02 (0.4380)	-0.04 (0.1549)	-0.01 (0.8077)	-0.03 (0.2406)	-0.00 (0.9780)	-0.02 (0.5905)	-0.06 (0.0474)	-0.02 (0.5275)	-0.03 (0.2873)	-0.09 (0.0023)

Diabetes questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.
Clinical variables: BMI: body mass index; SBP: systolic blood pressure; LDL: LDL cholesterol; HbA_{1c}: glycated haemoglobin level.

Table S4. Spearman's rank correlations with p-values between the Diabetes Questionnaire scale scores and clinical variables in type 2 diabetes

Clinical variable	GenW	MoE	FreW	ManD	DiEx	NLD	NLBS	SuO	SuDC	AcDC	CoDC	MDMT
Age	0.12 (<.0001)	0.14 (<.0001)	0.16 (<.0001)	0.12 (<.0001)	0.14 (<.0001)	0.07 (0.0061)	0.02 (0.3646)	0.13 (0.0002)	0.04 (0.1926)	0.02 (0.3657)	0.01 (0.6265)	0.07 (0.0089)
Diabetes duration	-0.03 (0.2226)	-0.07 (0.0202)	-0.11 (<.0001)	-0.02 (0.5662)	-0.04 (0.1868)	-0.10 (0.0007)	-0.13 (<.0001)	-0.09 (0.0184)	-0.04 (0.2043)	-0.03 (0.2353)	-0.06 (0.0570)	-0.01 (0.6150)
HbA_{1c}	-0.14 (<.0001)	-0.24 (<.0001)	-0.24 (<.0001)	-0.24 (<.0001)	-0.21 (<.0001)	-0.23 (<.0001)	-0.22 (<.0001)	-0.11 (0.0015)	-0.13 (<.0001)	-0.15 (<.0001)	-0.04 (0.1270)	-0.09 (0.0012)
BMI	-0.15 (<.0001)	-0.12 (<.0001)	-0.08 (0.0046)	-0.08 (0.0037)	-0.20 (<.0001)	-0.05 (0.0752)	-0.03 (0.3242)	-0.03 (0.4203)	-0.05 (0.0854)	-0.03 (0.3238)	-0.01 (0.6580)	-0.02 (0.5507)
SBP	0.03 (0.2195)	0.02 (0.5649)	0.01 (0.7496)	0.00 (0.9131)	0.00 (0.8954)	0.04 (0.1082)	0.01 (0.8433)	-0.05 (0.1746)	-0.05 (0.0781)	-0.01 (0.6444)	-0.02 (0.4327)	-0.03 (0.2736)
LDL	-0.07 (0.0151)	-0.04 (0.1773)	-0.04 (0.1310)	0.00 (0.9813)	0.02 (0.4793)	0.02 (0.5751)	0.04 (0.2250)	0.03 (0.4554)	-0.06 (0.0504)	-0.01 (0.7171)	0.02 (0.5061)	0.01 (0.8070)

Diabetes questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.
Clinical variables: BMI: body mass index; SBP: systolic blood pressure; LDL: LDL cholesterol; HbA_{1c}: glycated haemoglobin level.

Table S5. Spearman's rank correlations with p-values between the Diabetes Questionnaire scales and the SF-36v2 domains in type 1 diabetes

	SF-36v2 domain							
Diabetes Questionnaire scale	**PF**	**RP**	**BP**	**GH**	**VT**	**RF**	**SF**	**MH**
GenW	0.33 (<.0001)	0.43 (<.0001)	0.43 (<.0001)	0.56 (<.0001)	0.60 (<.0001)	0.43 (<.0001)	0.48 (<.0001)	0.53 (<.0001)
MoE	0.23 (<.0001)	0.40 (<.0001)	0.30 (<.0001)	0.55 (<.0001)	0.57 (<.0001)	0.46 (<.0001)	0.52 (<.0001)	0.60 (<.0001)
FreW	0.17 (<.0001)	0.29 (<.0001)	0.21 (<.0001)	0.46 (<.0001)	0.40 (<.0001)	0.31 (<.0001)	0.38 (<.0001)	0.41 (<.0001)
ManD	0.18 (<.0001)	0.28 (<.0001)	0.20 (<.0001)	0.47 (<.0001)	0.44 (<.0001)	0.29 (<.0001)	0.37 (<.0001)	0.41 (<.0001)
DiEx	0.26 (<.0001)	0.28 (<.0001)	0.23 (<.0001)	0.45 (<.0001)	0.51 (<.0001)	0.32 (<.0001)	0.35 (<.0001)	0.39 (<.0001)
NLD	0.29 (<.0001)	0.37 (<.0001)	0.24 (<.0001)	0.44 (<.0001)	0.34 (<.0001)	0.37 (<.0001)	0.42 (<.0001)	0.38 (<.0001)
NLBS	0.31 (<.0001)	0.39 (<.0001)	0.27 (<.0001)	0.43 (<.0001)	0.37 (<.0001)	0.35 (<.0001)	0.41 (<.0001)	0.36 (<.0001)
SuO	0.10 (0.0017)	0.15 (<.0001)	0.14 (<.0001)	0.29 (<.0001)	0.30 (<.0001)	0.23 (<.0001)	0.29 (<.0001)	0.32 (<.0001)
SuDC	0.15 (<.0001)	0.22 (<.0001)	0.16 (<.0001)	0.31 (<.0001)	0.29 (<.0001)	0.23 (<.0001)	0.27 (<.0001)	0.29 (<.0001)
AcDC	0.13 (<.0001)	0.20 (<.0001)	0.15 (<.0001)	0.30 (<.0001)	0.28 (<.0001)	0.23 (<.0001)	0.26 (<.0001)	0.31 (<.0001)
CoDC	0.01 (0.8176)	0.03 (0.3182)	0.03 (0.3309)	0.08 (0.0027)	0.02 (0.3822)	0.06 (0.0375)	0.06 (0.0297)	0.06 (0.0335)
MDMT	0.06 (0.0240)	0.14 (<.0001)	0.09 (0.0006)	0.30 (<.0001)	0.27 (<.0001)	0.19 (<.0001)	0.26 (<.0001)	0.30 (<.0001)

Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.
SF-36v2 domains: PF: physical functioning; RP: role-physical; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning; RE: role-emotional; MH: mental health.

Table S6. Spearman's rank correlations with p-values between the Diabetes Questionnaire scales and the SF-36v2 domains in type 2 diabetes

	SF-36v2 domain							
Diabetes Questionnaire scale	**PF**	**RP**	**BP**	**GH**	**VT**	**RF**	**SF**	**MH**
GenW	0.39 (<.0001)	0.44 (<.0001)	0.48 (<.0001)	0.56 (<.0001)	0.60 (<.0001)	0.44 (<.0001)	0.51 (<.0001)	0.53 (<.0001)
MoE	0.41 (<.0001)	0.45 (<.0001)	0.42 (<.0001)	0.57 (<.0001)	0.58 (<.0001)	0.51 (<.0001)	0.54 (<.0001)	0.60 (<.0001)
FreW	0.28 (<.0001)	0.35 (<.0001)	0.34 (<.0001)	0.47 (<.0001)	0.42 (<.0001)	0.38 (<.0001)	0.40 (<.0001)	0.43 (<.0001)
ManD	0.26 (<.0001)	0.32 (<.0001)	0.28 (<.0001)	0.44 (<.0001)	0.45 (<.0001)	0.34 (<.0001)	0.37 (<.0001)	0.42 (<.0001)
DiEx	0.32 (<.0001)	0.33 (<.0001)	0.36 (<.0001)	0.48 (<.0001)	0.51 (<.0001)	0.30 (<.0001)	0.36 (<.0001)	0.38 (<.0001)
NLD	0.38 (<.0001)	0.44 (<.0001)	0.34 (<.0001)	0.46 (<.0001)	0.43 (<.0001)	0.45 (<.0001)	0.47 (<.0001)	0.43 (<.0001)
NLBS	0.34 (<.0001)	0.40 (<.0001)	0.31 (<.0001)	0.40 (<.0001)	0.38 (<.0001)	0.44 (<.0001)	0.46 (<.0001)	0.42 (<.0001)
SuO	0.14 (0.0001)	0.19 (<.0001)	0.25 (<.0001)	0.31 (<.0001)	0.32 (<.0001)	0.20 (<.0001)	0.26 (<.0001)	0.32 (<.0001)
SuDC	0.14 (<.0001)	0.21 (<.0001)	0.21 (<.0001)	0.26 (<.0001)	0.25 (<.0001)	0.21 (<.0001)	0.26 (<.0001)	0.28 (<.0001)
AcDC	0.22 (<.0001)	0.26 (<.0001)	0.28 (<.0001)	0.32 (<.0001)	0.31 (<.0001)	0.26 (<.0001)	0.29 (<.0001)	0.32 (<.0001)
CoDC	0.07 (0.0130)	0.10 (0.0006)	0.11 (0.0001)	0.16 (<.0001)	0.13 (<.0001)	0.11 (0.0002)	0.13 (<.0001)	0.14 (<.0001)
MDMT	0.13 (<.0001)	0.20 (<.0001)	0.18 (<.0001)	0.24 (<.0001)	0.24 (<.0001)	0.22 (<.0001)	0.26 (<.0001)	0.28 (<.0001)

Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.
SF-36v2 domains: PF: physical functioning; RP: role-physical; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning; RE: role-emotional; MH: mental health.

Table S7. Least square mean estimates and 95% confidence intervals for the Diabetes Questionnaire scales in three glycated haemoglobin (HbA_{1c}) groups for type 1 and type 2 diabetes

Diabetes Questionnaire scale	Type 1 diabetes						Type 2 diabetes					
	Unadjusted analysis			Adjusted analysis			Unadjusted analysis			Adjusted analysis		
	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol
GenW	64.33 (63.46-65.20)	59.27 (58.74-59.79)	56.34 (55.49-57.19)	51.11 (49.14-53.07)	47.23 (45.44-49.01)	45.66 (43.80-47.53)	65.97 (65.41-66.54)	62.92 (62.24-63.60)	54.26 (52.90-55.62)	63.63 (62.10-65.15)	62.81 (61.29-64.32)	56.81 (54.85-58.78)
MoE	67.15 (66.29-68.01)	65.14 (64.62-65.66)	58.32 (57.48-59.16)	57.77 (55.87-59.66)	56.14 (54.41-57.86)	49.75 (47.96-51.54)	79.24 (78.74-79.74)	72.75 (72.15-73.35)	61.02 (59.80-62.25)	77.12 (75.78-78.46)	72.23 (70.91-73.56)	60.73 (58.99-62.46)
FreW	58.21 (57.41-59.01)	56.09 (55.61-56.58)	48.72 (47.96-49.49)	55.28 (53.51-57.05)	52.22 (50.61-53.82)	46.09 (44.42-47.75)	73.07 (72.57-73.57)	66.72 (66.12-67.32)	54.82 (53.62-56.03)	70.39 (69.03-71.75)	65.51 (64.16-66.86)	54.66 (52.90-56.42)
ManD	70.05 (69.33-70.78)	63.88 (63.45-64.32)	55.09 (54.40-55.79)	64.84 (63.20-66.47)	59.71 (58.23-61.19)	51.49 (49.95-53.03)	74.12 (73.67-74.56)	67.74 (67.20-68.28)	60.35 (59.26-61.43)	71.53 (70.33-72.74)	66.65 (65.46-67.85)	60.07 (58.51-61.63)
DiEx	63.95 (63.07-64.84)	56.52 (55.98-57.06)	50.18 (49.32-51.04)	54.44 (52.50-56.37)	50.59 (48.83-52.35)	45.40 (43.57-47.23)	62.48 (61.92-63.03)	55.86 (55.20-56.52)	50.13 (48.80-51.47)	57.97 (56.54-59.40)	55.31 (53.91-56.72)	52.85 (51.02-54.68)
NLD	76.79 (75.93-77.66)	76.59 (76.07-77.11)	70.75 (69.92-71.58)	68.78 (66.84-70.71)	70.09 (68.33-71.85)	64.26 (62.44-66.09)	87.94 (87.46-88.43)	81.82 (81.23-82.40)	71.54 (70.37-72.71)	83.17 (81.79-84.55)	78.57 (77.21-79.94)	69.61 (67.83-71.38)
NLBS	74.54 (73.54-75.54)	70.33 (69.73-70.93)	64.60 (63.63-65.58)	64.39 (62.08-66.69)	61.14 (59.05-63.23)	57.16 (54.98-59.33)	85.59 (84.98-86.20)	77.91 (77.18-78.64)	65.85 (64.37-67.33)	81.69 (79.96-83.43)	75.53 (73.81-77.25)	65.42 (63.19-67.65)
SuO	66.33 (65.31-67.35)	61.93 (61.32-62.54)	59.61 (58.63-60.59)	63.01 (60.74-65.28)	59.84 (57.79-61.88)	58.00 (55.86-60.14)	68.56 (67.83-69.29)	65.70 (64.89-66.51)	57.12 (55.49-58.74)	68.47 (66.77-70.16)	66.84 (65.20-68.48)	57.40 (55.25-59.56)
SuDC	79.87 (79.13-80.61)	79.34 (78.89-79.79)	74.41 (73.70-75.13)	77.71 (76.01-79.41)	77.27 (75.73-78.81)	73.04 (71.44-74.64)	80.06 (79.54-80.58)	76.49 (75.87-77.11)	70.89 (69.64-72.14)	77.76 (76.38-79.14)	75.23 (73.86-76.59)	72.46 (70.69-74.24)
AcDC	69.08 (68.32-69.84)	68.52 (68.06-68.98)	64.78 (64.05-65.51)	64.69 (62.96-66.42)	64.90 (63.33-66.47)	62.54 (60.91-64.17)	73.64 (73.12-74.16)	69.68 (69.06-70.30)	64.39 (63.14-65.64)	70.33 (68.92-71.75)	68.12 (66.72-69.52)	65.20 (63.37-67.02)

