Validation of a Diabetes-Specific Quality-of-Life Scale for Patients With Type 1 Diabetes

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OBJECTIVE — To validate a diabetes-specific quality-of-life scale and to assess its psychometric properties in a large sample of patients with type 1 diabetes.

RESEARCH DESIGN AND METHODS — To assess the quality of diabetes care in a population-based study, a representative sample of 684 patients with type 1 diabetes was examined. A total of 657 patients (42% female; mean age 36 years; mean diabetes duration 18 years) completed the diabetes-specific quality-of-life scale (DSQOLS), which comprised 64 items on individual treatment goals (10 items), satisfaction with treatment success (10 items), and diabetes-related distress (44 items). Statistical examinations covered factor analysis, internal consistency of subscales, and construct and discriminant validity.

RESULTS — Factor analysis of the 44 items on diabetes-specific burdens revealed six reliable components (Cronbach's α): social relations (0.88), physical complaints (0.84), worries about future (0.84), leisure time flexibility (0.85), diet restrictions (0.71), and daily hassles (0.70). All six subscales were significantly correlated with a validated well-being scale ($r = -0.35$ to -0.53, $P < 0.001$) and treatment satisfaction ($r = 0.28$ to 0.43, $P < 0.001$). Physical complaints ($r = 0.24$) and worries about future ($r = 0.17$) showed the highest correlations with HbA_{1c} ($P < 0.001$). A flexible insulin therapy, a liberalized diet, the absence of late complications, and a higher social status were significantly associated with more favorable scores in different domains.

CONCLUSIONS — The DSQOLS is a reliable and valid measure of diabetes-specific quality of life. The scale is able to distinguish between patients with different treatment and dietary regimens and to detect social inequities. Use of the DSQOLS for assessment of individual treatment goals as defined by the patients may be helpful to identify motivational deficits and to tailor individual treatment strategies.

In the evaluation of care in chronically ill patients, where both the diseases and therapeutic strategies can lead to symptoms, handicaps, and burdens on the lifestyle of patients and their families, the utility of quality-of-life assessments is generally accepted (1,2). Thus, it is well documented for people with type 1 diabetes that the diagnosis, the demands of daily treatment, and the emotional coping with the disease and its threatening acute and late complications have major effects on the patient's physical, social, and psychological well-being (3–6). In addition, psychosocial variables have an important impact on self-management, acceptance of therapeutic regimen, and treatment success (7,8). Consequently, any comprehensive approach to the evaluation of diabetes care must take into account individual perceptions of burdens in different life domains as determined in quality-of-life instruments (4,9). Effective treatment strategies must enable patients to achieve good glycemic control (10) and, at the same time, they should interfere as little as possible with an independent and flexible lifestyle (4).

In light of the rising number of treatment options for patients and health care providers (e.g., genetically engineered insulin analogs), quality-of-life assessment will increasingly contribute to the therapeutic decisions and in the context of the allocation of resources in health politics (2,11).

Quality of life can only be appropriately measured by assessing the opinions and perceptions of patients (12). Associations between subjective health-related quality of life and objective parameters such as variables of metabolic control may be weak (13), especially when good metabolic outcomes (e.g., HbA_{1c}) are accompanied by a high incidence of adverse events such as hypoglycemia (14).

Health-related quality of life can be evaluated either through generic or disease-specific questionnaires (15). Generic measures are designed to be applied to many different impairments, illnesses, patients, and populations. In clinical trials, when interventions and different treatment regimens have to be evaluated in terms of within-subject changes, disease-specific measures are most appropriate because they achieve a greater responsiveness and sensitivity (15,16).

In the field of diabetes, several studies revealed that generic measures achieved only poor discriminant validity and were merely able to discriminate between different patient groups on different treatments or, if at all, only if severe health problems had already developed (17–20). Therefore, several diabetes-specific measures of quality of life have recently been developed and validated (4,14,20–24).

The most widely used is the diabetes quality-of-life (DQOL) instrument (14,21, 25,26), which was used in the Diabetes Control and Complications Trial (DCCT). However, this measure did not detect any convincing differences regarding quality of life between intensively and conventionally treated patients, despite different levels of

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Abbreviations: ANOVA, analysis of variance; CFA, confirmatory factor analyses; DCCT; Diabetes Control and Complications Trial; DQOL, diabetes quality of life; DSQOLS, diabetes-specific quality-of-life scale; GFI, goodness of fit; PWTSS, preference-weighted treatment satisfaction score.

Table 1—*Characteristics of the study population (n = 657)*

Sex (women)	42
Age (years)	36 ± 11 (range 18–76)
Diabetes duration (years)	18 ± 11 (range 0–55)
HbA_{1c} (%, reference range 4.3–6.1)	8.0 ± 1.5
Participation in structured group treatment and teaching programs	62
Three or more injections per day or pump treatment (CSII)	80
Adaptation of insulin dosage to carbohydrate intake	62

Data are means ± SD or %. CSII, continuous subcutaneous insulin infusion.

glycemic control, different incidence rates of severe hypoglycemia, and different rates of incidence and progression of late complications (14). This casts some doubt on the sensitivity and discriminant validity of this instrument. In several clinical studies in Europe, the Diabetes Treatment Satisfaction Questionnaire was used to measure satisfaction with the treatment regimen (4). The scale (8 items) can be economically applied to all patient groups and has been shown to be sensitive to changes following modifications in diabetes management. However, treatment satisfaction is predominantly based on comparisons between the actual status quo and what patients perceive as achievable and realistic (27,28); it does not necessarily reflect perceptions of burdens and restrictions nor the quality of medical treatment (29) or the quality of life (11).

One approach to improve the validity and sensitivity of quality-of-life measures is to use instruments that give patients the opportunity to select the dimensions of most concern and their preferences (12). However, in the field of diabetes, preference-weighted measures taking different treatment goals of patients into account are rare (23), even though it is well-known that differences in individual treatment goals heavily reflect on self-management and treatment outcome (30).

Therefore, we have developed and validated a diabetes-specific quality-of-life measure that reaches beyond traditional treatment satisfaction scales and that achieves sufficient sensitivity to distinguish between different treatment and dietary regimen.

RESEARCH DESIGN AND METHODS

In a population-based study to assess the quality of diabetes care within the district of Northrhine, Germany, a representative sample of 684 patients with type 1 diabetes was recruited. The main purpose of this public health project was to assess glycemic control, the frequency of acute and late complications, and the overall diabetes care as well as social disparities regarding these outcome parameters (31,32).

A detailed description of the study protocol has been published (32). In short, a random sample of 630 office-based physicians was selected out of 5,800 internists and general practitioners in Northrhine by randomized computer lists. The physicians were asked to request formal consent of all patients with type 1 diabetes (aged >18 years, insulin therapy before the age of 31) who had attended the practice at least once within the preceding year. Patients then were contacted to make an appointment for interview and physical examination in a mobile ambulance. The results of the study are published elsewhere (33).

