

Monitoring and Discussing Health-Related Quality of Life in Adolescents With Type 1 Diabetes Improve Psychosocial Well-Being

A randomized controlled trial

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OBJECTIVE — To test the effects of monitoring and discussing of health-related quality of life (HRQoL) in adolescents with type 1 diabetes in a multicenter randomized controlled trial.

RESEARCH DESIGN AND METHODS — Four centers were randomly assigned to the HRQoL intervention (46 adolescents) or control (45 adolescents) group, with three regular visits scheduled within 12 months in both groups. In the HRQoL intervention group, HRQoL of adolescents was assessed using the Pediatric Quality of Life Inventory, and outcomes were discussed face-to-face during the consultation. The control group received care as usual. Mean differences between the groups at 12 months in physical and psychosocial well-being (Child Health Questionnaire [CHQ]-CF87/PF50, Diabetes-Specific Family Conflict Scale, and Center for Epidemiological Studies Scale for Depression), satisfaction with care (Patients' Evaluation of the Quality of Diabetes Care), and A1C were determined, controlling for baseline scores.

RESULTS — Mean scores on the CHQ subscales of psychosocial health ($P < 0.001$), behavior ($P < 0.001$), mental health ($P < 0.001$), and family activities ($P < 0.001$) improved in the HRQoL intervention group, except for adolescents with the highest A1C values. Adolescents in the HRQoL intervention group reported higher self-esteem (CHQ) at follow-up ($P = 0.016$), regardless of A1C, and were more satisfied with care ($P = 0.009$) than control subjects. No significant differences between the two groups over time were observed in A1C levels.

CONCLUSIONS — Periodic monitoring and discussion of HRQoL in adolescents with diabetes is appreciated and has positive effects on their psychosocial well-being, except for those in poorest control.

Diabetes Care 31:1521–1526, 2008

Hormonal and psychosocial changes related to puberty can seriously complicate diabetes regulation. Indeed, adolescents with type 1 diabetes as a group display the worst glycemic control compared with other age-groups (1,2). From a developmental perspective,

the daily demands of self-regulation can interfere with adolescents' normal routines and friendships, thereby compromising their emotional and social well-being (3). Moreover, teenagers tend to give high priority to fulfilling their psychosocial needs here and now rather than taking preven-

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Received 25 February 2008 and accepted 14 May 2008.

Published ahead of print at <http://care.diabetesjournals.org> on 28 May 2008. DOI: 10.2337/dc08-0394.

Clinical trial reg. no. ISRCTN65138334, www.ISRCTN.org.

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tive action to avoid health risks long term (4). Attaining good health-related quality of life (HRQoL) as well as strict glycemic control is a challenge for adolescents with diabetes, their families, and health care providers.

Periodic evaluation and discussion of the adolescents' HRQoL as an integral part of diabetes care is recommended to ensure recognition of the teenagers' perspective, identify psychosocial barriers, and promote healthy coping (5,6). The utility of such an approach has not been tested in pediatric diabetes, but was shown to be beneficial in pediatric rheumatic patients as well as adult diabetes and cancer patients (7–9). We set out to test the effects of systematic monitoring and discussion of HRQoL of adolescents with type 1 diabetes in a randomized controlled trial. We hypothesized this would have a positive effect on the well-being and satisfaction with care of the adolescents, subsequently improving self-care and glycemic control.

RESEARCH DESIGN AND METHODS

Participants in the age range of 13–17 years were recruited from four pediatric diabetes clinics in the Netherlands. Clinics were selected based on willingness to participate, number of patients, and similar clinical routines. Exclusion criteria were as follows: diabetes duration <6 months, mental retardation, and not fluent in the Dutch language. The study was approved by the medical ethical committees of the participating centers; written informed consent was obtained from patients and parents.

Design

After a baseline assessment of demographics, diabetes duration, and treatment regimen, the four outpatient clinics were randomly assigned to either the control or HRQoL intervention group. There were seven pediatricians in the HRQoL intervention and six in the control group. Center rather than patient randomization

was used to avoid contamination at the pediatricians' level. During the 12-month study period, all adolescents had three regular appointments at 3-month interval. At each consultation, data were gathered on height, weight, A1C levels, and treatment regimen.

Power calculations, taking into account the intercluster correlation ($\rho = 0.006$), indicated that a difference of five points in mean well-being (range 0–100 and $SD = 11$) and a difference of 0.5% in mean A1C ($SD = 1.1$) at a 5% significance level with 80% power could be detected with 21 adolescents in each cluster (hospital) and thus 42 in each group.