Diabetes Questionnaire scale	Type 1 diabetes						Type 2 diabetes					
	Unadjusted analysis			Adjusted analysis			Unadjusted analysis			Adjusted analysis		
	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol
CoDC	78.03 (77.13-78.92)	80.76 (80.22-81.29)	80.05 (79.20-80.90)	74.89 (72.88-76.90)	77.58 (75.75-79.41)	76.08 (74.18-77.97)	72.45 (71.77-73.12)	70.90 (70.11-71.70)	67.72 (66.11-69.33)	72.22 (70.34-74.09)	70.45 (68.59-72.31)	68.43 (66.01-70.84)
MDMT	77.14 (76.34-77.94)	75.78 (75.30-76.26)	72.81 (72.04-73.58)	72.21 (70.41-74.01)	71.74 (70.11-73.38)	70.14 (68.45-71.84)	82.46 (82.02-82.90)	78.80 (78.29-79.31)	76.45 (75.41-77.48)	81.42 (80.23-82.62)	78.79 (77.62-79.96)	76.64 (75.11-78.17)

Table S7 continued. GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

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		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1

Abstract	#1b	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	5
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	5
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-8
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment	5-7

		(measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	
Bias	#9	Describe any efforts to address potential sources of bias	5,8,16
Study size	#10	Explain how the study size was arrived at	5
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	5-8
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	7-8
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	7-8
Statistical methods	#12c	Explain how missing data were addressed	8
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	5
Statistical methods	#12e	Describe any sensitivity analyses	n/a

Results

Participants	#13a	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. Give information separately for for exposed and unexposed groups if applicable.		5
Participants	#13b	Give reasons for non-participation at each stage	n/a With reference to ethical guidelines we did not ask potential participants to give their reasons for non-participation.	
Participants	#13c	Consider use of a flow diagram		n/a
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.		9-11
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest		8
Outcome data	#15	Report numbers of outcome events or summary measures. Give information		9

		separately for exposed and unexposed groups if applicable.	
Main results	#16a	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	7-8,13-14
Main results	#16b	Report category boundaries when continuous variables were categorized	7,10-11,13-14
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	9,12-13
Discussion			
Key results	#18	Summarise key results with reference to study objectives	14
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.	16

Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	15-17
Generalisability	#21	Discuss the generalisability (external validity) of the study results	16
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	18-19

Notes:

- 13b: n/a With reference to ethical guidelines we did not ask potential participants to give their reasons for non-participation.
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BMJ Open

New diabetes questionnaire to add patients' perspectives to diabetes care for adults with type 1 and type 2 diabetes – Nationwide cross-sectional study of construct validity assessing associations with generic health-related quality of life and clinical variables

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Title:

New diabetes questionnaire to add patients' perspectives to diabetes care for adults with type 1 and type 2 diabetes – Nationwide cross-sectional study of construct validity assessing associations with generic health-related quality of life and clinical variables

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Abstract

Objectives: To study evidence for construct validity, the aim was to describe the outcome from the recently developed Diabetes Questionnaire, assess the associations of that outcome with clinical variables and generic health-related quality of life, and study the sensitivity to differences between clinically relevant groups of glycaemic control in adults with type 1 and type 2 diabetes in a nationwide setting.

Design: Cross-sectional survey.

Setting: Swedish diabetes care clinics connected to the National Diabetes Register (NDR).

Participants: Among 2,479 adults with type 1 diabetes and 2,469 with type 2 diabetes selected at random from the NDR, 1373 (55.4%) with type 1 and 1353 (54.8%) with type 2 diabetes chose to participate.

Outcome measures: The Diabetes Questionnaire, the generic 36-item Short Form version 2 (SF-36v2) health survey and clinical variables.

Results: Related to the pre-specified assumptions, supporting evidence for construct validity for the Diabetes Questionnaire was found. Supporting divergent validity, the statistically significant correlations with the clinical variables were few and weak. In relation to the SF-36v2 and in support of convergent validity, the strongest correlations were seen in the Diabetes Questionnaire scales General Well-being and Mood and Energy. In those scales, machine learning analyses showed that about 40-45% of the variance was explained by the SF-36v2 results and clinical variables. In multiple regression analyses among three groups with differing levels of HbA_{1c} adjusted for demographics, other risk factors, and diabetes complications, the high-risk group had, in support of sensitivity to clinically relevant groups, statistically significant lower scores than the well-controlled group in most Diabetes Questionnaire scales.

Conclusions: This nation-wide study shows that the Diabetes Questionnaire captures some generic health-related quality-of-life dimensions, in addition to adding diabetes-specific information not covered by the SF-36v2 and clinical variables. The Diabetes Questionnaire is also sensitive to differences between clinically relevant groups of glycaemic control.

Keywords: Diabetes Mellitus, Type 1; Diabetes Mellitus, Type 2; Patient-reported outcome; Cross-Sectional Study; Construct validity

Article Summary

Strengths and limitations of this study

- The cross-sectional study used a large, heterogeneous nationwide sample of adults with type 1 diabetes and adults with type 2 diabetes selected at random.
- Respondents were representative of the 2015 population in the Swedish National Diabetes Register.
- The Diabetes Questionnaire scales scores were related to relevant clinical variables and a well-known and often recommended measure of generic health-related quality of life.
- The analyses were limited to the respondents and might reflect a group with greater motivation for participation.
- The questionnaires were only offered in Swedish.

Main text:

INTRODUCTION

Everyday life with diabetes as an adult is a complex challenge. Diabetes makes individuals responsible for self-management to avoid serious short-term and long-term complications, while balancing self-perceived health and well-being in the present as well as in the future.[1-6] To support skills for self-management is a central task of diabetes care, and the individual patient's prerequisites, wishes, and available evidence must be taken into account.[1, 4-6] An important step for the Swedish National Diabetes Register (NDR) has therefore been to broaden health-care provider perspectives and enable a systematic collection of adults' perspectives of living with diabetes and their experiences of whether they are offered adequate support from diabetes care.[7-10] The newly developed Diabetes Questionnaire is intended to support meetings with individuals and provide a means for quality improvement at the local, regional, and national levels.[7-9]

The Diabetes Questionnaire was developed from interviews with adults with type 1 or type 2 diabetes that identified a broad range of aspects important to the target group, such as well-being, impact on daily life, capabilities to manage diabetes, and support from diabetes care.[9] In line with Sen's capability approach,[11, 12] the Diabetes Questionnaire focuses on the individual's opportunities, prerequisites, and possible barriers to live a good life with diabetes.[7-9] Supporting evidence for content validity, face validity, and ease of items understandability and answerability has been presented.[8, 9] In addition, supporting evidence for test-retest reliability and that the scales can be used for comparison between men and women, between different age groups, and, for most scales, between type 1 and type 2 diabetes have been provided.[7, 8] Furthermore, the scales can detect differences between clinically relevant subgroups, such as diabetes type, diabetes treatment, age group, and gender.[7] We have also begun to study the associations with clinical variables by showing low individual-level correlations with glycated haemoglobin (HbA_{1c}), systolic blood pressure (SBP), and LDL cholesterol.[7]

This study adds to previous work and reports on an extended analysis of the evidence for construct validity. Construct validity concerns the confidence that a questionnaire captures the construct it was intended to measure[13]. It is a measurement property that involves a complex process using a variety of techniques studying differences between relevant groups and pre-specified assumptions of logical relationships to scores of a range of other measures

and patient characteristics[13, 14]. The assumptions can postulate which aspects are expected to be related to each other, presenting evidence for convergent validity, and which aspects are expected to be relatively unrelated, supporting evidence for divergent, also known as discriminant, validity[13] For this work, we chose to focus on differences between subgroups of glycaemic control as measured by HbA_{1c} and the relations to clinical variables relevant for diabetes care and an often-recommended generic measure of health-related quality of life, the 36-item Short Form (SF-36v2) health survey. To study evidence for construct validity, the aim was to describe the outcome from the Diabetes Questionnaire, to assess the associations of that outcome with clinical variables and generic health-related quality of life, and to study the sensitivity to differences between clinically relevant groups of glycaemic control in adults with type 1 and type 2 diabetes in a nationwide setting.

METHODS

Sample and data-collection

In this cross-sectional survey, 2,479 adults with type 1 diabetes and 2,469 with type 2 diabetes were selected at random without replacement from the Swedish NDR. Eligibility criteria were being alive, 18-80 years of age, and recorded in the NDR during the period from September 30th 2014 to October 1st 2015 with at least one recorded test of HbA_{1c} level during the previous 12 months. With these criteria, 29,245 adults with type 1 diabetes at hospital out-patient clinics and 208,852 adults with type 2 diabetes at primary health care centres were eligible for recruitment. In the data collection phase, we aimed at a sample size allowing for subgroup analyses.

The Diabetes Questionnaire, the SF-36v2 survey, and a prepaid return envelope were sent by mail in October 2015 to survey selectees and again to non-respondents after 30 days.[7, 15] Both questionnaires were answered by 1,373 (55.4%) individuals with type 1 diabetes and 1,353 (54.8%) with type 2 diabetes[15]. With small differences in response rate depending on the questionnaires in question, the sample has been described as previously focusing on the scale development of the Diabetes Questionnaire[7] and separate analyses of the SF-36v2 data[15]. Age, sex, and clinical variables (diabetes type defined by clinical diagnosis, diabetes duration, HbA_{1c} level, cardiovascular risk factors, complications, physical activity level, and receipt of medical treatment) recorded because of their relevance to high-quality diabetes care were collected from the NDR.