Of the entire study population of 684 type 1 diabetic patients, 657 patients (Table 1) performed the diabetes-specific quality-of-life scale (DSQOLS).

The items of the newly developed DSQOLS were partially selected from two instruments developed in Germany (34–36) to assess diabetes-specific burdens and restrictions in different domains of daily living. However, both scales were not taking account of the differences between type 1 and type 2 diabetes (37) and individual treatment goals. The DSQOLS was designed to assess specifically the four main components of quality of life (i.e., physical, emotional, and social burdens along with daily functioning) in patients with type 1 diabetes.

New items on patients' constraints, treatment goals, and treatment satisfaction were derived from structured group discussions with experienced type 1 diabetic patients in the framework of a structured treatment and teaching program (38). The review of existing instruments and the results of structured group discussions guided the composition and content of the DSQOLS. Two physicians, a diabetes educator, a diet specialist, and two pedagogues reviewed the questionnaire and helped to improve wording and item selection. The final self-administered instrument comprised 64 items that were rated on a six-point Likert scale:

1. treatment goals (10 items);
2. treatment satisfaction according to treatment goals (10 items);
3. physical complaints (10 items);
4. emotional burdens and worries (8 items);
5. social problems (9 items);
6. daily functions (work, leisure, time requirements; 11 items); and
7. diet restrictions (6 items).

A validated positive well-being scale (6 items) was used to estimate convergent validity (4,20,23) and to compare discriminant validity of generic and diabetes-specific scales. The well-being scale comprises generic nondiabetes-related items (e.g., "my daily life has been full of things that were interesting to me").

To estimate a preference-weighted treatment satisfaction score (PWTSS), the patient's rating on each treatment goal (1 = totally unimportant; 6 = very important) was multiplied by the corresponding degree of satisfaction with the achievement in these treatment goals (−2.5 = totally dissatisfied; 2.5 = very satisfied). The sum of all 10 products provides the PWTSS (39).

It was hypothesized that the newly developed scales on quality of life and treatment satisfaction would prove their validity in demonstrating significant statistical associations with regard to glycemic control, treatment regimen, diabetic complications, and sociodemographic variables (e.g., diabetes duration, social status) and that these potential statistical associations would be stronger than those of a general well-being scale.

Statistical analysis

Data are expressed as means ± SD unless indicated otherwise. Except for confirmatory factor analyses, all statistical analyses were performed with the Statistical Package for the Social Sciences (SPSS) (40,41). Exploratory factor analyses (principal components) were performed to derive independent subscales out of the 44 items dealing with daily burdens and restrictions. The final factor structure was validated by

Table 2—*Intercorrelations of subscales*

	1	2	3	4	5	6	7
1. Social relations	—	—	—	—	—	—	—
2. Leisure time flexibility	0.66*	—	—	—	—	—	—
3. Physical complaints	0.55*	0.64*	—	—	—	—	—
4. Worries about future	0.42*	0.50*	0.45*	—	—	—	—
5. Diet restrictions	0.52*	0.53*	0.47*	0.47*	—	—	—
6. Daily hassles	0.50*	0.60*	0.41*	0.36*	0.50*	—	—
7. Positive well-being	0.53*	0.52*	0.52*	0.38*	0.35*	0.39*	—
8. Treatment satisfaction	0.34*	0.43 *	0.42*	0.30*	0.28*	0.34*	0.43*

n = 570–642. *$P < 0.001$.

confirmatory factor analyses using the SAS procedure CALIS (42). Reliability coefficients (Cronbach's α) were computed for all subscales. Convergent validity was assessed by correlational analysis (Pearson's product-moment correlation, Spearman's rank correlation). Because many statistical tests were performed, only those correlations with $P < 0.001$ were considered significant. For group comparisons, *t*-tests and one-way analysis of variance were performed. All statistical analyses of patients' perceptions with respect to treatment goals and treatment satisfaction (single items) were based on nonparametric procedures for ordinal scales (Spearman's rank correlation, Mann-Whitney *U* test, Kruskal-Wallis test). Cluster analysis was conducted to identify different patterns of treatment goals in the study population. Analysis of variance (ANOVA) was performed to elucidate potential interaction effects between different treatment goals and treatment regimen on treatment satisfaction. ANOVA was also applied when group comparisons had to be adjusted for further explanatory variables (covariates).

RESULTS

Factor analysis

To explore the structure of the DSQOLS, a factor analysis (principal components) was performed including the 44 items dealing with daily diabetes-specific restrictions and burdens. A varimax-rotation revealed 10 factors with eigenvalues >1. The scree-test indicated a 6-factor solution explaining 50.1% of the total variance. Of the 44 items, 4 did not achieve significant loadings on any of the 6 homogeneous factors, and 1 item showed in spite of a high factor loading an unsatisfactory item-scale correlation (< 0.30). These five items were eliminated. Six items revealed high loadings on two factors (the highest factor loading was considered for the aggregation of subscales).

Confirmatory factor analyses (CFA) confirmed a better goodness of fit (GFI) for the six-factor solution (GFI = 0.81) compared with the a priori model with five factors (GFI = 0.79).

The following components were derived from factor analysis considering item-component loadings of >0.40 as significant:

1. Social relations (11 items; Cronbach's α 0.88): "Diabetes again and again leads me to problems with other people. Because of my diabetes it is much harder to make friends."
2. Leisure time flexibility (6 items; Cronbach's α 0.83): "Diabetes prevents me from spontaneous physical activities. Because of my disease I can't spend my leisure time the way I would like to."
3. Physical complaints (8 items; Cronbach's α 0.84): "I feel dull or sluggish. Because of diabetes I often have physical troubles."
4. Worries about future (5 items; Cronbach's α 0.84): "I am often worried about diabetic late complications. I often ponder over diabetes and its consequences."
5. Diet restrictions (5 items; Cronbach's α 0.71): "It bothers me that I can't eat like other people. I have to give up tasty food."
6. Daily hassles (4 items; Cronbach's α 0.70): "It bothers me that I have to spend so much time on my diabetes treatment. It bothers me that I have to take my medical instruments (e.g., syringes) with me, whatever I do."

The ten weighted items of the treatment satisfaction scale achieved a Cronbach's α of 0.77. To facilitate the comparability of the different scores, all crude scores were converted to a 100% scale: (score − minimum score) × 100/(maximum score − minimum score). High scores indicate a good quality of life or high treatment satisfaction, respectively.

Construct validity and convergent validity

A further factor analysis including the six newly developed subscales (factor analysis of second order) revealed only one eigenvalue >1, indicating that the subscales represent different domains within a homogeneous construct of quality of life. CFA revealed a GFI of 0.98 for the one-factor model.