HRQoL intervention group

The HRQoL intervention consisted of two parts: 1) monitoring the HRQoL right before the 3-month appointment with the pediatrician and 2) discussion of the HRQoL scores with the teenager during the appointment. The adolescents completed the Pediatric Quality of Life Inventory (PedsQL) Generic and PedsQL Diabetes-specific modules on a computer before the consultation with their pediatrician. The generic module of the PedsQL comprises a Physical and Psychosocial subscale. The latter consists of an Emotional, Social, and School subscale (10).

The Diabetes module contains items on symptoms, treatment barriers, treatment adherence, worries, and communication (11). A total of 51 questions were answered on a five-point Likert scale. The computer program automatically calculated the subscale scores of the PedsQL, between 0 and 100, with higher scores representing better HRQoL. Reports with the outcomes of the PedsQL were printed for the pediatrician and the adolescent to be discussed during the consultation.

Before the study, pediatricians had received a short training on how to interpret and discuss HRQoL scores and were offered a small guide with instructions and a list of the individual items of each PedsQL subscale as a backup for discussing PedsQL scores.

Pediatricians were instructed to start with discussing Generic PedsQL scores, with Dutch norm scores as reference, and respectfully invite the adolescent to comment and discuss the outcomes. Thereafter, the Diabetes-specific subscales of the PedsQL were discussed, exploring possible solutions and actions. Pediatricians were asked to fill out a checklist to document topics and decisions. At the follow-

ing (second and third) appointments, the pediatrician and adolescent could track and discuss changes in PedsQL scores over time (if any).

Patients and parents were informed at the start of the study that parents were welcome to join the consultation during the last 10 min and of course could be present during the whole consultation if so wished by patient and parent.

Control group

The adolescents received care as usual in the control group. To control for answering questions on the computer before the consultation, adolescents completed a lifestyle questionnaire instead of an HRQoL questionnaire on the computer, with items on eating, drinking, leisure activities, sports, and friends. Patients in the control group were informed that the outcomes of this measurement were not to be discussed during the consultation or thereafter.

Outcome measures

Baseline and follow-up assessment took place separate from the clinical appointments. Before the first appointment, baseline measures were assessed by sending adolescents and parents a questionnaire booklet on physical and psychosocial well-being to their home address. After the third appointment, a similar booklet was sent again and returned to the research team. Parent data will be reported elsewhere.

Physical and psychosocial well-being. Physical and psychosocial well-being of the adolescents was measured using the 87-item child report version of the Child Health Questionnaire (CHQ) (CHQ-CF87), covering domains of physical, emotional, social, and mental health, rated over the previous 4 weeks (12). Scores are standardized to 0–100, with higher scores indicating better well-being.

Depression. Depressive symptomatology was assessed with the 20-item Center for Epidemiological Studies scale for Depression (CES-D) (13). Items are scored on the basis of frequency of depressive symptoms reported in the past week, from 0 (never) to 3 (daily). Total CES-D scores range between 0 (no depressive symptoms) to 60 (most frequent/severe depressive symptoms).

Diabetes-specific family conflict. As previous studies have shown that family conflicts contribute to poor well-being and glycemic control (14,15), we decided

to assess the amount of Diabetes-specific family conflicts with the revised version of the Diabetes-Specific Family Conflict Scale (DFCS). The DFCS assesses the degree of family conflict on 19 management tasks, rated on a 3-point scale (14). Scores range from 19 (minimum) to 57 (maximum).

Satisfaction with care. The Patients' Evaluation of the Quality of Diabetes Care (PEQ-D) assesses the patients' judgment about the quality of diabetes care over the past 12 months (16). An example item is "the clarity of the information I receive from my doctor." Items are scored on a five-point Likert scale and summated to calculate overall Quality of Care score, ranging from 0 to 100 (poor to optimal quality of diabetes care).

Glycemic control. Glycemic control was assessed by A1C values that were retrieved from the charts, using the assessment closest to the date of completion of the booklets.

Statistical analysis

Scoring and substitution of missing values was performed according to manuals (12,17). For the CHQ, in the case of <50% missing data per subscale, substitution of the mean was used. For the CES-D and DFCS, we substituted missing data with the mean if <25% of the data were missing. None of the patients had over 25% missing data.