Diabetes Questionnaire

The Diabetes Questionnaire is a 33-item self-reporting questionnaire having a total of 12 scales divided into 2 main parts.[7, 8] Part 1 has 22 items on 8 scales and acts as a patient-reported outcome measure (PROM). These scales are General Wellbeing (GenW), Mood and Energy (MoE), Free of Worries about blood sugar (FreW), Capabilities to Manage your Diabetes (ManD), Diet and Exercise (DiEx), Not Limited by Diabetes (NLD), Not Limited by Blood Sugar (NLBS), and Support from Others (SuO). Part 2 is an 11-item patient-reported experience measure (PREM) with 4 scales. Those scales are Support from Diabetes Care (SuDC), Access to Diabetes Care (AcDC), Continuity in Diabetes Care (CoDC), and Medical Devices and Medical Treatment (MDMT). All scales are scored from 0 to 100, with higher scores representing the more desirable outcome. The scales ManD, NLBS, and MDMT are specific to diabetes type.[7]

SF-36v2 survey

The SF-36v2 survey is a self-reporting questionnaire for generic health-related quality of life with support for its validity and reliability in overall populations, such as people with diabetes.[3, 16-20] We used the self-administered standard form in Swedish and software from QualityMetric Inc. The eight domains produced are physical functioning (PF); role-physical (RP), that is role limitations due to physical health problems; bodily pain (BP); general health (GH); vitality (VT); social functioning (SF); role-emotional (RE), that is role limitations due to mental health problems; and mental health (MH). The domains are scored from 0 to 100. Higher scores indicate a better general health-related quality of life.[16, 17]

Pre-specified assumptions

As the Diabetes Questionnaire is intended to measure patient perspectives on how they feel, how their diabetes treatment is going, and their experiences of support from diabetes care, the pre-specified assumptions for correlations with clinical variables and the SF-36v2 were as follows:

- Based on clinical experience, it was proposed that, in support of divergent validity, a small number of negative and weak correlations would be found between the Diabetes Questionnaire scales and the clinical variables, mostly related to the HbA_{1c} level. There would be no correlations with SBP and LDL cholesterol.
- Based on examinations of the content in the two questionnaires, it was proposed that in support of convergent validity, the Diabetes Questionnaire PROM scales GenW,

MoE, FreW, ManD, DiEx, NLD, and NLBS would have more and stronger correlations to the SF-36v2 domains, as compared to the PROM scale SuO and the PREM scales (SuDC, AcDC, CoDC, and MDMT). Observed correlations would be positive, with the strongest in GenW and MoE. In support of divergent validity strong correlations were not expected across the other scales. Correlations ≥0.60 were considered as very strong, 0.50 to <0.60 as strong, 0.40 to <0.50 as moderate, and <0.40 as weak.

Statistical Analysis

The data for participants with type 1 and type 2 diabetes were analysed separately. The descriptive statistics for each variable are based on non-missing observations. The continuous variables are given as means and standard deviations for normal distributions and as medians and interquartile ranges for skewed distributions. The categorical variables are presented as numbers and percentages. The generation of scale scores from the Diabetes Questionnaire is described in detail elsewhere.[7] The SF-36v2 domain scores were generated using the manual and licensed software from QualityMetric.[17]

In relation to the pre-specified assumptions, Spearman's rank correlation was used to study the monoton associations between the Diabetes Questionnaire scale scores and the clinical variables age, diabetes duration, HbA_{1c} level, body mass index (BMI), LDL cholesterol, and SBP, as well as between the scores from the Diabetes Questionnaire scales and the SF-36v2 domains. To broaden the analysis, machine learning using random forests was conducted to investigate non-linear associations between the Diabetes Questionnaire scales and the SF-36v2 domains together with clinical variables (age, sex, diabetes duration, HbA_{1c} level, BMI, LDL cholesterol, and SBP). Random forest is a general tree-based regression and classification method that uses bootstrapping to create a large number of regressions of classification trees that are combined to produce a model prediction.[21] The use of a large number of trees allows the model to depict non-linear associations without the need to prespecify these in a model, while at the same time guarding against overfit.[21] First, the variance in all Diabetes Questionnaire scales was examined in relation to the SF-36v2 domains and the clinical variables together. Next, the variable importance of the SF-36v2 domains and the clinical variables as predictors of the PROM scales GenW and MoE were examined. We also examined the percent variance in HbA_{1c} explained by another clinical

variable, the Diabetes Questionnaire scales, and the SF-36v2 domains together. The results are given as percent of the total variance. Each model contained 1000 trees.

To study the sensitivity of the Diabetes Questionnaire scales to clinically relevant groups of glycaemic control, group-level associations between the Diabetes Questionnaire scales and glycaemic control as measured by HbA_{1c}, unadjusted and adjusted multiple regression analyses were conducted in the same manner as previously described for the SF-36v2 data.[15] HbA_{1c} was considered as a categorical variable divided into three clinically relevant groups corresponding to differing levels of glycaemic control and consequently differing levels of the risk of diabetes complications according to international and Swedish treatment guidelines.[4, 22] The three groups were well-controlled (<52 mmol/mol), sub-optimal (52-69 mmol/mol), and high-risk (≥70 mmol/mol). For the three HbA_{1c} groups, the least square mean estimates and 95% confidence intervals were calculated for each scale. The scale observations were modelled with a linear model with fixed effects for the HbA_{1c} group (exposure), age, sex, diabetes duration, BMI, SBP, LDL-cholesterol, micro- and macro-albuminuria, estimated glomerular filtration rate, retinopathy, smoking status, physical activity level, previous coronary heart disease, previous stroke, and receipt of antihypertensive and lipid lowering treatments. Missing data were imputed 10 times, using multiple chained equations. The analyses were performed separately for each imputed data set, and the results were subsequently combined using Rubin's rules. The results are presented as least square mean estimates with 95% confidence intervals.

The extent of missing data was 0% for age and sex, 7.2% for clinical variables (range 0-36.5%), 1.7% for the SF-36v2 domains (range 0-3.3% for individual dimensions), and 4.8% for the Diabetes Questionnaire scales (range 0.3-34.7% for individual scales). For the Diabetes Questionnaire, the higher extent of missing data is likely related to having "not applicable" as a response alternative in some scales, which at this stage was treated as missing data. For scales without "not applicable" as a response alternative, the range for missing data was 0.3-2.8%.

The standardized mean difference was used to examine the data balance between the HbA_{1c} groups and the deviation from the means in the clinical and demographic data. A significance level of 5% was used throughout; no allowance was made for multiplicity of statistical tests. The analyses were conducted using SAS 9.4 and R 3.4.4.

Patient and public involvement statement

The Diabetes Questionnaire was based on qualitative interviews with adults living with diabetes.[8, 9] Adults with diabetes and representatives from patient organizations participated in expert reviews during the development and initial testing.[8] Adults with diabetes were involved in the pre-testing phase by participating in cognitive interviews and being consulted to comment on questionnaire revisions.[8] The analyses presented here as the previous scale development and evaluation of reliability and validity relied on the contributions from those adults with diabetes who responded to the questionnaires.[7, 8] The Swedish Diabetes Foundation, the national patient organization, has expressed their support for the project.

Ethical considerations

The study conforms to the Declaration of Helsinki and was approved by the Regional Ethical Review Board in Gothenburg, Sweden (No. 029-15, T600-15). Participants gave their informed consent. The letter to the participants contained information about the study's purpose, the voluntary nature of their participation, and their right to end participation. The letter also disclosed information about the NDR, methods of handling personal data, confidentiality measures, and contact details.

RESULTS

Among respondents with type 1 diabetes, 50.3% were men. The averages of key statistics were 48.6 years for age, 24.7 years for diabetes duration, and 62 mmol/mol for HbA_{1c} level. Among respondents with type 2 diabetes, 60.8% were men. Corresponding averages were 66.6 years for age, 9.4 years for diabetes duration, and 53 mmol/mol for HbA_{1c} level (Table 1). The crude means and standard deviations for the Diabetes Questionnaire scales are given in Table S1. The clinical characteristics of non-respondents are given in Table S2.

Table 1. Clinical and demographic characteristics of the respondents separated by diabetes type and glycated haemoglobin (HbA_{1c}) level

Variable	Type 1 diabetes					Type 2 diabetes				
	All	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	Standardized mean difference, SMD	All	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	Standardized mean difference, SMD
Number (%)	1373	284 (20.7%)	781 (56.9%)	308 (22.4%)		1353	725 (53.6%)	503 (37.2%)	125 (9.2%)	
Men, n (%)	690 (50.3)	152 (53.5)	391 (50.1)	147 (47.7)	0.077	822 (60.8)	444 (61.2)	302 (60.0)	76 (60.8)	0.016
Age, years (SD)	48.6 (16.4)	46.9 (17.0)	49.6 (16.1)	47.8 (16.3)	0.113	66.6 (9.1)	66.5 (9.1)	66.9 (9.0)	65.5 (9.7)	0.103
Diabetes duration, years (IQR)	22.0 (12.0-36.0)	19.0 (7.0-32.0)	23.0 (13.0-37.0)	24.0 (13.0-37.0)	0.150	8.0 (4.0-14.0)	6.0 (3.0-11.0)	10.0 (6.0-16.0)	13.0 (6.0-17.0)	0.443
HbA_{1c} mmol/mol (SD)	62 (12.7)					53 (12.5)				
BMI, kg/m^2 (SD)	26.0 (4.2)	25.2 (3.8)	26.0 (4.2)	26.7 (4.6)	0.239	29.9 (5.3)	29.3 (5.2)	30.3 (5.4)	32.0 (5.5)	0.332
Systolic blood pressure, mmHg (SD)	127.0 (14.0)	124.8 (14.0)	127.5 (13.8)	127.8 (14.2)	0.145	134.3 (14.3)	134.0 (14.4)	134.5 (13.7)	135.1 (16.5)	0.046
Antihypertensive medication, n (%)	589 (44.7)	99 (36.9)	341 (45.3)	149 (50.2)	0.179	1070 (80.1)	572 (79.6)	404 (81.9)	94 (76.4)	0.091
LDL-cholesterol, mmol/L (SD)	2.4 (0.8)	2.5 (0.8)	2.4 (0.8)	2.5 (0.8)	0.077	2.5 (0.9)	2.5 (0.9)	2.4 (0.9)	2.5 (1.0)	0.026
Lipid-lowering medication, n (%)	642 (48.4)	94 (34.6)	378 (49.8)	170 (57.6)	0.315	900 (68.1)	472 (66.6)	344 (70.1)	84 (69.4)	0.050
Micro-albuminuria, n (%)	132 (10.3)	12 (4.6)	70 (9.5)	50 (17.6)	0.285	194 (18.0)	80 (13.9)	83 (20.1)	31 (34.1)	0.323
Macro-albuminuria, n (%)	31 (2.6)	5 (2.1)	12 (1.8)	14 (5.2)	0.126	52 (5.0)	27 (4.8)	20 (5.1)	5 (6.1)	0.037
Estimated Glomerular Filtration Rate,	90.0 (23.5)	90.6 (20.7)	89.1 (22.6)	91.6 (27.7)	0.071	82.3 (23.5)	82.5 (22.3)	81.9 (24.0)	83.4 (27.9)	0.038

Variable	Type 1 diabetes					Type 2 diabetes				
	All	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	Standardized mean difference, SMD	All	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	Standardized mean difference, SMD
eGFR, mL/min (SD)										
Retinopathy, n (%)	875 (65.9)	137 (50.6)	520 (68.2)	218 (74.1)	0.333	327 (29.4)	128 (21.7)	153 (36.3)	46 (47.0)	0.366
Coronary heart disease, n (%)	83 (6.3)	9 (3.3)	53 (7.0)	21 (7.1)	0.113	279 (22.4)	136 (20.2)	111 (24.0)	32 (28.6)	0.130
Stroke, n (%)	48 (3.6)	5 (1.9)	32 (4.2)	11 (3.7)	0.093	96 (7.8)	48 (7.2)	40 (8.9)	8 (7.1)	0.043
Smoker, n (%)	135 (10.1)	14 (5.1)	78 (10.2)	43 (14.4)	0.214	162 (12.9)	79 (11.7)	58 (12.3)	25 (23.1)	0.203
Physical activity, daily, n (%)	359 (27.6)	90 (33.5)	203 (27.2)	66 (23.2)	0.334	426 (34.9)	251 (38.7)	157 (33.9)	18 (16.7)	0.410
Diabetes treatment					0.136					0.813
Diet alone, n (%)						195 (14.4)	172 (23.7)	19 (3.8)	4 (3.3)	
Oral hypoglycaemic agent alone, n (%)						718 (53.1)	419 (57.8)	261 (52.0)	38 (30.9)	
Insulin alone, n (%)	1335 (97.2)	271 (95.4)	764 (97.8)	300 (97.4)		130 (9.6)	46 (6.3)	63 (12.5)	21 (17.1)	
Insulin and oral agent, n (%)	32 (2.3)	9 (3.2)	15 (1.9)	8 (2.6)		266 (19.7)	76 (10.5)	140 (27.9)	50 (40.7)	
Insulin pump users, n (%)	356 (26.2)	66 (23.8)	221 (28.5)	69 (22.5)	0.091	2 (0.5)	1 (0.9)	1 (0.5)	0 (0.0)	0.093

The descriptive statistics are presented as the means and standard deviations (SD) for normally distributed continuous variables, the median and interquartile range (IQR) for skewed distributions, or number and percentages for categorical variables.