All six subscales and the PWTSS were significantly intercorrelated and associated with the positive well-being scale (Table 2). Social relations (r = 0.53), physical complaints (r = 0.52), and leisure time flexibility (r = 0.52) showed the highest correlations with the positive well-being score. The PWTSS revealed modest correlations with all six subscales of the quality-of-life questionnaire and the positive well-being scale. There were only weak statistical associations between the quality-of-life scales and HbA_{1c} (Table 3). Physical complaints (r = −0.24), treatment satisfaction (r = −0.22), and worries about future (r = −0.17) demonstrated the highest correlations. Leisure time flexibility and physical complaints showed the highest correlations with age and diabetes duration, indicating that younger patients and patients with a shorter diabetes duration achieved slightly better quality-of-life scores.

Treatment satisfaction revealed the highest correlation with the frequency of mild hypoglycemia per week (r = −0.23; $P < 0.001$). Further ANOVAs, dividing patients into three groups with no events, 1–2 events, or >2 events per week, indicated that patients with more than two events achieved particularly low scores regarding leisure time flexibility, physical complaints, daily hassles, positive well-being, and treatment satisfaction (data not shown).

The social status of patients was estimated by a combined score (range: 1–24) considering educational level, income per month, and professional status (43). Patients with higher status achieved higher scores with respect to physical complaints (r = 0.24) and worries about future (r = 0.19; $P < 0.001$).

Table 3—*Correlations of subscales with glycemic control and sociodemographic variables*

	HbA_{1c}	Age	Diabetes duration	Age at onset of diabetes	Frequency of mild hypoglycemia/week*	Social status
Social relations	−0.05	−0.14	−0.11	−0.03	−0.07	0.09
Leisure time flexibility	−0.08	−0.23†	−0.22†	−0.01	−0.09	0.10
Physical complaints	−0.24†	−0.20†	−0.19†	0.00	−0.10	0.24†
Worries about future	−0.17†	−0.07	−0.09	0.04	−0.07	0.10
Diet restrictions	−0.10	−0.08	0.02	−0.14	−0.03	0.19†
Daily hassles	0.00	−0.01	−0.02	0.02	−0.11	−0.02
Positive well-being	−0.08	0.01	−0.07	0.11	−0.10	0.04
Treatment satisfaction	−0.22†	0.00	−0.06	0.09	−0.23†	−0.04

n = 600–642. All correlations are Pearson's correlation except *Spearman's rank correlation. †$P < 0.001$.

Discriminant validity

The type of insulin treatment was significantly associated with different subscales (Table 4). Patients with pump treatment achieved the highest scores regarding the subscales for leisure time flexibility and worries about future. With regard to diet restriction, any treatment regimen differed from each other: patients on pump treatment achieved the highest scores, patients with less than three insulin injections per day achieved the lowest scores.

A flexible adaptation of insulin dosage according to the carbohydrate intake was strongly associated with different subscales (Table 4). Patients with a flexible adaptation of insulin dosage achieved better scores on the subscales of social relations, leisure time flexibility, worries about future, and diet restrictions. There was also a tendency to better scores regarding physical complaints. Regarding the scores on the positive well-being and treatment satisfaction scales, there were no differences between patients with different insulin therapies and different flexibility regarding self-adaptation of insulin dosages.

With the exception of one subscale, the frequency of severe hypoglycemia (glucagon or glucose administered intravenously) was not associated with quality of life (data not shown). Patients were divided into three groups with no events, 1–2 events, or >2 events during the preceding year. Patients with a maximum of two events during the preceding year achieved better scores on the physical complaints subscale (focusing mainly on hyperglycemic symptoms) than patients without severe hypoglycemia. However, after adjustment for HbA_{1c} and age, this effect was no longer significant (ANOVA, P = 0.11).

The presence of diabetic late complications was significantly associated with restrictions in quality of life with respect to different dimensions (Table 5). Especially patients with blindness in at least one eye were most strongly affected regarding social relations, leisure time flexibility, physical complaints, and worries about the future. Although there was a linear relationship between the degree of retinopathy and limitations of quality of life, only if patients reached the status of proliferative retinopathy did the differences compared with patients without retinopathy become statistically significant. Patients with nephropathy had significantly lower scores on the subscales leisure time flexibility, physical complaints, worries about future, and positive well-being. Treatment satisfaction was less affected by late complications than quality-of-life scales. In contrast to what was expected, patients with blindness in at least one eye achieved similar scores on treatment satisfaction when compared to patients without retinopathy.

Patients living with a partner achieved better scores regarding the positive well-being scale and the treatment satisfaction scale (data not shown). The other diabetes-

Table 4—*Statistical associations between flexibility of insulin treatment and quality-of-life subscales*

	Type of insulin treatment			Adaptation of insulin dosage according to carbohydrate intake	
	<3 injections/day	≥3 injections/day	CSII	No	Yes
n	132	465	60	248	408
Social relations	83.0 ± 18.7	85.2 ± 15.6	88.0 ± 13.2	82.2 ± 19.0	86.6 ± 13.9†
Leisure time flexibility	76.0 ± 24.2[a]	76.6 ± 21.6[b]	85.4 ± 14.7[ab]†	72.2 ± 24.4	80.3 ± 19.3‡
Physical complaints	77.2 ± 21.3	78.9 ± 18.8	81.6 ± 15.0	76.9 ± 20.9	79.9 ± 17.7§
Worries about future	49.6 ± 27.3[a]	49 7 ± 23.9[b]	61.2 ± 24.4[ab]‡	47.8 ± 24.9	52.5 ± 24.6*
Diet restrictions	67.1 ± 23.2[a]	74.6 ± 20.0[a]	86.4 ± 11.9[a]‡	67.9 ± 21.6	78.1 ± 19.1‡
Daily hassles	68.2 ± 24.4	66.3 ± 23.5	71.5 ± 19.6	66.9 ± 23.3	67.2 ± 23.5
Positive well-being	77.3 ± 21.2	77.1 ± 19.3	80.7 ± 14.4	76.5 ± 20.7	78.1 ± 18.5
Treatment satisfaction	50.3 ± 34.3	46.1 ± 35.0	51.8 ± 29.8	46.8 ± 37.1	47.6 ± 32.7

Data are means ± SD. Comparisons are based on t test or one-way analysis of variance. *$P < 0.05$; †$P < 0.01$; ‡$P < 0.005$; §$P < 0.06$; means with the same index (a, b) are significantly different at $P < 0.05$ (Scheffé test for pairwise comparison of means).