After exploring the change in scores from baseline to follow-up for each group with a paired *t* test or Wilcoxon's signed-rank test in case of non-normality, repeated-measures ANOVA analyses using general linear modeling in SPSS 14.0 were used. The effect of the HRQoL intervention was compared with that of the control group on physical and psychosocial well-being, satisfaction with care, and glycemic control, controlling for baseline levels and baseline characteristics (age, sex, center, ethnic minority, family structure, diabetes duration, and treatment regimen). Multilinear regression analysis was used to examine the possibility of interaction and confounding effects of demographic and diabetes-related variables with the HRQoL intervention and control group.

First, the effect of the HRQoL intervention on the physical and psychosocial health summary and subscale scores was examined, controlling for its baseline score. In the next step, demographic (sex, age, center, ethnic minority, and family structure) and diabetes-related variables (diabetes duration, A1C, and treatment

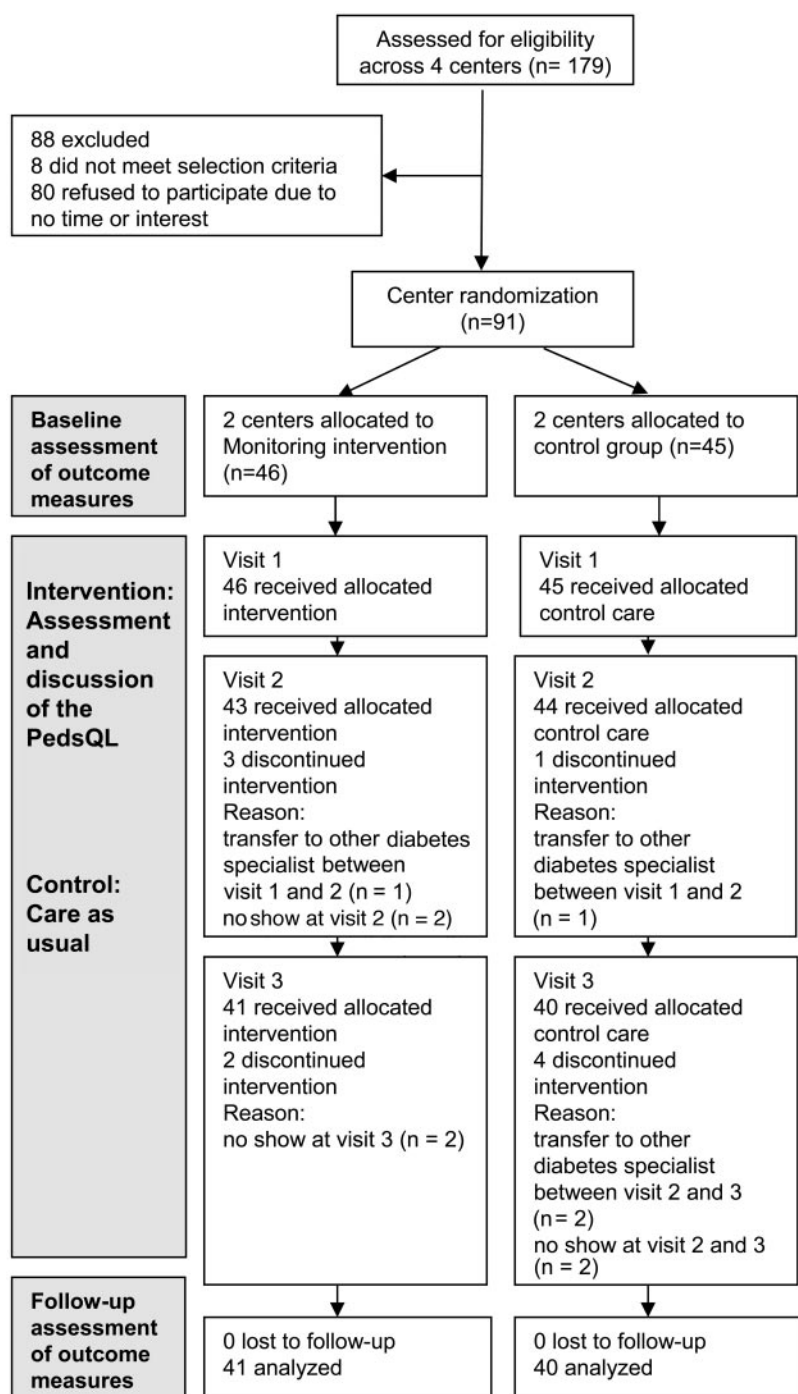


Figure 1—Flow diagram of the participants through each stage of the trial.

regimen), as well as interaction terms with the groups, were added to correct for possible confounders and maintained in the model if significant.