Monoton correlations related to the proposed assumptions between the Diabetes Questionnaire scale scores and the clinical variables

In line with the assumptions and in support for divergent validity, there were few statistically significant monoton correlations between the Diabetes Questionnaire scales and the clinical variables. Observed correlations were weak, and most were negative. The results are shown as heat maps in Figs. S1-S2 with details provided in Tables S3-S4.

As assumed, the HbA_{1c} level was the variable with most statistically significant correlations across the Diabetes Questionnaire scales. Statistically significant but weak correlations between having a lower and better HbA_{1c} level and higher and better scores were seen in several Diabetes Questionnaire scales. For participants with type 1 diabetes, significant weak negative correlations (-0.12 to -0.25) were seen in the five Diabetes Questionnaire PROM scales GenW, FreW, ManD, DiEx, and NLBS. The strongest correlations were seen in ManD and DiEx. Among participants with type 2 diabetes, statistically significant but weak negative correlations (-0.13 to -0.24) were seen in the seven Diabetes Questionnaire PROM scales GenW, MoE, FreW, ManD, DiEx, NLD, and NLBS and in the two PREM scales SuDC and AcDC. The strongest correlations were seen in MoE, FreW, and ManD, with generally stronger correlations in the PROM scales than in the PREM scales (Figs. S1-S2, Tables S3-S4).

For age, statistically significant positive correlations showed that a higher age was weakly associated with higher and better scores in several Diabetes Questionnaire scales. For participants with type 1 diabetes, statistically significant weak positive correlations (0.11 to 0.19) were seen in the four PROM scales MoE, FreW, ManD, and DiEx, and in the two PREM scales AcDC and MDMT. The highest correlations were seen in MoE, FreW, and MDMT. Among participants with type 2 diabetes, statistically significant weak positive correlations (0.12 to 0.16) were seen in the six PROM scales GenW, MoE, FreW, ManD, and DiEx. The highest correlations were seen in MoE, FreW, and DiEx. For LDL cholesterol and SBP, the results came up to the expectations of no statistically significant correlations. However, for participants with type 1 diabetes, a statistically significant negative correlation showed that a lower SBP was weakly associated with better scores in MoE. A lower BMI showed statistically significant weak negative correlations with higher scores in DiEx in both diabetes types as with GenW and MoE in type 2 diabetes. For diabetes duration, statistically significant positive correlations showed that a longer duration was weakly associated with

higher scores in FreW and ManD for participants with type 1 diabetes. For those with type 2 diabetes, statistically significant negative correlations showed that a longer duration was associated with lower scores in FreW and NLBS (Figs. S1-S2, Tables S3-S4).

Monoton correlations related to the proposed assumptions between scores in the Diabetes Questionnaire scales and the SF-36v2 domains

In line with the assumptions and in support for convergent validity, the statistically significant monoton correlations between the Diabetes Questionnaire scales and the SF-36v2 domains were stronger in seven of the PROM scales as compared to the PROM scale SuO and the PREM scales. As expected, the observed statistically significant correlations were all positive, showing an association between higher scores in both questionnaires. The results are shown in Figs. 1-2 and Tables S5-S6.

As assumed, the strongest correlations were seen in the Diabetes Questionnaire PROM scales GenW and MoE. Statistically significant positive correlations showed that higher scores in GenW and MoE were strongly associated with higher scores in about half of the SF-36v2 domains. In GenW, statistically significant positive correlations were seen with the SF-36v2 domains PF, GH, VT, and MH. The correlations were very strong with VT (0.60), strong with GH and MH (0.51 to 0.56), and weak with PF. Among those with type 2 diabetes, there were also statistically significant strong positive correlations between GenW and SF (0.51). In MoE, statistically significant positive correlations were seen with the SF-36v2 domains GH, VT, SF, and MH. The correlations were very strong with MH (0.60) and strong with GH, VT, and SF (0.51 to 0.58). Among those with type 2 diabetes, statistically significant strong positive correlations were also seen between MoE and RF (0.51). For both diabetes types, statistically significant strong positive correlations were also seen between the PROM scale DiEx and the VT domain (0.51). Statistically significant moderate positive correlations were also seen between the PROM scales and SF-36v2 domains. In NLD and NLBS, statistically significant moderate positive correlations were more common in type 2 diabetes than in type 1 diabetes. In support for divergent validity, the PROM scale SuO and the PREM scales, statistically significant correlations were weak (0.11 to 0.32) or absent (Figs. 1-2, Tables S5-S6).

Non-linear associations to clinical variables and SF-36v2 domains together

The results from the machine learning analysis are shown in Figs. 3 and S3. Similar results were seen for type 1 and type 2 diabetes. Among the PROM scales, the variance was explained by the SF-36v2 domains together with the clinical variables to almost 40% in GenW and to around 45% in MoE. In FreW, ManD, DiEx, NLD, and NLBS, the variance was explained to about 25-30% and in SuO to about 10%. Among the PREM scales, SuDC, AcDC, and MDMT were explained to about 10% or below. In CoDC, almost no variance was explained (Fig. 3). As predictors of the Diabetes Questionnaire PROM scales GenW and MoE, the variables with the highest importance were the SF-36v2 domains GH, VT, and MH. LDL cholesterol and SBP had low variable importance (Fig. S3). The percent variance in HbA_{1c} explained by other clinical variables, the SF-36v2 domains, and the Diabetes Questionnaire scales together was low, around 5% in type 1 diabetes and around 10% in type 2 diabetes. Consequently, the importance of the other clinical variables, the SF-36v2 domains, and the Diabetes Questionnaire scales as predictors of HbA_{1c} was not examined.

Sensitivity of the Diabetes Questionnaire scales to clinically relevant groups of glycaemic control

The results from the adjusted regression analyses of the Diabetes Questionnaire scales and the HbA_{1c} groups are presented separately for participants with type 1 and type 2 diabetes in Fig. 4. The least square mean estimates and confidence intervals from the unadjusted and adjusted analyses are given in detail in Table S7.

Among those with type 1 diabetes, the adjusted analysis of the HbA_{1c} groups showed significantly lower scores for the high-risk group than the well-controlled group in the eight PROM scales GenW, MoE, FreW, ManD, DiEx, NLD, NLBS, and SuO as in the PREM scale SuDC. The largest between-group differences were seen in the PROM scales ManD and DiEx, where the well-controlled group had the significantly highest means, followed by the sub-optimal group and the high-risk group. Among those with type 2 diabetes, the adjusted analysis showed that the high-risk group had significantly lower scores than the well-controlled group in all scales but CoDC. In the five PROM scales MoE, FreW, ManD, NLD, and NLBS, the well-controlled group had the significantly highest means, followed by the sub-optimal and high-risk groups. The largest between-group differences were seen in MoE, FreW, NLD, and NLBS (Fig. 4, Table S7).

DISCUSSION

From a nationwide setting with a large sample of adults with type 1 and type 2 diabetes selected at random, we present the outcome from the Diabetes Questionnaire. To study construct validity, we assess convergent and divergent associations of that outcome with clinical variables and generic health-related quality of life, as measured by the SF-36v2 and assess the sensitivity to differences between clinically relevant groups of glycaemic control. We found supporting evidence for construct validity in both type 1 and type 2 diabetes. As expected, and in support for divergent validity, there were few statistically significant correlations with the clinical variables. The observed correlations were weak, and most were negative. Also as expected, and in support for convergent validity, the correlations with the SF-36v2 domains were positive; the strongest correlations were found in the Diabetes Questionnaire PROM scales GenW and MoE. Furthermore, either weak or no correlations were seen in the PREM scales, supporting divergent validity. In machine learning analyses, the SF-36v2 domains and the clinical variables together explained the variance in the PROM scales GenW and MoE to about 40-45%. In the other scales, the variance explained was low. In regression analyses among three groups with differing levels of HbA_{1c} adjusted for demographics, other risk factors, and diabetes complications, the high-risk group had, in support of sensitivity to clinically relevant groups of glycaemic control, statistically significantly lower scores than the well-controlled group in most Diabetes Questionnaire scales for participants with type 1 diabetes and in almost all scales for those with type 2 diabetes. Statistically significant differences between all three groups of glycaemic control were seen in two scales for type 1 diabetes and in five scales for type 2 diabetes.

Findings and implications

Evaluating the measurement qualities of a questionnaire is a complex and cumulative effort.[13, 14] In this study, we continue the evaluation of the Diabetes Questionnaire by addressing its construct validity. The results in relation to divergent validity show supporting evidence that the Diabetes Questionnaire targets different concepts than the clinical variables for diabetes care traditionally covered by the NDR. Thus, the central aspects covered by the Diabetes Questionnaire including patient perspectives on how they feel, how their diabetes treatment is going, or their experiences of support from diabetes care cannot be measured by HbA_{1c} or other tested clinical variables. Nor can the clinical variables be estimated through the Diabetes Questionnaire. We need the combination. There is a growing emphasis that the perspectives of those living with diabetes should be part of clinical meetings and be given

priority among outcomes in diabetes care assessments.[1, 5, 6, 23-25] Supplementing decision-making by adding the patient's perspective is suggested to increase the focus on these aspects in clinical meetings[2, 26] and to enhance the quality of care.[26-28] In Sweden, the Patient Act strengthens the patient's position and possibilities for shared decision-making and states that the individual patient's prerequisites and wishes should be taken into account.[29] There is also a growing movement towards person-centred care aiming for partnership that is centred on the patient's experience and individual prerequisites, resources, and barriers. An important basis is the patient's story.[30] We hope that the Diabetes Questionnaire can support the patient story if used in the clinical meetings together with the clinical variables.

The Diabetes Questionnaire is unique in being developed to support clinical meetings with individuals and to be used as a means for quality improvement through longitudinal assessment at a local, regional, and national levels within the frame of a nationwide healthcare quality register.[7-9] Many other questionnaires for diabetes were developed to target a specific aspect within intervention studies.[3, 18, 19] The Diabetes Questionnaire has a broad approach with aspects identified as important to adults with diabetes.[8, 9] The Diabetes Questionnaire is also developed using the vocabulary and phrasing of people with diabetes,[8] unlike many other questionnaires that often use academic or professional jargon. In this study, we found supporting evidence that the Diabetes Questionnaire is sensitive to statistically significant differences between clinically relevant subgroups with differing levels of glycaemic control. The Diabetes Questionnaire was also in support of convergent validity found to capture some aspects of generic health-related quality of life, while also in support of divergent validity adding aspects that are not covered by the often-recommended SF-36v2. For routine use within clinical diabetes care, the Diabetes Questionnaire is likely more relevant than the generic SF-36v2. A limitation of the Diabetes Questionnaire is, however, that it is currently only available in Swedish. Consequently, there is limited opportunity for international comparisons. The opportunities and barriers related to clinical use of the Diabetes Questionnaire are currently being studied from the perspectives of professionals and adults with diabetes.