Table 5—*Statistical associations between late complications and quality-of-life subscales*

	Retinopathy				Nephropathy	
	None	Nonproliferative	Proliferative	Blindness (at least one eye)	Normal or microproteinuria	Macroproteinuria, renal insufficiency, renal replacement therapy
n	335	165	116	31	580	76
Social relations	86.8 ± 14.6[a]	84.9 ± 15.1[b]	82.9 ± 17.3[c]	72.9 ± 25.5[abc]‡	85.4 ± 15.7	81.5 ± 19.2
Leisure time flexibility	81.3 ± 18.3[a]	77.5 ± 20 4[b]	73.5 ± 23.8[ac]	49.9 ± 30.0[abc]‡	78.7 ± 20.6	66.0 ± 26.9‡
Physical complaints	81.9 ± 16.5[a]	80.1 ± 17.2[b]	73.3 ± 22.3[abc]	61.2 ± 23.8[abc]‡	80.3 ± 17.6	66.8 ± 25.3‡
Worries about future	55.1 ± 24.1[a]	49.1 ± 23.5[b]	46.8 ± 25.8[ac]	30.9 ± 21.8[abc]‡	52.2 ± 24.2	39.1 ± 27.0‡
Diet restrictions	74.4 ± 21.9	75.0 ± 18.0	73.8 ± 21.2	70.1 ± 16.7	74.1 ± 20.8	75.0 ± 19.3
Daily hassles	67.0 ± 23.4	68.9 ± 22.8	67.7 ± 23.3	60.0 ± 28.2	66.8 ± 23.2	69.6 ± 25.0
Positive well-being	78.2 ± 18.7	79.6 ± 17.4	74.7 ± 21.0	70.6 ± 26.0*	78.1 ± 18.2	69.4 ± 25.3†
Treatment satisfaction	51.0 ± 33.8	45.4 ± 31.4	40.4 ± 37.6	51.0 ± 37.4*	48.4 ± 34.2	39.6 ± 36.0§

Data are means ± SD. Comparisons are based on *t* test or one-way analysis of variance. *$P < 0.05$; †$P < 0.01$; ‡$P < 0.001$; §$P < 0.06$; means with the same index (a, b, c) are significantly different at $P < 0.05$ (Scheffé test for pairwise comparison of means).

related subscales were not affected by this social condition.

A comparison of patients with a flexible adaptation of insulin dosages according to carbohydrate intake and patients with a more rigid insulin therapy indicated that both groups had different treatment goals (Fig. 1). Patients with a flexible insulin therapy were aiming to a higher degree at a flexible diet, flexible leisure time, and physical fitness. Patients without a flexible therapy were striving more intensively for constant blood glucose values, the avoidance of mild hypoglycemia, a low frequency of blood glucose self-monitoring, and the concealment of diabetes in public. Comparison of satisfaction scores indicated that patients without a flexible insulin therapy were more satisfied with the stability and the level of their blood glucose control than patients with a flexible therapy, who were more satisfied with the flexibility in their nutrition and during their leisure time (Fig. 2).

Patterns of treatment goals and interaction effects

A categorization of patients by cluster analysis revealed two groups with different treatment goals (Fig. 3) (39): patients with avoiding treatment goals were aiming at good and stable blood glucose levels, very much like those patients with active goals, but at the same time intending to avoid frequent self-monitoring, to avoid even mild hypoglycemia and to conceal their disease from other people. ANOVA revealed a two-way interaction between treatment goals and insulin therapy on treatment satisfaction ($P < 0.01$; Fig. 4). Patients with avoiding treatment goals achieved the lowest scores under intensified insulin therapy. Patients with active goals achieved the highest scores when intensively treated.

Avoiding treatment goals were more frequent in patients with a low social status and in patients with conventional insulin therapy (data not shown; $P < 0.001$). Patients with avoiding treatment goals had higher treatment satisfaction scores but a less favorable glycemic control and poorer scores on all six quality-of-life subscales (Fig. 5).

CONCLUSIONS — The present study describes the validation of a diabetes-specific quality-of-life questionnaire comprising 64 items on daily restrictions and burdens, individual treatment goals, and preference-weighted treatment satisfaction in 657 representative patients with type 1 diabetes.

The questionnaire took ~10–20 min to complete. Only 27 patients (3.9%) declined to complete the questionnaire and a further 18 patients (2.6%) did not answer more than three questions. Considering that the study population did not represent a selection of highly motivated patients but a representative sample at the community level, the acceptance was very satisfactory.

The factor analysis of the 44 items dealing with daily burdens and restrictions

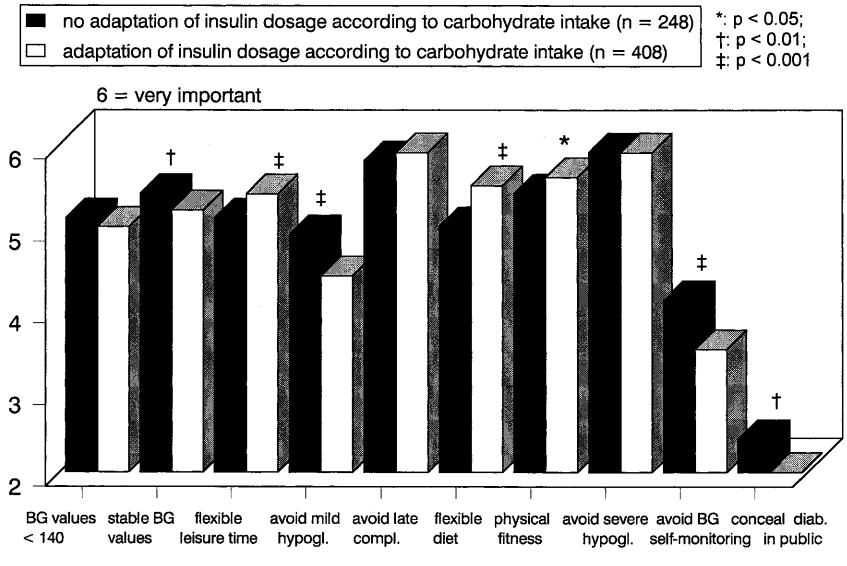

Figure 1—*Treatment goals in patients with different flexibility in insulin treatment.*