RESULTS— The trial profile is depicted in Fig. 1. Of the 171 patients meeting inclusion criteria, 91 (53%) agreed to participate. Baseline characteristics of the study sample have been reported in detail elsewhere (18). There were no differences

between participants and nonparticipants in sex, age, diabetes duration, or glycemic control. Ten adolescents (five in each group) were lost to follow-up during the year because of transfer to other diabetes specialists or no-show. Those who dropped out had higher A1C levels at baseline than participants (9.9% vs. 8.7%, $P = 0.02$). There were no other differences in demographic and psychosocial variables. The final sample con-

tained 81 patients: 41 in the HRQoL intervention group and 40 in the control group (Table 1). At baseline, there were no significant differences between the four clinics or between the HRQoL intervention and control group.

Physical and psychosocial health

Main effects. Physical and psychosocial well-being scores for the HRQoL intervention and control group at baseline and follow-up are shown in the online appendix A1 (available at <http://dx.doi.org/10.2337/dc08-0394>).

General linear modeling repeated-measure analyses with correction for baseline levels showed a significant effect of group over time for the Psychosocial health summary scale of the CHQ-CH87 ($P = 0.006$) (Fig. 2A). This effect was mainly due to an improvement in the subscales Behavior ($P = 0.007$) and Self-Esteem ($P = 0.016$) for the HRQoL intervention group, while the scores remained unchanged for the control group. **Interaction effects.** Linear regression analyses with inclusion of the interaction terms and possible confounders revealed an interaction effect on the Psychosocial summary scale between the study groups and baseline A1C level ($R^2 = 0.382$, $P < 0.001$). For lower A1C levels, scores of the HRQoL intervention group improved, whereas they remained stable in the control group. Closer inspection of the subscales revealed a significant interaction effect for the subscales Behavior ($R^2 = 0.562$, $P < 0.001$), Mental Health ($R^2 = 0.404$, $P < 0.001$), and Family Activities ($R^2 = 0.370$, $P < 0.001$). For adolescents with highest A1C values ($>9.5\%$), however, there was no difference between baseline and follow-up scores in the HRQoL intervention (or control) group. For the Self-Esteem subscale, we found that scores improved for the HRQoL intervention group between baseline and follow-up, regardless of A1C values ($R^2 = 0.382$, $P < 0.001$).

No differences over time between the two groups on Physical Health, family conflicts (DFCS), or depression (CES-D) were observed.

Satisfaction with care

Adolescents in the HRQoL intervention group reported to be more satisfied with their care (on the PEQ-D) at 1 year follow-up compared with the control group ($P = 0.009$) (Fig. 2B). This effect was independent of A1C, demographic, and diabetes-related variables.

Table 1—Baseline characteristics of participating adolescents by group

	HRQoL intervention group	Control group
Patients (n)	41	40
Girls/boys (n)	19/22	19/21
Age (years)	14.8 ± 1.1	14.9 ± 1.0
BMI (kg/m ²)	21.1 ± 3.6	21.1 ± 3.0
Diabetes duration (years)	7.2 ± 4.3	6.2 ± 4.3
Injections per day (%)		
2	9.8	5
3	51.2	30
4	29.3	45
Pump	9.8	20
A1C (%)	8.6 ± 1.4	8.8 ± 1.3
Single-parent families (n)	5	9
Ethnic minority (n)	4	5

Data are means ± SD unless otherwise indicated. There were no significant differences between the HRQoL intervention and control group.

Glycemic control

At follow-up, mean A1C was 8.4 ± 1.6% for the HRQoL intervention group and 8.3 ± 1.3% for the control group, with no significant difference between the groups in decline in A1C levels over time ($P = 0.54$).