Strengths and weaknesses

Among the strengths of this study are the large and heterogeneous sample of adults with type 1 and type 2 diabetes selected at random from the nationwide NDR. The respondents

were representative of the 2015 population in the NDR (data on file). The results can be considered representative of the Swedish adult population with diabetes related to the coverage rate of about 90% in 2015 when around 40,000 adults with type 1 diabetes and 347,000 with type 2 diabetes were registered in the NDR. Through the NDR, we had access to clinical variables relevant for diabetes care and background data for the non-respondents. Another strength is the use of a well-known measure of health-related quality of life. As there is a lack of agreed-upon benchmarks for how strong positive correlations between questionnaires addressing subjective aspects should be to support convergent construct validity,[31, 32] this study based the division of the correlation strength on reports that such correlations generally are low,[31, 33] often within the range 0.20-0.40[33] or 0.40-0.60.[31] A correlation of 0.60 has been suggested to be extremely strong, as the random error of measurement of the two questionnaires impede perfect correlations.[31] As the Diabetes Questionnaire and the SF-36v2 do not measure the exact same construct, there were no prerequisites for broad strong correlations.[14, 31, 33]

Our study also has limitations. The analyses were limited to the respondents and might reflect a group that is more motivated to participate. Another limitation is that the questionnaires were only offered in Swedish, potentially resulting in a higher proportion of foreign-born individuals among the non-responders than among the respondents. Furthermore, the cross-sectional design means that it is not possible to make causal conclusions.

Future perspectives

The evaluation of construct validity is a work of putting the pieces together.[13, 14] Consequently, more studies are needed to relate the Diabetes Questionnaire to different concepts and measures. An important task for diabetes care is to identify suitable interventions that adequately can support individuals with diabetes. The Diabetes Questionnaire can be an important contribution to identify the need and focus for targeted interventions, especially for adults with low scores. In future studies, it is important to evaluate the potential of using scores from the Diabetes Questionnaire scales as the primary selection base or in combination with, for example, HbA_{1c} levels or BMI. It is also essential to evaluate whether the Diabetes Questionnaire scales are responsive to actual changes and can be used as an evaluative tool adding patient perspectives to both nursing and medical interventions, longitudinal assessments, and quality improvement. The NDR is established as a clinical and a national assessment tool in Swedish diabetes care.[4, 34-36] By now, the

Diabetes Questionnaire is digitally and freely available for use by all clinics in Sweden connected to the NDR. The Diabetes Questionnaire is also included as the basis for developmental quality indicators in the Swedish national guidelines for diabetes care.[4] In the future, the Diabetes Questionnaire can be amongst the established quality indicators bringing patient perspectives to the fore for diabetes care.

Conclusion

This nationwide study shows that the Diabetes Questionnaire captures some generic health-related quality of life dimensions as well as adds diabetes-specific information not covered by the SF-36v2 and clinical variables. The Diabetes Questionnaire is also sensitive to differences between clinically relevant groups of glycaemic control.

List of abbreviations

Abbreviations related to the Diabetes Questionnaire

GenW: General Well-being

MoE: Mood and Energy

FreW: Free of Worries about blood sugar

ManD: Capabilities to Manage your Diabetes

DiEx: Diet and Exercise

NLD: Not Limited by Diabetes

NLBS: Not Limited by Blood Sugar

SuO: Support from Others

SuDC: Support from Diabetes Care

AcDC: Access to Diabetes Care

CoDC: Continuity in Diabetes Care

MDMT: Medical Devices and Medical Treatment

PREM: Patient-reported experience measure

PROM: Patient-reported outcome measure

Abbreviations related to the SF-36v2 survey

PF: Physical functioning

RP: Role-physical

BP: Bodily pain

GH: General health

VT: Vitality

SF: Social functioning

RE: Role-emotional

MH: Mental health

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Competing interests

Dr. Eeg-Olofsson reports grants from the ALF agreement (ALFGBG 698991), during the conduct of the study; personal fees from Abbott, personal fees from Lilly, personal fees from Novo Nordisk, personal fees from Bayer, outside the submitted work; Dr. Gudbjörnsdottir reports grants from the ALF-agreement (ALFGBG 725311), during the conduct of the study; grants and personal fees from AstraZeneca, grants and personal fees from Boehringer Ingelheim, grants and personal fees from Eli Lilly, grants and personal fees from Merck Sharp & Dohme, grants and personal fees from Novo Nordisk, grants and personal fees from Sanofi, outside the submitted work; the other authors declare that they have nothing to disclose.

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Author Contributions

MSE made substantial contributions to the design of the work, applying for ethical approval and funding, interpreting the data, and drafting and revising the manuscript (major contributor). JL and UBJ supervised and made substantial contributions to the design of the work, applied for funding, made intellectual contributions in the interpretation of the data, critically revised the manuscript for important intellectual content, and contributed experience and knowledge from diabetes care and research in diabetes and health-related quality of life. SB made substantial contributions to the design of the work, made intellectual contributions in the interpretation of the data, and critically revised the manuscript for important intellectual content. BP made substantial contributions to the design of the work; performed the selection of the random sample; made intellectual contributions in the interpretation of the data; critically revised the manuscript for important intellectual content, and contributed statistical advice, experience, and knowledge in the research of generic health-related quality of life and patient-reported outcome. SF made substantial contributions to the design of the work, contributed substantial statistical advice, was the major contributor in analysing the data, made substantial intellectual contributions in the interpretation of the data, and critically revised the manuscript for important intellectual content. SG supervised and made substantial contributions to the design of the work; applied for ethical approval and funding; made intellectual contributions in interpretation of the data; critically revised the manuscript for important intellectual content, and contributed medical experience and knowledge from diabetes care, diabetes research, and research using health-care quality registers. KEO supervised and made substantial contributions to the design of the work; applied for ethical approval and funding; generated the SF-36v2 data; interpreted the data; critically revised the manuscript for important intellectual content, and contributed medical experience and knowledge from diabetes care, diabetes research, and research using health-care quality registers. All authors read and approved the final manuscript as well as consented to be on the author list.

Data sharing statement

The data that support the findings of this study are not publicly available. The study presented here has been subject to review by an ethical board and approved for publication related to the specific aim of our research project. With reference to the European General Data Protection Regulation, the data are personal and therefore confidential.

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Figure Legends

Fig. 1. Spearman's rank correlation between the Diabetes Questionnaire scales and the SF-36v2 domains in type 1 diabetes

Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment. SF-36v2 domains: PF: physical functioning; RP: role-physical; BP: bodily pain; GH: general health.

Fig. 2. Spearman's rank correlation between the Diabetes Questionnaire scales and the SF-36v2 domains in type 2 diabetes

Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment. SF-36v2 domains: PF: physical functioning; RP: role-physical; BP: bodily pain; GH: general health.

Fig. 3. Percent variance in the Diabetes Questionnaire scales explained by the SF-36v2 domains and clinical variables in type 1 (A) and type 2 diabetes (B)

GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.

Fig. 4. Adjusted least square mean estimates with 95% confidence intervals for the Diabetes Questionnaire scales in type 1 diabetes (A) and type 2 diabetes (B) separated by glycated haemoglobin (HbA_{1c}) level

Adjusted for age, sex, diabetes duration, body mass index, systolic blood pressure, LDL cholesterol level, micro- and macro-albuminuria, estimated glomerular filtration rate, retinopathy, smoking status, physical activity level, receipt of antihypertensive and lipid lowering treatments, previous coronary heart disease and previous stroke.

GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.

Supplementary material

Supplementary figures

Fig. S1. Spearman's rank correlation between the Diabetes Questionnaire scales and clinical variables in type 1 diabetes

Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment. Clinical variables: BMI: body mass index, SBP: systolic blood pressure, LDL: LDL cholesterol, HbA_{1c}: glycated haemoglobin level.

Fig. S2. Spearman's rank correlation between the Diabetes Questionnaire scales and clinical variables in type 2 diabetes

Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.
Clinical variables: BMI: body mass index, SBP: systolic blood pressure, LDL: LDL cholesterol, HbA_{1c}: glycated haemoglobin level.

Fig. S3. Variable importance of clinical variables and the SF-36v2 domains as predictors of the Diabetes Questionnaire scales GenW (General Wellbeing) and MoE (Mood and Energy) in type 1 (A and B) and type 2 diabetes (C and D)

Clinical variables: BMI: body mass index, SBP: systolic blood pressure, LDL: LDL cholesterol, HbA_{1c}: glycated haemoglobin level.
SF-36v2 domains: PF: physical functioning; RP: role-physical; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning; RE: role-emotional; MH: mental health.

Supplementary tables

Table S1. Crude means and standard deviations for the Diabetes Questionnaire scales and the SF-36v2 domains for participants with type 1 diabetes and those with type 2 diabetes

Table S2. Clinical and demographic characteristics for non-respondents separated for type 1 and type 2 diabetes

Table S3. Spearman's rank correlations with p-values between the Diabetes Questionnaire scale scores and clinical variables in type 1 diabetes

Table S4. Spearman's rank correlations with p-values between the Diabetes Questionnaire scale scores and clinical variables in type 2 diabetes

Table S5. Spearman's rank correlations with p-values between the Diabetes Questionnaire scales and the SF-36v2 domains in type 1 diabetes

Table S6. Spearman's rank correlations with p-values between the Diabetes Questionnaire scales and the SF-36v2 domains in type 2 diabetes

Table S7. Least square mean estimates and 95% confidence intervals for the Diabetes Questionnaire scales in three glycated haemoglobin (HbA_{1c}) groups for type 1 and type 2 diabetes

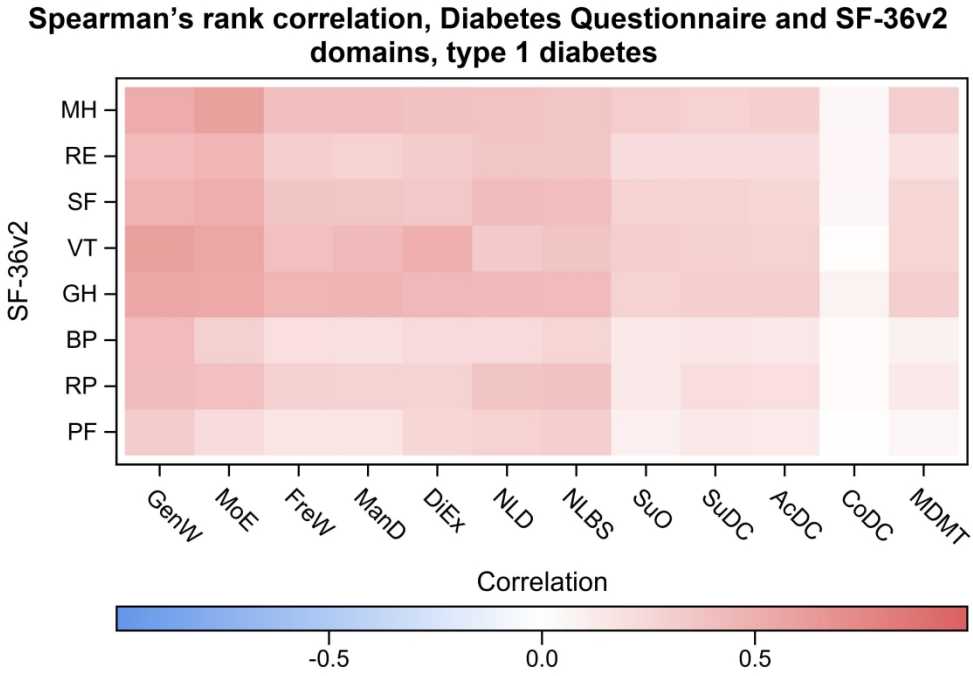

Fig. 1. Spearman's rank correlation between the Diabetes Questionnaire scales and the SF 36v2 domains in type 1 diabetes

127x88mm (600 x 600 DPI)