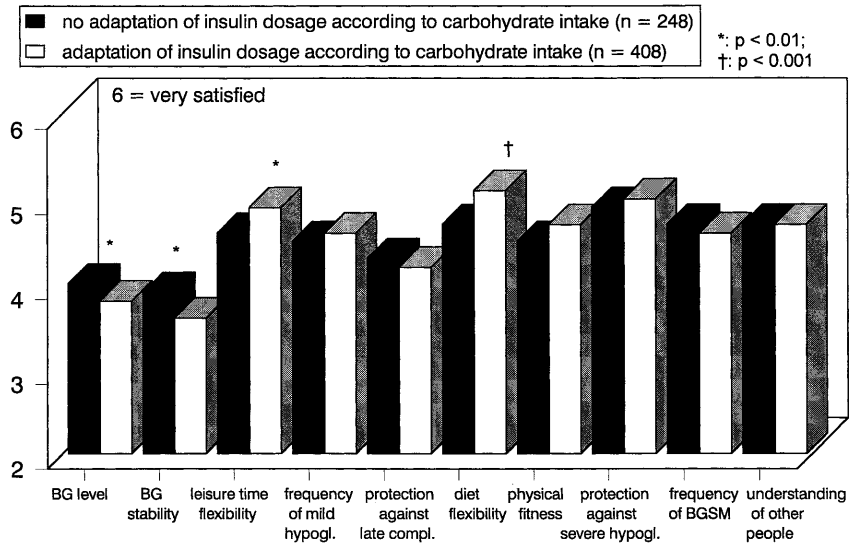

Figure 2—*Treatment satisfaction in patients with different flexibility in insulin treatment.*

led to six subscales, which adequately reflect the theoretical concept of quality of life comprising physical, psychological, and social burdens as well as limitations in daily functions. Of the 44 items, 5 had to be eliminated because of low factor loadings or unsatisfactory item-scale correlation, and six items revealed high loadings on two factors. These items reflect very important burdens for patients (e.g., physical troubles, problems during traveling), and it seems justified to maintain them within the subscales according to the highest factor loading.

All six newly developed subscales had high degrees of internal consistency. Two subscales showed homogeneity coefficients (Cronbach's α) of >0.70, four subscales achieved values of >0.80. The high intercorrelations and a factor analysis of the six components confirmed that the subscales characterize a homogeneous construct of diabetes-specific quality of life. However, further studies are progressing, which include selected new items to further improve homogeneity and distinction of subscales.

The statistical correlations with the already validated positive well-being scale supported the validity of the newly generated subscales. Age and diabetes duration were significantly associated with physical complaints and leisure time flexibility. The latter factor also incorporates items regarding physical fitness as an important prerequisite for an active leisure time. Not surprisingly, age and diabetes duration were more strongly associated with physical components than with other quality-of-life dimensions, providing further evidence for construct validity. In accordance with other studies (13,14,17), glycemic control was only weakly correlated with aspects of quality of life, underlining that glycemic control and quality of life are distinct outcome parameters with different implications. The strongest correlation with HbA_{1c} ($r = 0.24$) emerged with the physical complaints subscale. Actually, many items of this component refer to hyperglycemic symptoms. The frequency of mild hypoglycemia seemed to have a stronger impact on treatment satisfaction than on different dimensions of quality of life.

The results of the discriminant validation supported the relevance and the benefits of disease-specific scales compared to generic measures.

A flexible insulin therapy and, even more important, a liberalized diet based on self-adaptation of insulin dosages according to carbohydrate intake were most strongly associated with better quality-of-life scores in different domains. This is in accordance with other studies indicating that diet is still the most inconvenient aspect of diabetes treatment (44,45). Chantelau et al. have shown in two studies of IDDM patients that dietary barriers may be overcome by intensifying insulin therapy (45,46). In one study, using a German version of the DQOL, the authors found an improved quality of life after intensification of insulin therapy based on a structured treatment and teaching program (46). Mühlhauser et al. (47) have shown that under the conditions of such a structured program for intensified insulin therapy, liberalization of the diabetes diet is not associated with adverse effects on glycemic control. In sharp contrast, the DCCT did not find any difference in quality of life between conventional and intensive diabetes treatment (14). Noteworthy, DCCT researchers even expected to find less favorable results in intensively treated patients. However, regarding diet strategies, the DCCT relied on the recommendations of the American Diabetes Association (48), including a complex system of food

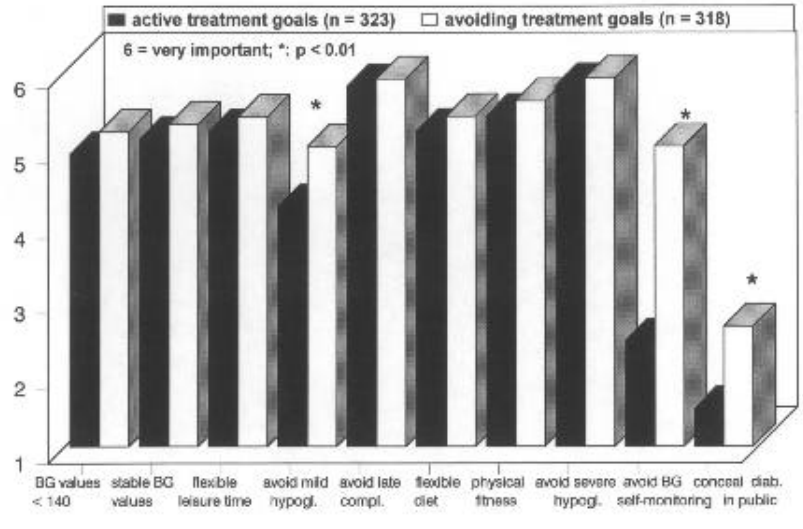

Figure 3—*Different patterns of treatment goals revealed by cluster analysis.*

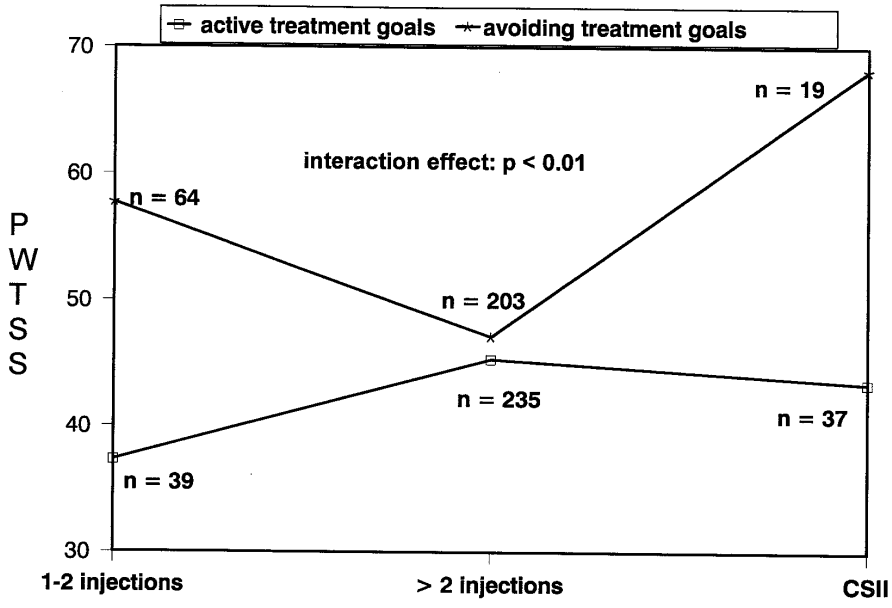

Figure 4—*Interaction of treatment goals and therapy regimen on PWTSS.*

exchange lists and imposing high demands on patient motivation. In addition, patients in the intensive treatment group were requested to follow meal planning strategies (49). Even though the DCCT intended to tailor diet prescriptions to the individual needs and lifestyles, patients had to follow a meal plan which "emphasizes consistency and regularity of caloric and carbohydrate intake" (50). This approach contrasts sharply with the liberalized diet (no meal planning, day-to-day variation of the number of meals, skipping main meals, moderate consumption of sugar-containing food), which was offered to many patients of the present population within structured treatment and teaching programs (47).