Post hoc analyses

Change in PedsQL scores in relation to CHQ and PEQ-D scores at follow-up in the HRQoL intervention group. To explore if the changes in PedsQL scores were related to CHQ-CF87 (well-being) and PEQ-D (satisfaction with care) scores at follow-up, we used linear regression analyses, controlling for baseline CHQ scores. Change in PedsQL treatment barrier scores were related to change in CHQ Behavior scores ($R^2 = 0.612$, $P < 0.001$; β treatment barriers = 0.218, $P = 0.035$), whereas change in the PedsQL Diabetes module total score was related to the CHQ Self-Esteem subscale scores at follow-up ($R^2 = 0.486$, $P < 0.001$, β total diabetes = 0.478, $P = 0.016$). Change in the Emotional subscale scores of the PedsQL were related to CHQ Mental health subscale scores at follow-up ($R^2 = 0.409$, $P < 0.001$; β emotional = 0.316, $P = 0.029$).

Change in the PedsQL Psychosocial summary score (especially the Emotional and School subscales) was associated with the Family activities subscale of the CHQ at follow-up ($R^2 = 0.693$, $P < 0.001$; β psychosocial = 0.514, $P = 0.026$).

PEQ-D scores at follow-up were not predicted by change in PedsQL scores, suggesting that the reported increased satisfaction with care was independent of changes in HRQoL.

Predictors of A1C at follow-up. Because we did not find a significant change in glycemic control, we collapsed both groups to explore predictors for change in A1C levels. In a forward linear regression analysis, over 20% of the variance in change in A1C was explained by baseline A1C levels and amount of family conflict (DFCS scores) ($R^2 = 0.204$, $P < 0.001$; β baseline A1C = -0.391 , $P < 0.001$; β DFCS = 0.057, $P = 0.024$). A1C explained 14.7% and DFCS scores explained an additional 5.6% of the variance in change.

CONCLUSIONS— This is the first trial to demonstrate the positive effects of periodic assessment and discussion of

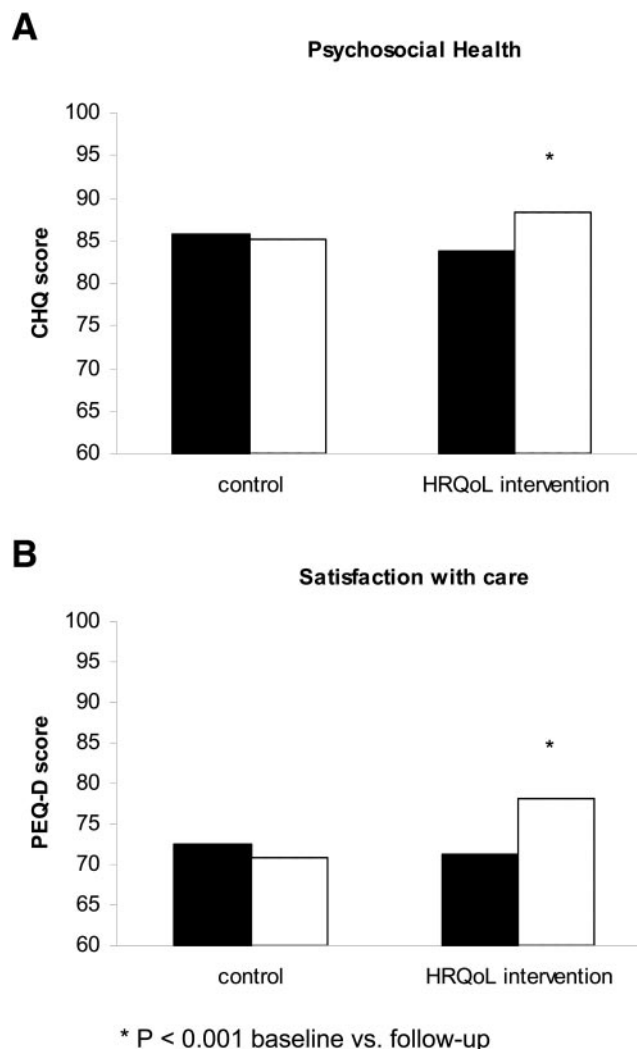


Figure 2—A: CHQ Psychosocial Health sum score at baseline (■) and follow-up (□). CHQ scores were similar at baseline for the control and HRQoL intervention groups. The follow-up scores were significantly higher for the HRQoL intervention group compared with baseline ($P < 0.01$). B: PEQ-D scores at baseline (■) and follow-up (□). PEQ-D scores were similar at baseline for the control and HRQoL intervention groups. The follow-up scores were significantly higher for the HRQoL intervention group compared with baseline ($P < 0.01$). * $P < 0.001$ baseline vs. follow-up.