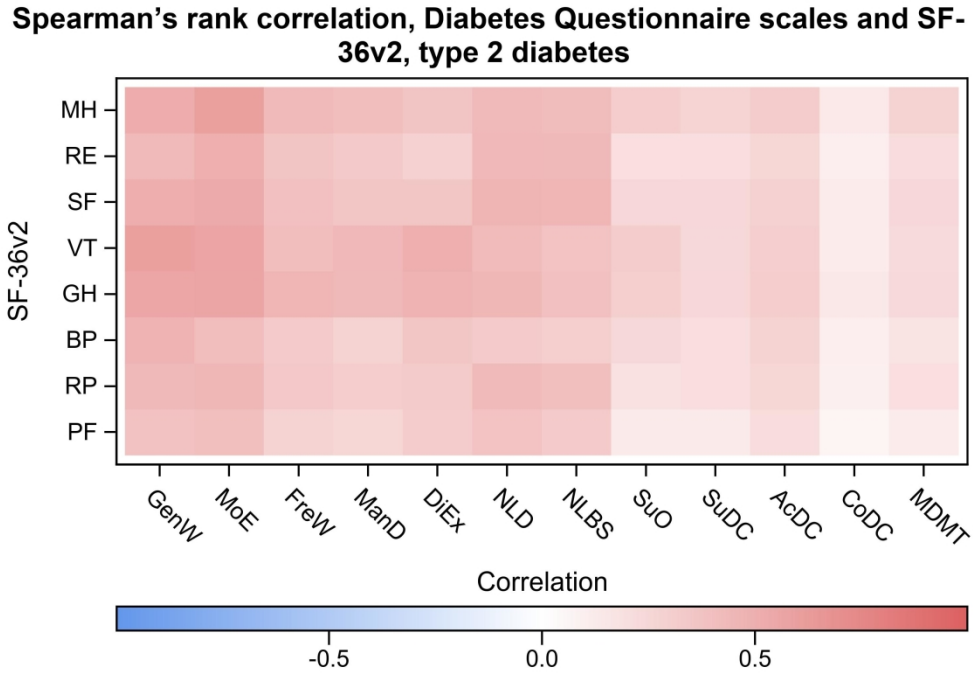

Fig. 2. Spearman's rank correlation between the Diabetes Questionnaire scales and the SF 36v2 domains in type 2 diabetes

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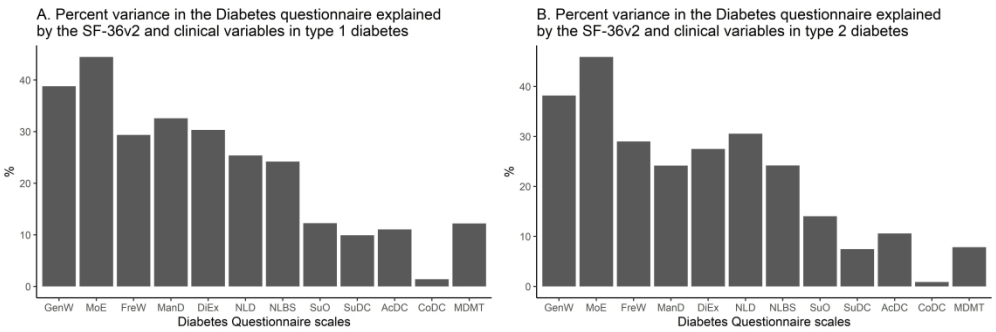

Fig. 3. Percent variance in the Diabetes Questionnaire scales explained by the SF 36v2 domains and clinical variables in type 1 (A) and type 2 diabetes (B)

304x101mm (600 x 600 DPI)

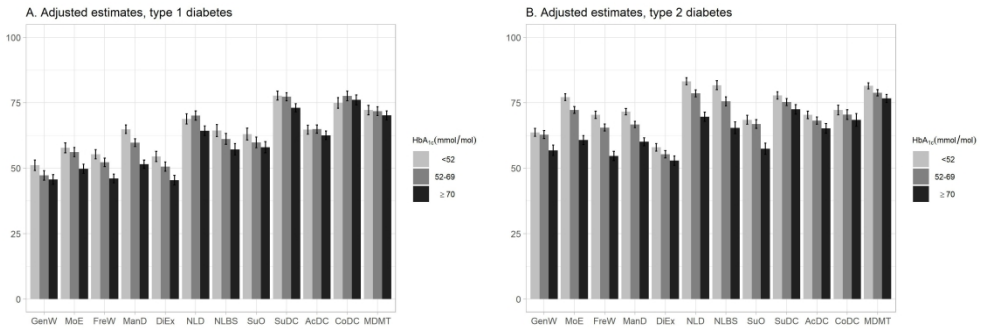

Fig. 4. Adjusted least square mean estimates with 95% confidence intervals for the Diabetes Questionnaire scales in type 1 diabetes (A) and type 2 diabetes (B) separated by glycated haemoglobin (HbA1c) level

349x119mm (300 x 300 DPI)

SUPPLEMENTARY MATERIAL

To the article titled

New diabetes questionnaire to add patients' perspectives to diabetes care for adults with type 1 and type 2 diabetes – Nationwide cross-sectional study of construct validity assessing associations with generic health-related quality of life and clinical variables

By

Maria Svedbo Engström; Janeth Leksell; Unn-Britt Johansson; Sixten Borg, Bo Palaszewski; Stefan Franzén; Soffia Gudbjörnsdottir; Katarina Eeg-Olofsson

Submitted to BMJ Open

Supplementary figures

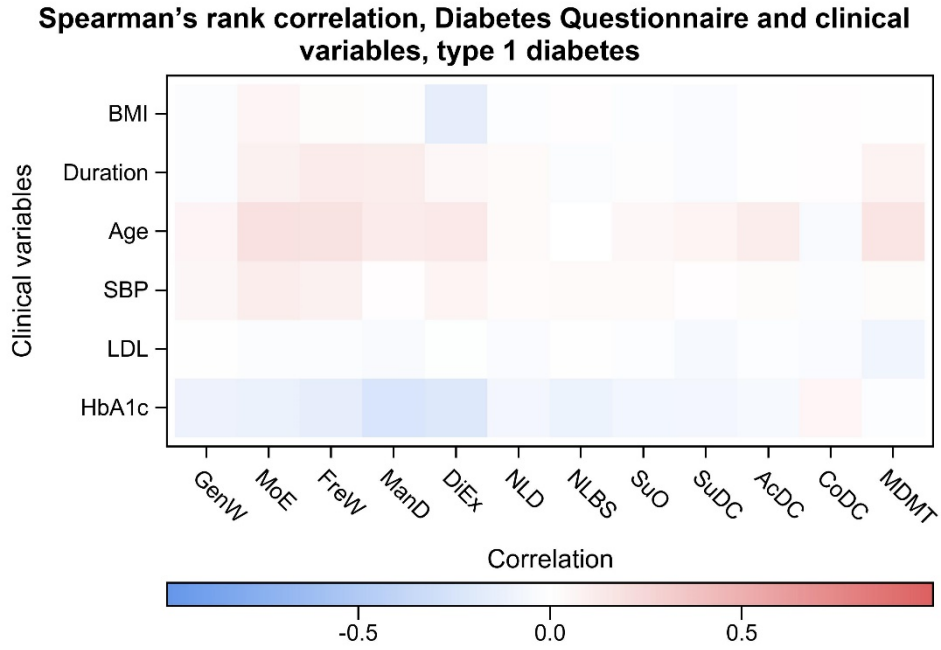

Fig. S1. Spearman's rank correlation between the Diabetes Questionnaire scales and clinical variables in type 1 diabetes

Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.
Clinical variables: BMI: body mass index, SBP: systolic blood pressure, LDL: LDL cholesterol, HbA_{1c}: glycated haemoglobin level.

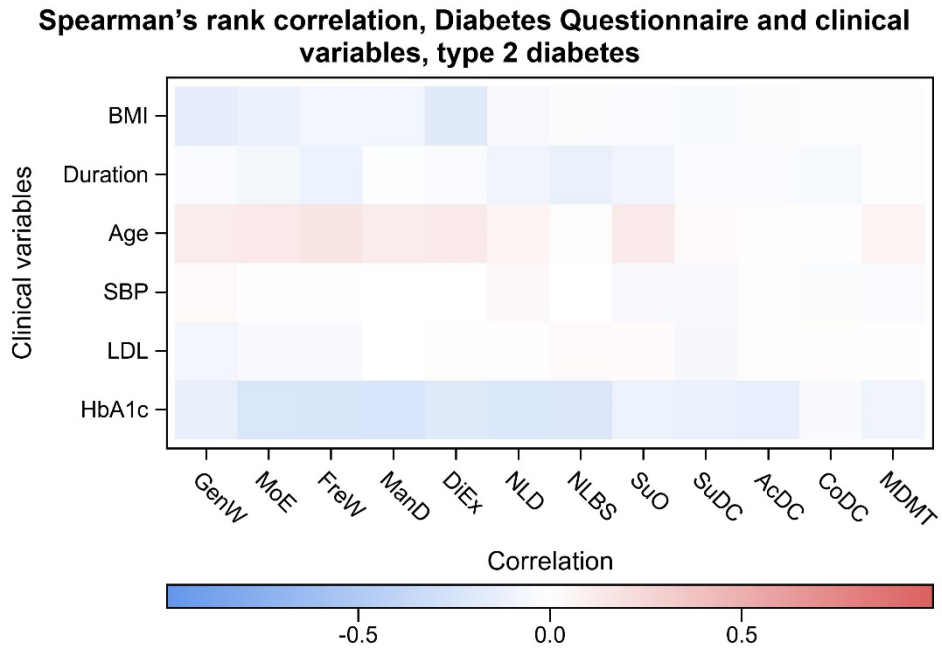

Fig. S2. Spearman's rank correlation between the Diabetes Questionnaire scales and clinical variables in type 2 diabetes

Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.
Clinical variables: BMI: body mass index, SBP: systolic blood pressure, LDL: LDL cholesterol, HbA_{1c}: glycated haemoglobin level.

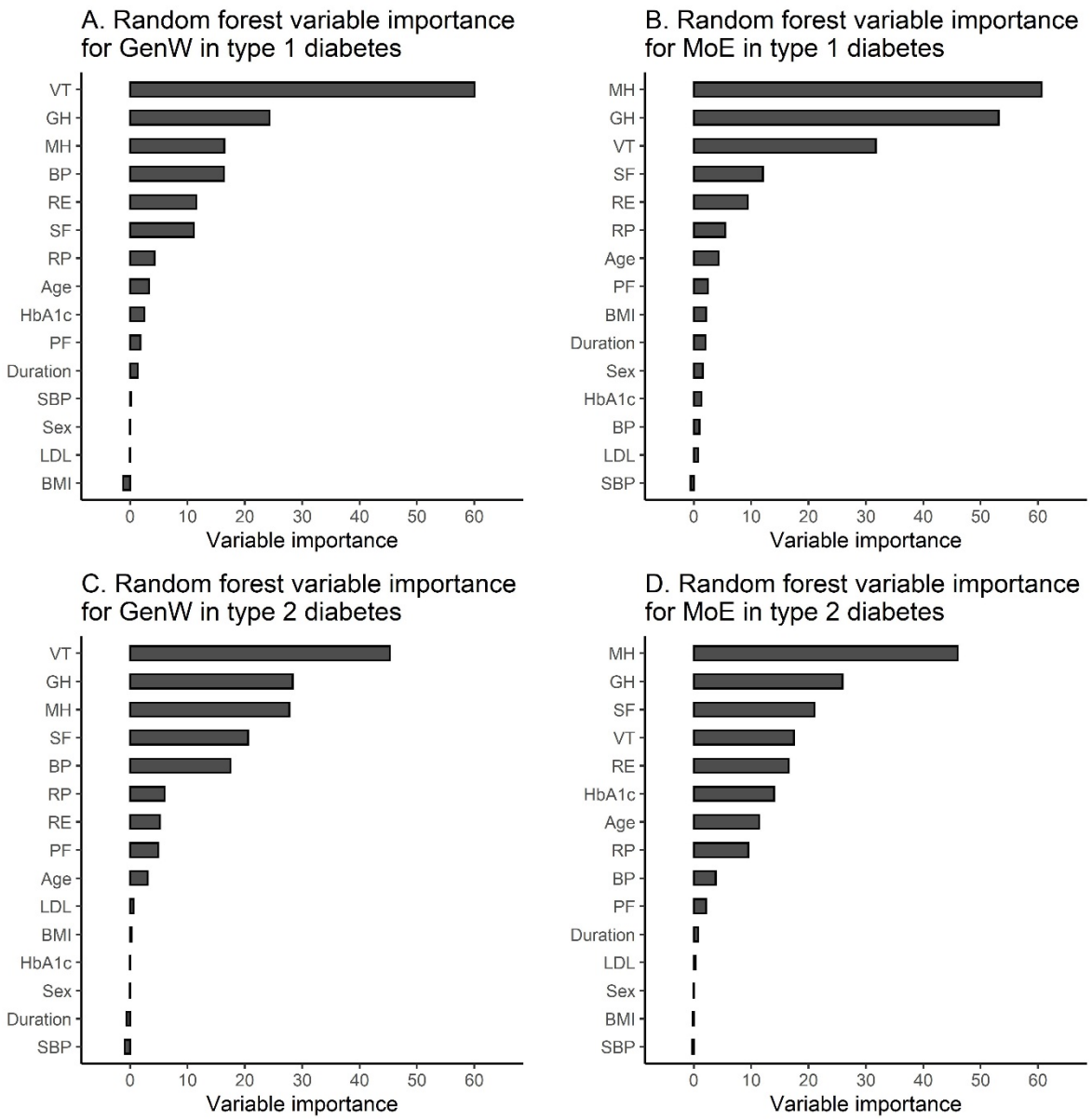

Fig. S3. Variable importance of clinical variables and the SF-36v2 domains as predictors of the Diabetes Questionnaire scales GenW (General Wellbeing) and MoE (Mood and Energy) in type 1 (A and B) and type 2 diabetes (C and D)