In the present study, patients who did not follow a meal plan, nearly identical with patients performing a flexible adaptation of insulin dosage according to carbohydrate intake, scored better on different quality-of-life subscales (data not shown) without adverse effects on HbA_{1c} levels. It might be speculated that the greater demands of intensive insulin therapy (e.g., frequent injections and self-monitoring) can only be efficiently balanced, in terms of quality of life, when a flexible diet and a flexible lifestyle is achieved. The results of the present validation indicate that not only diet-related burdens can be reduced by flexible treatment strategies, but also restrictions regarding leisure time flexibility, restrictions in social relations, and worries about the future, which are mainly based on the anticipation of developing late complications.

As expected, the presence of late complications was strongly associated with different quality-of-life subscales. Again, with respect to discriminant validity, the diabetes-specific scales confirmed their superiority over generic measures like the positive well-being scale. If patients with retinopathy or foot ulcer tend to report a better psychological well-being than those without complications, as observed by Bradley and Lewis (20), it seems that the general well-being measures must be affected by variables unrelated to diabetes and its treatment (e.g., social support, general health beliefs).

In accordance with the DCCT results obtained by the DQOL (14), the frequency of severe hypoglycemia had no significant impact on the quality of life of patients. However, in this study there were only 12 patients with more than two events of severe hypoglycemia (glucose intravenous or glucagon injection) during the year preceding the study. In the DCCT study, a frequency of three episodes of severe hypoglycemia per year (coma or seizure) was suggested as a threshold for a more evident deterioration of quality of life (14).

A lower social status was significantly associated with less favorable scores regarding different quality-of-life subscales and a higher preference for avoiding treatment goals. Regarding treatment satisfaction, further analyses (33) indicated that patients with a lower social status were less satisfied with their flexibility during leisure time ($P < 0.01$) but more satisfied with their perceived protection against late complications ($P < 0.05$), despite higher HbA_{1c} levels ($r = -0.19$ for total score of social status and HbA_{1c}; $P < 0.001$). The specific preferences of patients with a lower social status for certain treatment goals might reflect deficits in health motivation (51). In addition, if patients with a lower status feel more protected against late complications

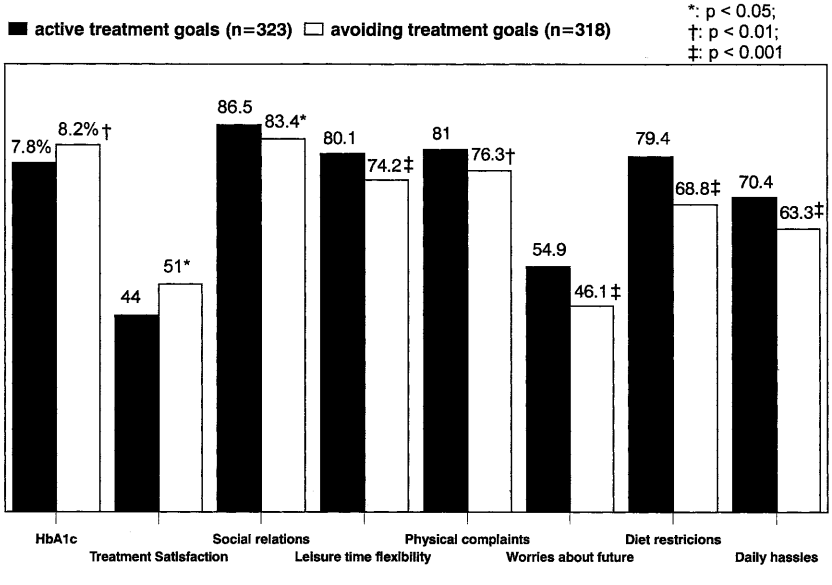

Figure 5—*Difference between patients with active and avoiding treatment goals.*

despite higher HbA_{1c} levels, they might prefer coping strategies relying on unrealistic optimism.

In general, it is remarkable that not the type of treatment regimen but the frequency of mild hypoglycemia and HbA_{1c} values demonstrated the strongest statistical association with treatment satisfaction. These results confirm the assumption that perceptions of satisfaction have different implications than perceptions and descriptions of burdens or restrictions. Treatment satisfaction is predominantly based on comparisons patients make and does not necessarily reflect good medical treatment (29). A certain treatment may have severe disadvantages (e.g., conventional insulin therapy in type 1 diabetic patients), but from the patients' perspective it may be satisfactory if they don't know of any better alternatives. Becoming acquainted with a new therapy that is associated with certain benefits (e.g., liberalization of the diet based on intensified insulin therapy), patients are likely to change their perceptions. In addition, patient expectations are likely to modify their perceptions of treatment benefits, and these expectations are subject to manipulation by certain information given by physicians or other significant people (52). This could be the reason why the treatment with insulin lispro led to a greater treatment satisfaction without improving quality of life (11). Furthermore, it seems that treatment satisfaction does rather reflect a personal assessment within a certain frame of reference than a temporary description of burdens and restrictions (28). In the present study, living with a partner as an indication of social support was significantly associated with higher positive well-being scores and treatment satisfaction, whereas treatment regimen was not associated with any of these scales.

The most important advantage of preference-weighted measures of treatment satisfaction over unweighted measures is based on the opportunity to investigate individual preferences and goals, revealing motivational structures that have to be considered while treating, educating, or counseling patients (12). Disregard of individual preferences would conceal very important attitudes that might indicate why patients are sometimes very satisfied with poor treatment (29) and which motivational deficits need to be considered and managed.

By soliciting patient preferences, perceptions of satisfaction could be evaluated more precisely. For example, patients with seriously impaired vision (blindness of at least one eye) achieved a degree of treatment satisfaction comparable to those patients without retinopathy. In detail, they were less motivated to achieve flexibility of leisure time ($P < 0.005$) but more eager to avoid mild hypoglycemia ($P < 0.06$). With respect to treatment satisfaction, patients with blindness in at least one eye were less satisfied with their leisure time flexibility and physical fitness ($P < 0.05$), compared with patients without retinopathy, but they showed a tendency to greater satisfaction with the level and the stability of their blood glucose control. Therefore, keeping in mind the different implications of perceptions of burdens and restrictions compared with perceptions of satisfaction, certain patterns of individual treatment goals may lead to high satisfaction scores despite lower levels of quality of life due to less flexible treatment regimen or diabetic complications.