HRQoL in adolescents with type 1 diabetes as an integral part of diabetes outpatient care. At the 1-year follow-up, patients in the HRQoL intervention group reported significantly fewer behavioral problems, improved self-esteem and mental health, and increased participation in family activities. The adolescents in our study reported relatively high levels of well-being at study entry (18), yet we achieved clinically relevant improvements with effect sizes ranging between 0.36 (moderate) and 0.57 (large). Whether the same or larger effects can be established in teenagers with a less favorable psychological profile remains to be seen.

Interestingly, we found that adolescents with relatively high A1C values at baseline (>9.5%) did not show improvement (nor worsening) of psychosocial outcomes over time. This may reflect higher levels of complexity in these adolescents or may be related to how PedsQL outcomes were discussed. In this group, pediatricians may be inclined to focus on the importance of achieving strict glycemic control, putting less emphasis on psychosocial issues. Unfortunately, we cannot verify whether such differences in communication occurred, as we were not able to record the consultations. Examination of notes made by the pediatricians using a checklist confirmed that HRQoL scores were discussed based on the assessment but not how that was done. Future research should, if possible, include videotaping to observe the behavior of pediatricians and the interaction with the adolescent.

The positive effect of the HRQoL intervention on psychosocial well-being was associated with neither improvement nor worsening of glycemic control. A1C levels remained constant in both groups, in contrast to the often-observed deterioration during puberty. This might be due to a study effect or a selection bias.

The HRQoL intervention was overall well appreciated by the adolescents, independent of their A1C and whether or not there was improvement in psychosocial well-being. Adolescents indicated on the PEQ-D that discussing HRQoL during the consultation helped the pediatricians to be more supportive and offered more opportunities for shared decision-making. Moreover, no adverse effects of the monitoring procedure were reported, in concert with previous studies in adult populations (7,8).

Some limitations of our study need to be mentioned. Selection bias may have af-

ected our results, since about half of the eligible patients decided not to participate in the registered clinical trial. Previous studies in the adolescent population also showed large refusal rates (19,20). Poor glycemic control was obviously not a reason for decline, and the variation among individual adolescents in physical and psychosocial well-being was quite large. It is of note that the adolescents who dropped out of the study did have higher A1C levels at baseline compared with the others.

Another limitation is the fact that we did not assess self-care behavior. We can therefore not exclude the possibility that minor changes in self-management have occurred, although it is unlikely given the stable A1C in both groups. In contrast to our expectation, the HRQoL intervention did not affect glycemic control. We should acknowledge the fact that discussing HRQoL issues does not necessarily lead to talking about diabetes mismanagement (e.g., insulin omission) and indeed pediatricians were not instructed to do so in our study. It would seem worthwhile to test if adding a more focused assessment and discussion of self-care, using a goal-directed "conversation map," facilitates behavior change with subsequent improvements in glycemic control (19).

In line with previous studies, family functioning, along with baseline A1C, proved to be an important determinant of glycemic control at follow-up, with those having fewer family conflicts showing better outcomes (14,21). The PedsQL has good psychometric properties and utility (22), but it contains only one question on family functioning. Expanding the assessment of family functioning as part of periodic monitoring and discussion of HRQoL in teenagers with diabetes should therefore be considered.

Based on a two- to threefold increased rate of depression among teenagers with diabetes (23,24), screening for concurrent emotional problems is recommended in this age-group (5,6). However, in our study, only three patients reported CES-D scores indicative of depression. Future studies should determine if the PedsQL is suitable as a screener for depressive symptoms in adolescents or whether an additional depression screener is needed. In more general terms, further research is needed to test whether systematic monitoring and discussion of HRQoL can effectively help to detect psychological problems at an early stage, thereby preventing further deterioration.

Little is known about the optimal frequency of monitoring HRQoL. The positive results in our study were achieved by monitoring and discussing HRQoL every 3 or 4 months, linked to routine outpatient visits. Further research should test whether less frequent monitoring, for example on an annual basis, produces the same outcomes across different patient groups.

In sum, implementing a computer-assisted HRQoL intervention in routine pediatric diabetes care is feasible, well appreciated by adolescents and providers, and results in significant improvements in psychosocial well-being.

Acknowledgments— This study is supported by the Dutch Diabetes Research Foundation, grant 2003.00.020.

We thank all participating pediatricians and nurses from the following centers for their contribution: Medical Center Alkmaar, Spaarne Ziekenhuis Hoofddorp, and Juliana Kinderziekenhuis Den Haag.

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