Clinical variables: BMI: body mass index, SBP: systolic blood pressure, LDL: LDL cholesterol, HbA_{1c}: glycated haemoglobin level.
SF-36v2 domains: PF: physical functioning; RP: role-physical; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning; RE: role-emotional; MH: mental health.

Supplementary tables

Table S1. Crude means and standard deviations for the Diabetes Questionnaire scales and the SF-36v2 domains for participants with type 1 diabetes and those with type 2 diabetes

Diabetes Questionnaire scale	Type 1 diabetes	Type 2 diabetes	p-value	Standardized mean difference, SMD
GenW	59.69 (23.81)	63.76 (24.71)	<0.001	0.168
MoE	64.07 (23.60)	75.19 (22.25)	<0.001	0.485
FreW	54.89 (21.91)	69.03 (22.29)	<0.001	0.640
ManD	63.20 (20.16)	70.48 (19.89)	<0.001	0.364
DiEx	56.66 (24.36)	58.88 (24.08)	0.018	0.092
NLD	75.33 (23.47)	84.14 (21.70)	<0.001	0.390
NLBS	69.97 (26.94)	80.94 (26.84)	<0.001	0.408
SuO	62.32 (23.46)	66.26 (23.71)	<0.001	0.167
SuDC	78.35 (20.29)	77.89 (22.61)	0.574	0.022
AcDC	67.80 (20.73)	71.31 (22.61)	<0.001	0.162
CoDC	80.04 (23.29)	71.42 (27.39)	<0.001	0.339
MDMT	75.40 (21.78)	80.47 (18.39)	<0.001	0.252

Diabetes questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.

Table S2. Clinical and demographic characteristics for non-responders separated for type 1 and type 2 diabetes

Variable	**Type 1 diabetes** (n=1106)	**Type 2 diabetes** (n=1116)
Men, %	60.7	58.1
Age, years (SD)	41.2 (15.5)	62.8 (10.9)
Diabetes duration, years (SD)	21.7 (14.0)	8.7 (7.0)
HbA_{1c}, mmol/mol (SD)	65.2 (15.1)	54.7 (14.3)
BMI, kg/m^2 (SD)	26.1 (4.6)	30.9 (5.9)
Systolic blood pressure, mmHg (SD)	126.1 (14.0)	134.7 (15.8)
Antihypertensive medication, %	34.6	77.5
LDL-cholesterol, mmol/L (SD)	2.53 (0.79)	2.64 (0.93)
Lipid-lowering medication, %	37.1	60.5
Micro-albuminuria, %	11.4	18.4
Macro-albuminuria, %	5.6	5.0
Retinopathy, %	66.2	30.5
Smoker, %	15.7	18.4
Physical activity, daily, %	20.3	27.1
Diabetes treatment		
Diet alone, %	-	20.1
Oral hypoglycaemic agent alone, %	-	52.5
Insulin alone, %	97.2	8.1
Insulin and oral agent, %	2.3	16.7
Insulin pump users, %	19.9	-

The descriptive statistics are presented as the means and standard deviations (SD) for continuous variables or number and percentages for categorical variables.

Table S3. Spearman's rank correlations with p-values between the Diabetes Questionnaire scale scores and clinical variables in type 1 diabetes

Clinical variable	GenW	MoE	FreW	ManD	DiEx	NLD	NLBS	SuO	SuDC	AcDC	CoDC	MDMT
Age	0.06 (0.0184)	0.19 (<.0001)	0.18 (<.0001)	0.13 (<.0001)	0.14 (<.0001)	0.03 (0.2050)	0.01 (0.8445)	0.05 (0.0875)	0.07 (0.0093)	0.11 (<.0001)	-0.04 (0.1635)	0.17 (<.0001)
Diabetes duration	-0.02 (0.4673)	0.09 (0.0006)	0.13 (<.0001)	0.11 (<.0001)	0.05 (0.0456)	0.04 (0.1981)	-0.02 (0.4678)	-0.01 (0.6936)	-0.03 (0.2024)	-0.00 (0.9883)	0.01 (0.6045)	0.08 (0.0027)
HbA_{1c}	-0.12 (<.0001)	-0.12 (<.0001)	-0.16 (<.0001)	-0.25 (<.0001)	-0.21 (<.0001)	-0.07 (0.0073)	-0.12 (<.0001)	-0.08 (0.0101)	-0.07 (0.0070)	-0.05 (0.0542)	0.06 (0.0356)	-0.02 (0.5485)
BMI	-0.02 (0.4601)	0.07 (0.0151)	0.03 (0.2763)	-0.01 (0.6738)	-0.15 (<.0001)	-0.01 (0.6239)	0.02 (0.5767)	-0.01 (0.6620)	-0.03 (0.2568)	-0.00 (0.9175)	0.02 (0.5998)	0.01 (0.7292)
SBP	0.06 (0.0231)	0.12 (<.0001)	0.09 (0.0005)	0.02 (0.5036)	0.07 (0.0072)	0.03 (0.3393)	0.03 (0.2152)	0.03 (0.3092)	0.01 (0.6002)	0.03 (0.2773)	-0.03 (0.3239)	0.03 (0.2610)
LDL	-0.00 (0.9452)	-0.02 (0.4805)	-0.02 (0.4380)	-0.04 (0.1549)	-0.01 (0.8077)	-0.03 (0.2406)	-0.00 (0.9780)	-0.02 (0.5905)	-0.06 (0.0474)	-0.02 (0.5275)	-0.03 (0.2873)	-0.09 (0.0023)

Diabetes questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.
Clinical variables: BMI: body mass index; SBP: systolic blood pressure; LDL: LDL cholesterol; HbA_{1c}: glycated haemoglobin level.

Table S4. Spearman's rank correlations with p-values between the Diabetes Questionnaire scale scores and clinical variables in type 2 diabetes

Clinical variable	GenW	MoE	FreW	ManD	DiEx	NLD	NLBS	SuO	SuDC	AcDC	CoDC	MDMT
Age	0.12 (<.0001)	0.14 (<.0001)	0.16 (<.0001)	0.12 (<.0001)	0.14 (<.0001)	0.07 (0.0061)	0.02 (0.3646)	0.13 (0.0002)	0.04 (0.1926)	0.02 (0.3657)	0.01 (0.6265)	0.07 (0.0089)
Diabetes duration	-0.03 (0.2226)	-0.07 (0.0202)	-0.11 (<.0001)	-0.02 (0.5662)	-0.04 (0.1868)	-0.10 (0.0007)	-0.13 (<.0001)	-0.09 (0.0184)	-0.04 (0.2043)	-0.03 (0.2353)	-0.06 (0.0570)	-0.01 (0.6150)
HbA_{1c}	-0.14 (<.0001)	-0.24 (<.0001)	-0.24 (<.0001)	-0.24 (<.0001)	-0.21 (<.0001)	-0.23 (<.0001)	-0.22 (<.0001)	-0.11 (0.0015)	-0.13 (<.0001)	-0.15 (<.0001)	-0.04 (0.1270)	-0.09 (0.0012)
BMI	-0.15 (<.0001)	-0.12 (<.0001)	-0.08 (0.0046)	-0.08 (0.0037)	-0.20 (<.0001)	-0.05 (0.0752)	-0.03 (0.3242)	-0.03 (0.4203)	-0.05 (0.0854)	-0.03 (0.3238)	-0.01 (0.6580)	-0.02 (0.5507)
SBP	0.03 (0.2195)	0.02 (0.5649)	0.01 (0.7496)	0.00 (0.9131)	0.00 (0.8954)	0.04 (0.1082)	0.01 (0.8433)	-0.05 (0.1746)	-0.05 (0.0781)	-0.01 (0.6444)	-0.02 (0.4327)	-0.03 (0.2736)
LDL	-0.07 (0.0151)	-0.04 (0.1773)	-0.04 (0.1310)	0.00 (0.9813)	0.02 (0.4793)	0.02 (0.5751)	0.04 (0.2250)	0.03 (0.4554)	-0.06 (0.0504)	-0.01 (0.7171)	0.02 (0.5061)	0.01 (0.8070)

Diabetes questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.
Clinical variables: BMI: body mass index; SBP: systolic blood pressure; LDL: LDL cholesterol; HbA_{1c}: glycated haemoglobin level.

Table S5. Spearman's rank correlations with p-values between the Diabetes Questionnaire scales and the SF-36v2 domains in type 1 diabetes

	SF-36v2 domain							
Diabetes Questionnaire scale	**PF**	**RP**	**BP**	**GH**	**VT**	**RF**	**SF**	**MH**
GenW	0.33 (<.0001)	0.43 (<.0001)	0.43 (<.0001)	0.56 (<.0001)	0.60 (<.0001)	0.43 (<.0001)	0.48 (<.0001)	0.53 (<.0001)
MoE	0.23 (<.0001)	0.40 (<.0001)	0.30 (<.0001)	0.55 (<.0001)	0.57 (<.0001)	0.46 (<.0001)	0.52 (<.0001)	0.60 (<.0001)
FreW	0.17 (<.0001)	0.29 (<.0001)	0.21 (<.0001)	0.46 (<.0001)	0.40 (<.0001)	0.31 (<.0001)	0.38 (<.0001)	0.41 (<.0001)
ManD	0.18 (<.0001)	0.28 (<.0001)	0.20 (<.0001)	0.47 (<.0001)	0.44 (<.0001)	0.29 (<.0001)	0.37 (<.0001)	0.41 (<.0001)
DiEx	0.26 (<.0001)	0.28 (<.0001)	0.23 (<.0001)	0.45 (<.0001)	0.51 (<.0001)	0.32 (<.0001)	0.35 (<.0001)	0.39 (<.0001)
NLD	0.29 (<.0001)	0.37 (<.0001)	0.24 (<.0001)	0.44 (<.0001)	0.34 (<.0001)	0.37 (<.0001)	0.42 (<.0001)	0.38 (<.0001)
NLBS	0.31 (<.0001)	0.39 (<.0001)	0.27 (<.0001)	0.43 (<.0001)	0.37 (<.0001)	0.35 (<.0001)	0.41 (<.0001)	0.36 (<.0001)
SuO	0.10 (0.0017)	0.15 (<.0001)	0.14 (<.0001)	0.29 (<.0001)	0.30 (<.0001)	0.23 (<.0001)	0.29 (<.0001)	0.32 (<.0001)
SuDC	0.15 (<.0001)	0.22 (<.0001)	0.16 (<.0001)	0.31 (<.0001)	0.29 (<.0001)	0.23 (<.0001)	0.27 (<.0001)	0.29 (<.0001)
AcDC	0.13 (<.0001)	0.20 (<.0001)	0.15 (<.0001)	0.30 (<.0001)	0.28 (<.0001)	0.23 (<.0001)	0.26 (<.0001)	0.31 (<.0001)
CoDC	0.01 (0.8176)	0.03 (0.3182)	0.03 (0.3309)	0.08 (0.0027)	0.02 (0.3822)	0.06 (0.0375)	0.06 (0.0297)	0.06 (0.0335)
MDMT	0.06 (0.0240)	0.14 (<.0001)	0.09 (0.0006)	0.30 (<.0001)	0.27 (<.0001)	0.19 (<.0001)	0.26 (<.0001)	0.30 (<.0001)

Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.
SF-36v2 domains: PF: physical functioning; RP: role-physical; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning; RE: role-emotional; MH: mental health.