Because the validation of the DSQOLS was performed in a cross-sectional study, sensitivity could not be investigated. However, the university diabetes center in Frankfurt used the questionnaire to evaluate a structured inpatient treatment and teaching program for type 1 diabetic patients (53). A preliminary follow-up of 77 patients after participation in the program revealed significant improvements regarding treatment satisfaction, physical complaints, diet restrictions, worries about future ($P < 0.001$), social relations, and positive well-being ($P < 0.01$).

The DSQOLS seems to be superior to other instruments (like the DCCT measure or generic well-being scales) since it has sufficient discriminant validity to distinguish between different treatment and dietary regimen. In addition, based on the assessment of individual treatment goals, the measure allows detailed analyses with regard to motivational structures of patients. The DSQOLS is helpful in identifying patients with certain patterns of treatment goals that predispose them to have more or less benefit from certain treatment strategies. In the light of holistic approaches to patient care (4,6), the questionnaire is not only helpful as an outcome measure but may facilitate long-term care because preferences, treatment satisfaction, and restrictions in quality of life can be elucidated simultaneously. Hence, discrepancies between treatment satisfaction and quality of life can be clarified. If patients with high treatment satisfaction (preventing them from asking for better treatment strategies) but low quality-of-life scores (e.g., patients with low social status) are identified, individual treatment goals may be the key for the individual acceptance of more efficient treatment regimen like intensified insulin therapy. Detection of certain barriers and less favorable goals (i.e., avoidance of frequent self-monitoring, concealment of diabetes in public) will help to focus patient care and counseling on essential behavioral aspects (e.g., supporting acceptance of frequent self-monitoring, improving social competence, etc.).

In summary, the DSQOLS is a reliable and valid instrument for the assessment of diabetes-specific quality of life and treatment satisfaction. Using this scale, the absence of late complications, a higher social status, a flexible insulin therapy, and a liberalized diet were strongly associated with a higher level of quality of life. Assessment of individual treatment goals is helpful to clarify the association between treatment satisfaction and objective metabolic outcomes. High satisfaction scores do not necessarily indicate successful treatment with respect to glycemic control and quality of life. Assessment of individual treatment goals may be helpful to identify motivational deficits and to tailor individual treatment strategies. The DSQOLS was administered in German and the translated items are presented in the APPENDIX. An English version has not yet been validated.

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APPENDIX — Factor loadings for the 44 items regarding daily restrictions and burdens are shown in Table A1. The DSQOLS is shown in Fig. A1.

Table A1—*Factor loadings for the 44 items regarding daily restrictions and burdens*

Original factor item number	Social relations	Leisure time flexibility	Physical complaints	Worries about future	Diet restrictions	Daily hassles
Social-44	0.75	0.30	0.09	−0.02	0.10	−0.04
Social-38	0.72	0.23	0.05	0.06	0.02	0.14
Social-34	0.65	0.20	−0.05	0.16	0.02	0.10
Social-24	0.64	0.38	0.13	−0.02	0.14	0.00
Social-42	0.62	0.13	0.19	0.10	0.13	0.15
Social-6	0.62	0.13	0.19	0.19	0.09	0.07
Social-4	0.62	0.01	0.28	0.10	0.07	0.01
Social-9	0.59	−0.01	0.03	0.16	0.10	0.27
Social-18	0.49	0.17	0.16	0.11	0.02	0.23
Worries-16	0.46	0.23	0.23	0.12	0.30	0.12
Worries-7	0.45	0.18	0.31	0.29	0.21	0.27
Daily functions-35	0.22	0.63	0.09	0.21	0.17	0.22
Daily functions-13	0.25	0.63	0.12	0.12	0.10	0.32
Daily functions-29	0.26	0.61	0.14	0.07	0.27	0.27
Physical-43	0.16	0.60	0.42	0.21	0.13	0.12
Physical-30	0.44	0.44	0.21	0.11	0.22	−0.02
Daily functions-23	0.29	0.43	0.15	0.33	0.03	0.20
Physical-31	0.08	0.39	0.20	0.24	0.21	0.16
Worries-25	0.19	0.39	0.07	0.23	−0.08	0.12
Daily functions-21	−0.18	−0.35	−0.10	0.00	−0.06	0.05
Physical-27	0.14	0.34	0.71	0.14	0.04	0.13
Physical-10	0.14	0.24	0.70	0.16	0.02	0.15
Physical-17	0.03	−0.02	0.61	0.09	0.13	0.20
Physical-14	0.08	−0.05	0.59	−0.01	0.14	0.06
Physical-3	0.16	0.20	0.56	0.16	0.10	−0.03
Physical-19	0.27	0.50	0.55	0.18	0.07	0.03
Physical-22	0.23	0.46	0.55	0.20	0.09	0.01
Physical-26	0.19	0.22	0.45	0.18	−0.05	−0.01
Worries-33	0.05	0.15	0.14	0.81	0.13	0.00
Worries-36	0.15	0.07	0.13	0.72	0.23	0.10
Worries-8	0.08	0.14	0.20	0.71	0.07	0.15
Worries-5	0.14	0.06	0.12	0.69	0.12	0.12
Worries-40	0.23	0.25	0.07	0.67	0.11	0.00
Diet-20	0.14	0.11	0.23	0.12	0.67	0.11
Diet-32	0.12	0.15	−0.01	0.22	0.66	0.29
Diet-41	0.11	0.15	0.07	0.13	0.58	0.09
Diet-2	0.15	−0.13	0.17	0.23	0.47	0.43
Diet-37	0.08	−0.30	0.15	−0.05	−0.47	0.30
Diet-15	0.20	0.31	0.27	0.12	0.45	0.00
Daily functions-1	0.11	−0.06	0.22	0.00	0.24	0.12
Daily functions-39	0.18	0.20	−0.04	0.13	0.15	0.67
Daily functions-11	0.10	0.17	0.29	0.13	0.10	0.65
Daily functions-12	0.21	0.50	0.00	0.09	0.18	0.50
Daily functions-28	0.13	0.15	0.15	0.01	0.06	0.54

Therapeutic goals and therapeutic burdens of patients with insulin-treated diabetes

Name: _____ Date: _____

As we know, diabetes is for most of the people associated with several restrictions and burdens. With the help of this questionnaire we want to understand what goals you are aiming at regarding your treatment, to what extent diabetes bothers you in your daily life and how satisfied you are with your present treatment. You are requested to comment on every statement (please indicate) how far it is applicable to your personal situation. Please answer all questions one after the other without omitting any.

	For me this goal is ...					
With respect to diabetes treatment it is very important to me that, resp. it would be my goal that ...	**very important**	**quite important**	**rather important**	**rather unimportant**	**quite unimportant**	**totally unimportant**
1. my blood glucose values are always below 140 mg%.	☐	☐	☐	☐	☐	☐
2. my blood glucose values are as constant as possible.	☐	☐	☐	☐	☐	☐
3. I can plan my leisure flexibly.	☐	☐	☐	☐	☐	☐
4. I can avoid even mild hypoglycemia.	☐	☐	☐	☐	☐	☐
5. I can avoid late complications of diabetes in any case, resp. avoid their progress.	☐	☐	☐	☐	☐	☐
6. I can eat flexibly in the way that I can choose the kind, amount and time of the meals.	☐	☐	☐	☐	☐	☐
7. I am as physically fit as possible.	☐	☐	☐	☐	☐	☐
8. I can in any case avoid severe hypoglycemia with loss of consciousness.	☐	☐	☐	☐	☐	☐
9. I have to measure my blood glucose as rarely as possible.	☐	☐	☐	☐	☐	☐
10. other people don't find out that I have diabetes.	☐	☐	☐	☐	☐	☐

How satisfied have you been during the last weeks with ...	**very satisfied**	**quite satisfied**	**rather satisfied**	**rather dissatisfied**	**quite dissatisfied**	**totally dissatisfied**
1. the level of your blood glucose values?	☐	☐	☐	☐	☐	☐
2. the stability of your blood glucose values?	☐	☐	☐	☐	☐	☐
3. the flexibility in planning your leisure?	☐	☐	☐	☐	☐	☐
4. the frequency of mild hypoglycemia?	☐	☐	☐	☐	☐	☐
5. your assurance of being protected against late complications, resp. of being able to avoid their progress?	☐	☐	☐	☐	☐	☐
6. the flexibility of your diet?	☐	☐	☐	☐	☐	☐
7. your physical fitness?	☐	☐	☐	☐	☐	☐
8. your assurance of being protected against severe hypoglycemia with loss of consciousness?	☐	☐	☐	☐	☐	☐
9. the frequency of your blood glucose self-monitoring?	☐	☐	☐	☐	☐	☐
10. the extent to what other people are informed about your diabetes?	☐	☐	☐	☐	☐	☐

Figure A1—*The Diabetes-Specific Quality-of-Life Scale (DSQOLS). (Figure continues on p. 767.)*

Which burdens and restrictions from diabetes and its treatment have you experienced during the last four weeks?

		This statement meets my point of view ...					
		perfectly	quite good	a little	rather not	hardly	not at all
1.	I can't get used to the pricking for blood glucose self-monitoring.	☐	☐	☐	☐	☐	☐
2.	It burdens me that I always have to think about my nutrition.	☐	☐	☐	☐	☐	☐
3.	I suffer from pain because of diabetes.	☐	☐	☐	☐	☐	☐
4.	Because of diabetes the relationship to my partner has become worse.	☐	☐	☐	☐	☐	☐
5.	I am worried about the fact that my life could be shorter because of diabetes.	☐	☐	☐	☐	☐	☐
6.	I have the impression that I am less attractive for others because of diabetes.	☐	☐	☐	☐	☐	☐
7.	Because of diabetes I feel sad or depressed.	☐	☐	☐	☐	☐	☐
8.	I am worried about my future health.	☐	☐	☐	☐	☐	☐
9.	It burdens me how other people react on my diabetes.	☐	☐	☐	☐	☐	☐
10.	I feel tired and exhausted.	☐	☐	☐	☐	☐	☐
11.	It bothers me that I have to spend so much time on my diabetes treatment.	☐	☐	☐	☐	☐	☐
12.	Because of diabetes traveling is complicated and troublesome.	☐	☐	☐	☐	☐	☐
13.	Diabetes prevents me from spontaneous physical activities.	☐	☐	☐	☐	☐	☐
14.	I suffer from the frequent need to discharge urine.	☐	☐	☐	☐	☐	☐
15.	My diet plan forces me to eat even if I am not hungry.	☐	☐	☐	☐	☐	☐
16.	Because of diabetes I feel anxious and threatened.	☐	☐	☐	☐	☐	☐
17.	I suffer from thirst or dry mouth.	☐	☐	☐	☐	☐	☐
18.	Other people have difficulties to understand my problems with the diabetes treatment.	☐	☐	☐	☐	☐	☐
19.	I feel physically ill.	☐	☐	☐	☐	☐	☐
20.	I have to give up tasty food.	☐	☐	☐	☐	☐	☐
21.	In spite of diabetes, I can fulfill the demands of work, school or household very well.	☐	☐	☐	☐	☐	☐
22.	Because of diabetes I often have physical troubles.	☐	☐	☐	☐	☐	☐
23.	Diabetes restrains my future plans.	☐	☐	☐	☐	☐	☐
24.	Because of diabetes I have less contact to friends or acquaintances.	☐	☐	☐	☐	☐	☐
25.	My professional prospects are restricted because of diabetes.	☐	☐	☐	☐	☐	☐
26.	I suffer from frequent infections, itching or alterations of my skin.	☐	☐	☐	☐	☐	☐
27.	I feel dull or sluggish.	☐	☐	☐	☐	☐	☐
28.	I am not satisfied with the amount of time I have to spend for medical consultations.	☐	☐	☐	☐	☐	☐
29.	Because of my disease I can't spend my leisure time the way I would like to.	☐	☐	☐	☐	☐	☐
30.	I feel like a disabled person.	☐	☐	☐	☐	☐	☐
31.	Because of hypoglycemia I feel physically handicapped.	☐	☐	☐	☐	☐	☐
32.	It bothers me that I can't eat like other people.	☐	☐	☐	☐	☐	☐
33.	I am often worried about diabetic late complications.	☐	☐	☐	☐	☐	☐
34.	Because of diabetes other people treat me like a "sick person".	☐	☐	☐	☐	☐	☐
35.	Because of diabetes I can't follow my hobbies the way I would like to.	☐	☐	☐	☐	☐	☐
36.	I often ponder over diabetes and its consequences.	☐	☐	☐	☐	☐	☐
37.	My nutrition is the same as it would be without diabetes.	☐	☐	☐	☐	☐	☐
38.	Diabetes again and again leads me to problems with other people.	☐	☐	☐	☐	☐	☐
39.	It bothers me that I have to take my medical instruments (e.g. syringes) with me whatever I do.	☐	☐	☐	☐	☐	☐
40.	I am often worried about the fact that I could be helpless and needing care subsequently.	☐	☐	☐	☐	☐	☐
41.	I often cannot eat my fill.	☐	☐	☐	☐	☐	☐
42.	Because of diabetes my family-life is affected.	☐	☐	☐	☐	☐	☐
43.	Because of diabetes my physical fitness is restricted.	☐	☐	☐	☐	☐	☐
44.	Because of diabetes it is much harder to make friends.	☐	☐	☐	☐	☐	☐

Figure A1 (continued).

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