Table S6. Spearman's rank correlations with p-values between the Diabetes Questionnaire scales and the SF-36v2 domains in type 2 diabetes

	SF-36v2 domain							
Diabetes Questionnaire scale	**PF**	**RP**	**BP**	**GH**	**VT**	**RF**	**SF**	**MH**
GenW	0.39 (<.0001)	0.44 (<.0001)	0.48 (<.0001)	0.56 (<.0001)	0.60 (<.0001)	0.44 (<.0001)	0.51 (<.0001)	0.53 (<.0001)
MoE	0.41 (<.0001)	0.45 (<.0001)	0.42 (<.0001)	0.57 (<.0001)	0.58 (<.0001)	0.51 (<.0001)	0.54 (<.0001)	0.60 (<.0001)
FreW	0.28 (<.0001)	0.35 (<.0001)	0.34 (<.0001)	0.47 (<.0001)	0.42 (<.0001)	0.38 (<.0001)	0.40 (<.0001)	0.43 (<.0001)
ManD	0.26 (<.0001)	0.32 (<.0001)	0.28 (<.0001)	0.44 (<.0001)	0.45 (<.0001)	0.34 (<.0001)	0.37 (<.0001)	0.42 (<.0001)
DiEx	0.32 (<.0001)	0.33 (<.0001)	0.36 (<.0001)	0.48 (<.0001)	0.51 (<.0001)	0.30 (<.0001)	0.36 (<.0001)	0.38 (<.0001)
NLD	0.38 (<.0001)	0.44 (<.0001)	0.34 (<.0001)	0.46 (<.0001)	0.43 (<.0001)	0.45 (<.0001)	0.47 (<.0001)	0.43 (<.0001)
NLBS	0.34 (<.0001)	0.40 (<.0001)	0.31 (<.0001)	0.40 (<.0001)	0.38 (<.0001)	0.44 (<.0001)	0.46 (<.0001)	0.42 (<.0001)
SuO	0.14 (0.0001)	0.19 (<.0001)	0.25 (<.0001)	0.31 (<.0001)	0.32 (<.0001)	0.20 (<.0001)	0.26 (<.0001)	0.32 (<.0001)
SuDC	0.14 (<.0001)	0.21 (<.0001)	0.21 (<.0001)	0.26 (<.0001)	0.25 (<.0001)	0.21 (<.0001)	0.26 (<.0001)	0.28 (<.0001)
AcDC	0.22 (<.0001)	0.26 (<.0001)	0.28 (<.0001)	0.32 (<.0001)	0.31 (<.0001)	0.26 (<.0001)	0.29 (<.0001)	0.32 (<.0001)
CoDC	0.07 (0.0130)	0.10 (0.0006)	0.11 (0.0001)	0.16 (<.0001)	0.13 (<.0001)	0.11 (0.0002)	0.13 (<.0001)	0.14 (<.0001)
MDMT	0.13 (<.0001)	0.20 (<.0001)	0.18 (<.0001)	0.24 (<.0001)	0.24 (<.0001)	0.22 (<.0001)	0.26 (<.0001)	0.28 (<.0001)

Diabetes Questionnaire scales: GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment.
SF-36v2 domains: PF: physical functioning; RP: role-physical; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning; RE: role-emotional; MH: mental health.

Table S7. Least square mean estimates and 95% confidence intervals for the Diabetes Questionnaire scales in three glycated haemoglobin (HbA_{1c}) groups for type 1 and type 2 diabetes

Diabetes Questionnaire scale	Type 1 diabetes						Type 2 diabetes					
	Unadjusted analysis			Adjusted analysis			Unadjusted analysis			Adjusted analysis		
	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol
GenW	64.33 (63.46-65.20)	59.27 (58.74-59.79)	56.34 (55.49-57.19)	51.11 (49.14-53.07)	47.23 (45.44-49.01)	45.66 (43.80-47.53)	65.97 (65.41-66.54)	62.92 (62.24-63.60)	54.26 (52.90-55.62)	63.63 (62.10-65.15)	62.81 (61.29-64.32)	56.81 (54.85-58.78)
MoE	67.15 (66.29-68.01)	65.14 (64.62-65.66)	58.32 (57.48-59.16)	57.77 (55.87-59.66)	56.14 (54.41-57.86)	49.75 (47.96-51.54)	79.24 (78.74-79.74)	72.75 (72.15-73.35)	61.02 (59.80-62.25)	77.12 (75.78-78.46)	72.23 (70.91-73.56)	60.73 (58.99-62.46)
FreW	58.21 (57.41-59.01)	56.09 (55.61-56.58)	48.72 (47.96-49.49)	55.28 (53.51-57.05)	52.22 (50.61-53.82)	46.09 (44.42-47.75)	73.07 (72.57-73.57)	66.72 (66.12-67.32)	54.82 (53.62-56.03)	70.39 (69.03-71.75)	65.51 (64.16-66.86)	54.66 (52.90-56.42)
ManD	70.05 (69.33-70.78)	63.88 (63.45-64.32)	55.09 (54.40-55.79)	64.84 (63.20-66.47)	59.71 (58.23-61.19)	51.49 (49.95-53.03)	74.12 (73.67-74.56)	67.74 (67.20-68.28)	60.35 (59.26-61.43)	71.53 (70.33-72.74)	66.65 (65.46-67.85)	60.07 (58.51-61.63)
DiEx	63.95 (63.07-64.84)	56.52 (55.98-57.06)	50.18 (49.32-51.04)	54.44 (52.50-56.37)	50.59 (48.83-52.35)	45.40 (43.57-47.23)	62.48 (61.92-63.03)	55.86 (55.20-56.52)	50.13 (48.80-51.47)	57.97 (56.54-59.40)	55.31 (53.91-56.72)	52.85 (51.02-54.68)
NLD	76.79 (75.93-77.66)	76.59 (76.07-77.11)	70.75 (69.92-71.58)	68.78 (66.84-70.71)	70.09 (68.33-71.85)	64.26 (62.44-66.09)	87.94 (87.46-88.43)	81.82 (81.23-82.40)	71.54 (70.37-72.71)	83.17 (81.79-84.55)	78.57 (77.21-79.94)	69.61 (67.83-71.38)
NLBS	74.54 (73.54-75.54)	70.33 (69.73-70.93)	64.60 (63.63-65.58)	64.39 (62.08-66.69)	61.14 (59.05-63.23)	57.16 (54.98-59.33)	85.59 (84.98-86.20)	77.91 (77.18-78.64)	65.85 (64.37-67.33)	81.69 (79.96-83.43)	75.53 (73.81-77.25)	65.42 (63.19-67.65)
SuO	66.33 (65.31-67.35)	61.93 (61.32-62.54)	59.61 (58.63-60.59)	63.01 (60.74-65.28)	59.84 (57.79-61.88)	58.00 (55.86-60.14)	68.56 (67.83-69.29)	65.70 (64.89-66.51)	57.12 (55.49-58.74)	68.47 (66.77-70.16)	66.84 (65.20-68.48)	57.40 (55.25-59.56)
SuDC	79.87 (79.13-80.61)	79.34 (78.89-79.79)	74.41 (73.70-75.13)	77.71 (76.01-79.41)	77.27 (75.73-78.81)	73.04 (71.44-74.64)	80.06 (79.54-80.58)	76.49 (75.87-77.11)	70.89 (69.64-72.14)	77.76 (76.38-79.14)	75.23 (73.86-76.59)	72.46 (70.69-74.24)
AcDC	69.08 (68.32-69.84)	68.52 (68.06-68.98)	64.78 (64.05-65.51)	64.69 (62.96-66.42)	64.90 (63.33-66.47)	62.54 (60.91-64.17)	73.64 (73.12-74.16)	69.68 (69.06-70.30)	64.39 (63.14-65.64)	70.33 (68.92-71.75)	68.12 (66.72-69.52)	65.20 (63.37-67.02)

Diabetes Questionnaire scale	Type 1 diabetes						Type 2 diabetes					
	Unadjusted analysis			Adjusted analysis			Unadjusted analysis			Adjusted analysis		
	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol	HbA_{1c} <52 mmol/mol	HbA_{1c} 52-69 mmol/mol	HbA_{1c} ≥70 mmol/mol
CoDC	78.03 (77.13-78.92)	80.76 (80.22-81.29)	80.05 (79.20-80.90)	74.89 (72.88-76.90)	77.58 (75.75-79.41)	76.08 (74.18-77.97)	72.45 (71.77-73.12)	70.90 (70.11-71.70)	67.72 (66.11-69.33)	72.22 (70.34-74.09)	70.45 (68.59-72.31)	68.43 (66.01-70.84)
MDMT	77.14 (76.34-77.94)	75.78 (75.30-76.26)	72.81 (72.04-73.58)	72.21 (70.41-74.01)	71.74 (70.11-73.38)	70.14 (68.45-71.84)	82.46 (82.02-82.90)	78.80 (78.29-79.31)	76.45 (75.41-77.48)	81.42 (80.23-82.62)	78.79 (77.62-79.96)	76.64 (75.11-78.17)

Table S7 continued. GenW: General Wellbeing; MoE: Mood and Energy; FreW: Free of Worries about blood sugar; ManD: Capabilities to Manage your Diabetes; DiEx: Diet and Exercise; NLD: Not Limited by Diabetes; NLBS: Not Limited by Blood Sugar; SuO: Support from Others; SuDC: Support from Diabetes Care; AcDC: Access to Diabetes Care; CoDC: Continuity in Diabetes Care; MDMT: Medical Devices and Medical Treatment

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cross sectionalreporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1

Abstract	#1b	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	5
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	5
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-8
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of	5-8

		assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	
Bias	#9	Describe any efforts to address potential sources of bias	5,7-8,16-17
Study size	#10	Explain how the study size was arrived at	5
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	5-8
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	7-8
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	7-8
Statistical methods	#12c	Explain how missing data were addressed	8
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	5
Statistical methods	#12e	Describe any sensitivity analyses	n/a
Results			

Participants	#13a	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. Give information separately for for exposed and unexposed groups if applicable.		5
Participants	#13b	Give reasons for non-participation at each stage	n/a With reference to ethical guidelines we did not ask potential participants to give their reasons for non-participation	
Participants	#13c	Consider use of a flow diagram		n/a
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.		9-11
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest		8
Outcome data	#15	Report numbers of outcome events or summary measures. Give information		9

		separately for exposed and unexposed groups if applicable.	
Main results	#16a	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	8,14
Main results	#16b	Report category boundaries when continuous variables were categorized	8,10-11,14
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	12-14
Discussion			
Key results	#18	Summarise key results with reference to study objectives	15
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.	16-17

Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	15-18
Generalisability	#21	Discuss the generalisability (external validity) of the study results	16-17
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	19

Notes:

- 9: 5,7-8,16-17
- 13b: n/a With reference to ethical guidelines we did not ask potential participants to give their reasons for non-participation The STROBE checklist is distributed under the terms of the Creative Commons Attribution License CC-BY. This checklist was completed on 25. June 2020 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai