# Monitoring of Psychological Well-Being in Outpatients With Diabetes

## Effects on mood, $HbA_{1c}$, and the patient's evaluation of the quality of diabetes care: a randomized controlled trial

FRANÇOIS POUWER, PHD[1,4]
FRANK J. SNOEK, PHD[1,4]
HENK M. VAN DER PLOEG, PHD[1]
HERMAN J. ADÈR, PHD[2]
ROBERT J. HEINE, MD, PHD[3,4]

**OBJECTIVE** — To investigate whether monitoring and discussing psychological well-being in outpatients with diabetes improves mood, glycemic control, and the patient's evaluation of the quality of diabetes care.

**RESEARCH DESIGN AND METHODS** — This study was a randomized controlled trial of 461 outpatients with diabetes who were randomly assigned to standard care or to the monitoring condition. In the latter group, the diabetes nurse specialist assessed and discussed psychological well-being with the patient (with an interval of 6 months) in addition to standard care. The computerized Well-being Questionnaire was used for this purpose. Primary outcomes were mood, $HbA_{1c}$, and the patient's evaluation of the quality of diabetes care at 1-year follow-up. The number of referrals to the psychologist was analyzed as a secondary outcome. Intention-to-treat analysis was used.

**RESULTS** — The monitoring group reported better mood compared with the standard care group, as indicated by significantly lower negative well-being and significantly higher levels of energy, higher general well-being, better mental health, and a more positive evaluation of the quality of the emotional support received from the diabetes nurse. The two groups did not differ for $HbA_{1c}$ or in their overall evaluation of the quality of diabetes care. In the monitoring condition, significantly more subjects were referred to the psychologist.

**CONCLUSIONS** — Monitoring and discussing psychological well-being as part of routine diabetes outpatient care had favorable effects on the mood of patients but did not affect their $HbA_{1c}$. Our results support the recommendation to monitor psychological well-being in patients with diabetes.

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In 1989, representatives of government health departments and patients' organizations from all European countries met with diabetes experts in St. Vincent, Italy, under the aegis of the World Health Organization/International Diabetes Federation (WHO/IDF). This meeting resulted in the St. Vincent Declaration, which aimed to improve both the clinical care and social conditions of people with diabetes through guidelines and recommendations (1). This declaration also contained guidelines to help the diabetes team preserve or improve psychological well-being in diabetic patients. One of these guidelines was that psychological well-being, in addition to the monitoring of diabetes control, needs to be monitored using standardized questionnaires. Although psychological well-being is an important goal of diabetes management, little attention is often given to the psychological implications of diabetes (1,2). The monitoring of psychological well-being can be expected to increase the detection rates of psychological problems and thus facilitate the discussion and consequent treatment of these problems.

Indeed, there is indirect support for the premise that monitoring and discussing psychological well-being in diabetes care could improve clinical outcomes. It is known that the prevalence of depression is increased in people with diabetes, whereas the recognition and subsequent treatment of this condition is hampered in clinical practice (3–5). Depression not only adversely affects the quality of life of diabetic patients, but it also affects treatment adherence and glycemic control and increases health care costs and the risk for diabetic complications (3,6–11).

The routine use of standardized measures of mood in diabetes care has been advocated (12,13), but to our knowledge, this approach has yet to be evaluated. Hence, the aim of our study was to investigate whether the outcomes of outpatient diabetes care can be improved by adding a monitoring procedure for psychological well-being to standard care. Our hypothesis was that this intervention, as compared with standard care alone, would result in improved mood and glycemic control, more favorable patient evaluations of the quality of diabetes care, and an increased use of mental health care.

From the [1]Department of Medical Psychology, Vrije Universiteit Medical Center, Amsterdam, the Netherlands; the [2]Department of Clinical Epidemiology and Biostatistics, Vrije Universiteit Medical Center, Amsterdam, the Netherlands; the [3]Department of Endocrinology, Vrije Universiteit Medical Center, Amsterdam, the Netherlands; and the [4]Research Institute for Endocrinology, Reproduction and Metabolism, Vrije Universiteit Medical Center, Amsterdam, the Netherlands.

Address correspondence and reprint requests to F. Pouwer, EMGO Institute, Vrije Universiteit Medical Center, Van der Boechorststraat 7, 1081 BT, Amsterdam, the Netherlands. E-mail: f.pouwer.emgo@med.vu.nl.

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**Abbreviations:** ANCOVA, analysis of covariance; DNS, diabetes nurse specialist; ENE, energy; ES, effect size; GWB, general well-being; NWB, negative well-being; PAID, Problem Areas In Diabetes Scale; PEQD, Patient Evaluation of the Quality of Diabetes Care; PWB, positive well-being; SF-36, Medical Outcomes Health Survey Short Form 36; W-BQ, Well-being Questionnaire.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

## RESEARCH DESIGN AND METHODS

### Treatments

The study was conducted between May 1997 and December 1999 at the outpatient diabetes clinic of Vrije Universiteit Medical Center, Amsterdam, the Netherlands, which serves ~2,000 diabetic patients. The hospital's ethics committee approved the study. A standard letter was used to invite diabetic patients (aged ≥18 years) to participate ~2 weeks before their regular appointment with the internist. Written informed consent was obtained from all participants. Subjects were randomly allocated to the monitoring condition or to standard care using computer-generated random numbers. Patients who were unable to fill out questionnaires due to visual impairments or language problems were excluded.

The study period was 12 months for each participant. Standard care was defined as regular appointments with an internist (3- to 4-month intervals) and, if needed, other members of the diabetes team, added with at least two 15-min consultations with the diabetes nurse specialist (DNS) in which various topics related to diabetes could be discussed (including psychosocial issues). No formal assessment of psychological well-being was performed. For the intervention group, two monitoring procedures of ~15 min were scheduled in addition to standard care (Fig. 1). The monitoring of well-being was performed by the DNS, who used the computerized Well-being Questionnaire (W-BQ) (14–17). To facilitate the discussion, reference values were used for each W-BQ scale. A score between the null and the 20th percentile was defined as "very low," between the 21st and 40th percentile as "low," between the 41st and 60th percentile as "average," between the 61st and 80th percentile as "high," and between the 81st and 100th percentile as "very high" (17). Nurses were instructed not to use the reference values as diagnostic cutoff scores. They were trained to discuss the results with the patient in an explorative/nonjudgmental way. If indicated, the need for professional psychological support was discussed with the patient. The DNSs were trained by two psychologists (F.P. and F.J.S.) who used role-playing simulations. Skills included discussing results of the computerized assessment and counseling skills, e.g., active listening and exploration of feelings (18,19). At visit 3, the DNS assessed the psychological well-being of all subjects. Scores and actions were documented in the DNSs' charts.

### Demographics, clinical data, and questionnaires

Baseline data concerning marital status, education, height, weight, and history of treatment by a psychologist/psychiatrist were obtained by means of paper-and-pencil questionnaires (completed at home by both groups). Information concerning age, diabetes type, treatment for diabetes, and psychological treatment during the study was obtained from medical charts, as were data regarding retinopathy (background/proliferative), polyneuropathy, nephropathy (microalbuminuria, i.e., urinary albumin 30–300 mg/24 h, or proteinuria, i.e., urinary albumin >300 mg/24 h or serum creatinine >150 μmol/l), coronary artery disease, and hypertension. Glycemic control was determined at all three visits by measuring the percentage of $HbA_{1c}$ ($HbA_{1c}$ ion exchange high-performance liquid chromatography, reference range 4.3–6.1%). The DNSs' charts were used to determine topics of discussion during consultations.

Psychological well-being was monitored using the computerized W-BQ. Three 4-item subscales were calculated (15,16): Negative well-being (NWB), energy (ENE), positive well-being (PWB), and the 12-item overall scale measuring general well-being (GWB). After the three visits, all patients completed the Medical Outcomes Health Survey Short Form 36 (SF-36), in order to assess general mental health (20). This scale was completed anonymously at home to minimize observer bias.

The 14-item Patient Evaluation of the Quality of Diabetes Care (PEQD) questionnaire was completed at home after the first and third visits. The PEQD includes topics such as waiting times, clarity of information, emotional support, and medical-technical competence (21). Subjects evaluated the physician and the DNS using two separate 5-point Likert scales that ranged from 1 to 5 (1 [poor], 2 [fair], 3 [good], 4 [very good], and 5 [excellent]).

Patients in the control group with a low level of psychological well-being who completed the W-BQ at baseline at home may have become more aware of their mood and may then have decided to consult a psychologist. To investigate whether completing the W-BQ at home (without discussing responses with the DNS) had an effect on the use of mental health care, the control group was randomly split into groups C1 and C2. The only difference between C1 and C2 was that subjects in C1 completed the W-BQ and the PEQD at home (after visit 1), whereas the subjects of C2 did not complete both instruments at baseline.

### Data analysis

This study had 90% power to detect a 0.5 SD between the monitoring and standard care group with regard to psychological well-being, PEQD, or $HbA_{1c}$ (i.e., a difference of 0.7%). Analysis was by intention to treat and complete case analysis (22). Differences in demographic and clinical characteristics were determined using Student's *t* test for continuous data and $\chi^2$ and McNemar tests for percentages. The effects of the intervention on the primary outcome measures were assessed using analysis of covariance (ANCOVA), which focused on the effect of group membership on the follow-up measures while controlling for the analogous baseline score as a covariate. We used an $\alpha$ level of 0.05, two-sided hypothesis testing and 95% confidence intervals. Effect sizes (ESs) were used as a supplement to standard statistical testing, in order to interpret the clinical relevance of differences in primary outcomes (23). ES was defined as the difference between the means of the monitoring and standard care group at visit 3 (both adjusted for corresponding baseline values) and divided by the pooled pretreatment standard deviation for both groups. An ES of 0.20 was defined as a small but clinically meaningful effect size, 0.50 was defined as a moderate effect size, and ≥0.80 was defined as a large effect size (23).

## RESULTS

### Baseline comparability and drop-out

Of 461 invited patients, 23 (5%) were excluded: 13 did not speak Dutch sufficiently, and 10 had reading/vision problems. This left 438 patients who met entry criteria, but 38 refused to participate (trial profile). Those who were excluded or refused to participate were significantly older and more often had

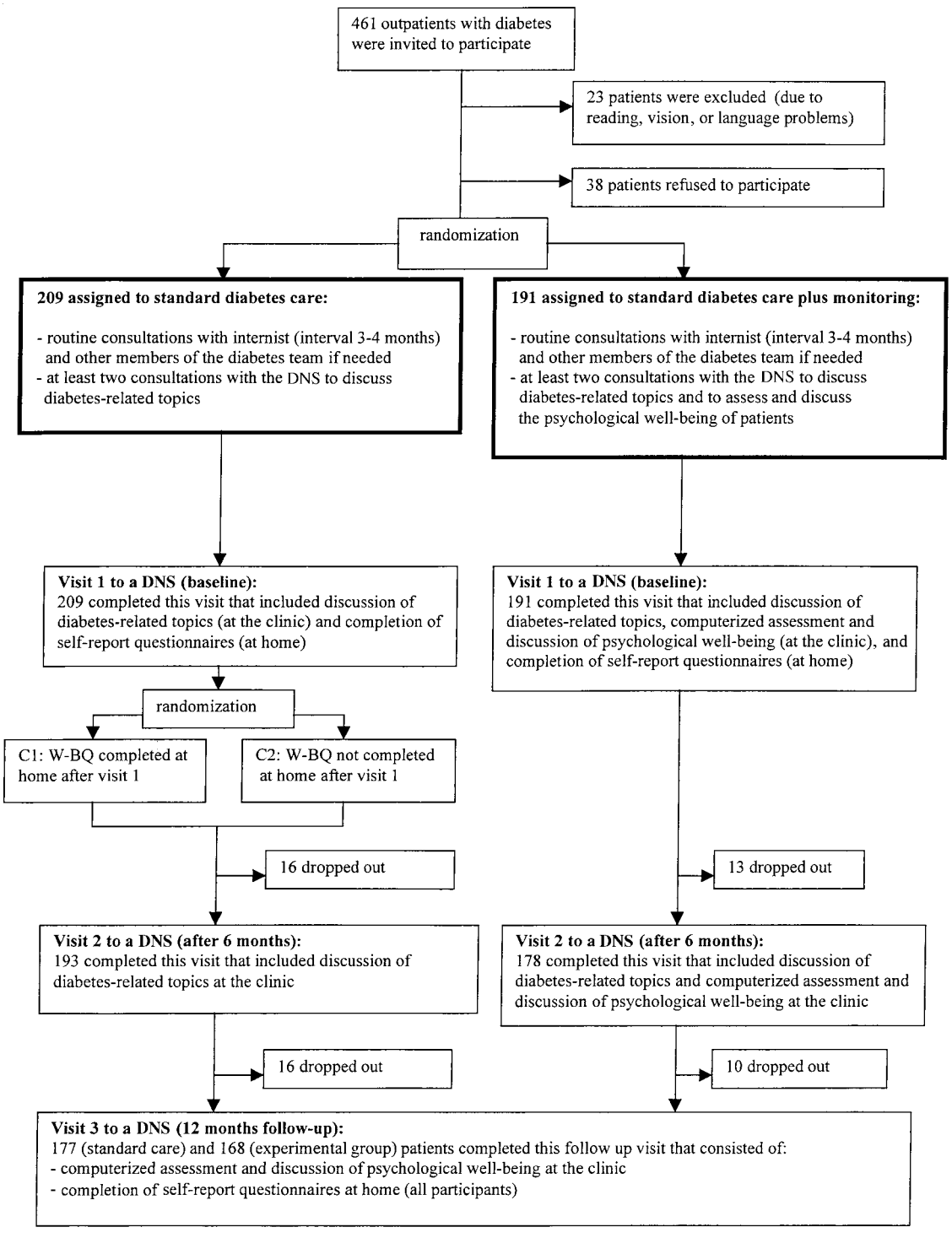


**Figure 1**—*Profile of the randomized controlled trial.*

type 2 diabetes ($P \leq 0.001$) (Table 1). The monitoring group did not differ significantly from the standard care group with regard to demographic, clinical, and psychological variables at baseline (Tables 1 and 2). For both groups, the mean duration of the interval between visits 1 and 2 was 8 ± 3 months and between visits 2 and 3 was 7 ± 3 months. A total of 55 (12%) participants dropped out or were excluded from the trial after visit 1 for the following reasons: 18 found the investigation to be too time consuming, 16 moved, 10 died, 4 subjects in the standard care group appeared to have problems with reading (visual acuity/language) at visit 3, 4 subjects did not make an appointment with the physician, and 3 visited the physician but not the DNS. In total, 345 subjects, or 79% of those eligible, completed the study.

**Table 1—*Baseline characteristics***

| | Monitoring group | Standard care group | Excluded group | Refusers |
|---|---|---|---|---|
| *n* | 191 | 209 | 23 | 38 |
| Demographics | | | | |
| Age (years) | 53 ± 16 | 54 ± 18 | 65 ± 15* | 62 ± 17* |
| Sex (M/F) | 82/109 | 108/101 | 11/12 | 17/21 |
| Marital status (single/partner) | 65/104 | 74/118 | — | — |
| Education (years) | 12 ± 3.6 | 11 ± 3.4 | — | — |
| Clinical values | | | | |
| $HbA_{1c}$ (%) | 7.8 ± 1.4 | 7.8 ± 1.3 | 8.8 ± 2.2 | 7.7 ± 1.4 |
| BMI (kg/m$^2$) | 28 ± 7.2 | 28 ± 6.7 | — | — |
| Type of diabetes (1/2) | 80/111 | 86/123 | 1/22* | 11/27 |
| Type 2 treated with insulin | 97 (87) | 106 (86) | 19 (86) | 21 (78) |
| Retinopathy | 52 (28) | 74 (36) | 10 (44) | 12 (33) |
| Hypertension | 85 (46) | 104 (52) | 12 (55) | 13 (35) |
| Cardiovascular disease | 45 (24) | 54 (26) | 6 (26) | 13 (35) |
| Nephropathy | 46 (25) | 53 (26) | 9 (39) | 11 (30) |
| Neuropathy | 32 (17) | 41 (20) | 6 (26) | 7 (19) |
| Treated by psychologist/psychiatrist (ever) | 34 (18) | 28 (13) | 4 (17) | 8 (21) |

Data are *n*, means ± SD, or *n* (%). *$P \leq 0.001$ compared with all participants (of both groups).

## Primary outcomes

At visit 3, the monitoring group reported significantly lower NWB and significantly higher ENE and GWB than the standard care group, after adjusting for the corresponding baseline scores (Table 2). In the monitoring group, the mean for NWB decreased from 3.2 (visit 1) to 3.1 (visit 2) and then to 2.6 (visit 3). ENE and GWB also showed small, stable improvements during the study. ESs ranged from 0.18 to 0.29, indicating small, clinically meaningful differences. The monitoring group also had a significantly higher level of mental health after adjusting for GWB scores at visit 1 (Table 2). No statistically significant differences between groups were found for $HbA_{1c}$, PWB, or both PEQD scales. However, additional ANCOVAs with PEQD item 8 (emotional support by DNS) showed that the monitoring group reported a more favorable evaluation of the quality of the emotional support received from the DNS at follow-up compared with the standard care group, after controlling for baseline PEQD item 8 (3.5 vs. 3.0, respectively, $P = 0.045$). In the subgroup with relatively low psychological well-being at baseline (NWB >4.0), the means were 3.6 vs. 2.6 ($P = 0.007$).

## Secondary outcomes

Both standard care subgroups C1 (W-BQ completed at home after visit 1) and C2 (no baseline W-BQ) did not differ significantly in regard to the number of referrals to a psychologist during the study or on the primary outcomes of the study (data not shown).

The number of subjects who were being treated by the psychologist (including admissions interview) increased in the monitoring group from 9 (5%) at visit 1 to 36 (20%, $P \leq 0.001$) between visits 1 and 2 and then decreased to 24 (14%) between visits 2 and 3. However, in the standard care group, the number of subjects remained stable: 8 (4%) on visit 1, 10 (5%) between visits 1 and 2, and 9 (5%) between visits 2 and 3. For those who visited the psychologist, the mean number of visits to the psychologist was 2.4 ± 1.4 (monitoring) and 3.4 ± 4.1 (standard care, NS). In the monitoring group, the reasons for referral, as described in the psychologist's charts, were depressed mood ($n = 15$), fear of complications ($n = 5$), eating disorder ($n = 4$), marital problems ($n = 2$), not accepting diabetes ($n = 3$), and agoraphobia ($n = 1$). For the standard care group, the reasons were depressed mood ($n = 5$), fear of complications ($n = 1$), eating disorder ($n = 1$), injection phobia ($n = 1$), addiction ($n = 1$), and schizophrenia ($n = 1$).

During the study, subjects in the monitoring group had an average of 1.4 ± 2.6 extra visits and 2.2 ± 4.1 telephone calls with the DNS compared with a mean of 1.1 ± 1.8 extra visits and 1.5 ± 3.7 telephone calls in the control group (NS for both). The DNSs discussed psychological well-being with all subjects in the monitoring group (visits 1 and 2) compared with 23% (43/184) at visit 1 and 26% (46/175) at visit 2 in the standard care group ($P \leq 0.001$ for both comparisons). Based on the DNSs' charts, it appeared that three topics were less often discussed in the monitoring condition than in the standard care group. They were insulin regimen/glycemic control (visit 1: 28% [51/182] vs. 44% [80/184]; visit 2: 24% [39/165] vs. 46% [80/175]), self-monitoring of blood glucose (visit 1: 8% [15/182] vs. 16% [30/184]; visit 2: 7% [12/163] vs. 21% [36/175]), and injection technique (visit 1: 12% [21/182] vs. 21% [39/184]; visit 2: 6% [9/163] vs. 12% [21/175]) for the monitoring versus standard care group, respectively, with all differences significant at $P \leq 0.05$. Additional ANCOVAs in both groups, with discussion of one of the topics (yes/no) as a fixed factor and the primary outcomes as dependent variables (using the corresponding baseline score as a covariate), showed that the differences in these discussed topics had not significantly influenced the primary outcomes (data not shown).

Although our trial had not been designed for this purpose, we conducted additional analyses to explore the effective ingredient(s) of our intervention. In multivariate analyses, the 12-item GWB scale was used as the only dependent variable in order to limit the number of analyses. Firstly, a subgroup with good psychological well-being at baseline was selected (highest quartile GWB scores ranging from 31 to 36). It appeared that one patient was referred to a psychologist during the study, and the scores of this patient were excluded from these analyses. ANCOVAs with the remaining subjects showed a significant favorable effect of the monitoring intervention on GWB (31.6 vs. 28.1 in the control group, $P = 0.004$).

We also conducted a 2 × 2 ANCOVA with group (experimental/control) and referral to a psychologist (yes/no) as independent variables. In this analysis, group was significantly associated with GWB (follow-up) after controlling for baseline GWB, sex, and referral to psychologist, with a mean of 24.3 (95% CI 23.5–25.0) in the experimental group and 20.4

**Table 2—*Primary outcome measures for the monitoring and standard care conditions***

| Measures | Monitoring group ($n$ = 191) | Standard care group ($n$ = 101/209) | Adjusted difference | $P$ | ES |
|---|---|---|---|---|---|
| NWB | | | | | |
| Baseline | 3.2 (2.8–3.6) | 3.1 (2.4–3.8) | | | |
| Visit 2 | 3.1 (2.7–3.5) | — | | | |
| Follow-up* | 2.6 (2.3–2.9) | 3.5 (3.0–3.9) | 0.9 (0.1–1.2) | 0.002 | 0.29 |
| ENE | | | | | |
| Baseline | 7.2 (6.7–7.6) | 7.2 (6.5–7.9) | | | |
| Visit 2 | 7.5 (7.0–8.0) | — | | | |
| Follow-up* | 7.6 (7.3–7.9) | 7.0 (6.5–7.5) | 0.6 (0.0–1.2) | 0.045 | 0.18 |
| PWB | | | | | |
| Baseline | 8.0 (7.6–8.4) | 7.7 (7.1–8.3) | | | |
| Visit 2 | 7.9 (7.5–8.3) | — | | | |
| Follow-up* | 8.5 (8.2–8.8) | 7.9 (7.4–8.4) | 0.6 (0.0–1.1) | 0.057 | 0.20 |
| GWB‡ | | | | | |
| Baseline | 23.9 (22.8–25.0) | 23.8 (22.1–25.6) | | | |
| Visit 2 | 24.2 (23.1–25.4) | — | | | |
| Follow-up* | 25.1 (24.4–25.8) | 22.9 (21.8–23.9) | 2.2 (0.9–3.5) | 0.001 | 0.29 |
| Mental health | | | | | |
| Baseline | — | — | | | |
| Follow-up† | 73.4 (71.2–75.6) | 67.6 (64.0–71.1) | 5.8 (1.7–10.0) | 0.006 | — |
| Quality of care, physician | | | | | |
| Baseline | 47.7 (45.6–49.7) | 50.1 (47.3–52.9) | | | |
| Follow-up* | 47.5 (45.8–49.2) | 45.5 (43.2–47.8) | 2.0 (−0.8–4.9) | 0.165 | 0.17 |
| Quality of care, diabetes nurse | | | | | |
| Baseline | 51.5 (49.2–53.8) | 50.9 (47.8–54.1) | | | |
| Follow-up* | 49.5 (47.7–51.2) | 47.1 (44.7–49.4) | 2.4 (−0.5–5.3) | 0.105 | 0.22 |
| $HbA_{1c}$ | | | | | |
| Baseline | 7.8 (7.6–8.0) | 7.8 (7.7–8.0) | | | |
| Visit 2 | 7.8 (7.6–8.0) | 7.7 (7.5–7.9) | | | |
| Follow-up* | 7.7 (7.6–7.9) | 7.7 (7.6–7.9) | 0.0 (−0.2–0.2) | 0.819 | 0.00 |

Data are means (95% CI). Means at follow-up and mean differences at follow-up were adjusted for *corresponding baseline scores or †GWB at baseline using ANCOVA. ‡Calculation of GWB: 12 − NWB + ENE + PWB.

(17.7–23.0) in the control group. As expected, those who were referred to a psychologist during the study had lower psychological well-being at visit 3 than those who were not (20.4 [17.7–23.0] vs. 24.3 [23.6–25.0]). The interaction between group and referral to a psychologist was not statistically significant ($P$ = 0.08), but suggested that subjects who were referred to a psychologist in the control group had a lower well-being than those in the experimental group who were referred to a psychologist (17.6 vs. 23.1).

**CONCLUSIONS** — Our data suggest that monitoring and discussing psychological well-being had favorable effects on the mood of the patients but not on their glycemic control. Subjects in the monitoring group had significantly more positive evaluations of the quality of the emotional support given by the DNS, which provides further support for the intervention.

We consider our analyses as conservative, as the interval between the intervention (first/second visit) and follow-up was relatively long for most subjects (~6 months). The beneficial effects of the monitoring procedure may have been more pronounced in the earlier phases of the study. We also need to appreciate the fact that the study was conducted in a tertiary diabetes clinic where patients already had easy access to a psychologist. We acknowledge that in many clinics, diabetes health care teams cannot easily refer patients to a psychologist when needed. Consequently, we can assume that the implementation of a monitoring procedure for psychological well-being and the standard availability of psychological services may result in greater improvements in the mood of diabetic patients in these clinics. Our intervention had no effect on $HbA_{1c}$, but this may be due to a "floor effect"; with an average $HbA_{1c}$ of 7.8%, there was relatively little room for improvement.

Several potential threats to the internal validity of our study need to be mentioned. Obviously, the trial could not be carried out with concealment of treatment group, which may have caused ascertainment bias (24). Some participants allocated to standard care may have been disappointed and therefore less willing to report improvements. Yet, in practice, none of the participants expressed disappointment or a wish to change their study group. The drop-out rate was low. Moreover, we emphasize that both groups did not differ in their access to a DNS or psychologist. A tendency to pretend/suggest an improved mood during the follow-up assessments with the DNS by subjects of

the monitoring group may also have biased our results (social desirability). However, results with the computerized W-BQ were replicated with the SF-36, which was completed anonymously at home without discussion of the score. This replication makes it unlikely that "faking improvement" biased the results.

Another possible limitation is that all four DNSs involved in this study participated in the monitoring as well as the standard care condition. This was done to avoid a "competent nurse bias"; the nurses may have become more skilled in detecting and discussing emotions during the study, and this may have changed the characteristics of the standard care condition. However, the finding that both the percentage of patients who discussed psychosocial issues with the DNS and the number of referrals to the psychologist remained stable in the standard care group suggests that this was probably not the case. The finding that recognition of psychological problems improved only in the monitoring group leads us to conclude that even nurses who are accustomed to addressing psychosocial issues can benefit from the systematic use of standardized measures of mood. This result corroborates the finding that an educational program concerning recognition and treatment of depression, without the routine use of standardized measures of mood, did not improve recognition of or recovery from depression (25).

With the current design, it is difficult to determine the exact active ingredient of this multicomponent intervention. The results of subgroup analyses in patients with good psychological well-being at baseline who had no contact with the psychologist during the study suggest that the intervention of the DNSs had a unique beneficial effect on the psychological well-being of subjects. Whether the contacts with the psychologist had an additional effect is unclear because the decision to consult a psychologist was not on a random basis but instead could have depended on several factors that were not assessed (e.g., personality and attitude toward mental health care).

One may hypothesize that the beneficial effects of our intervention can be attributed to getting more attention. Indeed, consultation time in the intervention group was twice as long as in the control group. However, the latter group did receive significantly more attention for some diabetes-related topics. When considering the amount of time, they received significantly less attention than the intervention group. We believe that the key difference between both groups was the systematic assessment and discussion of psychological well-being in the intervention group, which did not occur in the control group.

We acknowledge that the methodological quality of our study may have been improved by the use of a scripted verbal intervention, by protocolized discussion of diabetes-related topics, by the use of stricter time schedules, and by the use of videotapes to monitor the quality of the intervention and standard care. We decided not to prescribe the use of standard phrases or topics and strict time schedules, as they could make the care delivered by the nurse too rigid and less adjusted to the needs of the patients. We decided not to use videotapes to monitor the quality of the intervention because being recorded could give patients and DNSs an uneasy feeling of "being watched."

With the use of standardized, computerized instruments such as the W-BQ12, psychological well-being can be assessed in a few minutes. Future studies should investigate whether the monitoring procedure can be further improved. First, because the W-BQ is a measure of general psychological well-being, it may be that diabetes-related emotional problems, such as fear of hypoglycemia or worries about complications, are less easily detected with this instrument (26,27). This idea is supported by the moderate correlations between the W-BQ12 and the Problem Areas In Diabetes Scale (PAID), which is a measure of diabetes-related emotional distress (27). Thus, adding the PAID to the monitoring procedure may further improve the detection rates of diabetes-related emotional problems. Second, further research into the optimal frequency of monitoring psychological well-being is warranted. For example, patients who repeatedly show good psychological functioning may be monitored less intensively, whereas others may benefit from more frequent monitoring.

In sum, we conclude that the implementation of a computer-aided monitoring procedure for psychological well-being had beneficial effects on the mood of diabetes outpatients and on their evaluations of the quality of the emotional support given by the DNS. These results support the recommendation to include this monitoring procedure of psychological well-being in routine diabetes care (1,2,12,13,28).

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**References**

1. Krans HMJ, Porta M, Keen H, Staehr Johansen K (Eds): *Diabetes Care and Research in Europe: The St Vincent Declaration Action Programme Implementation Document*. Copenhagen, WHO, 1995
2. Bradley C, Gamsu DS: Guidelines for encouraging psychological well-being: report of a working group of the World Health Organization Regional Office for Europe and International Diabetes Federation European Region St Vincent Declaration Action Programme for Diabetes. *Diabet Med* 11:510–516, 1994
3. Anderson RJ, Freedland KE, Clouse RE, Lustman PJ: The prevalence of comorbid depression in adults with diabetes: a meta-analysis. *Diabetes Care* 24:1069–1078, 2001
4. Kessler D, Lloyd K, Lewis G, Gray DP: Cross sectional study of symptom attribution and recognition of depression and anxiety in primary care. *BMJ* 318:436–439, 1999
5. Penn JV, Boland R, McCartney JR, Kohn R, Mulvey T: Recognition and treatment of depressive disorders by internal medicine attendings and housestaff. *Gen Hosp Psychiat* 19:179–184, 1997
6. Talbot F, Nouwen A: A review of the relationship between depression and diabetes in adults: is there a link? *Diabetes Care* 23:1556–1562, 2000
7. Ciechanowski PS, Katon WJ, Russo JE: Depression and diabetes: impact of depressive symptoms on adherence, function, and costs. *Arch Intern Med* 160: 3278–3285, 2000
8. Jacobson AM: The psychological care of patients with insulin-dependent diabetes mellitus. *N Engl J Med* 334:1249–1253, 1996
9. Jacobson AM, De Groot M, Samson JA: The effects of psychiatric disorders and symptoms on quality of life in patients with type I and type II diabetes mellitus.

*Qual Life Res* 6:11–20, 1997
10. Lustman PJ, Griffith LS, Gavard JA, Clouse RE: Depression in adults with diabetes. *Diabetes Care* 15:1631–1639, 1992
11. Lustman PJ, Anderson RJ, Freedland KE, de Groot M, Carney RM, Clouse RE: Depression and poor glycemic control: a meta-analytic review of the literature. *Diabetes Care* 23:934–942, 2000
12. Feifer C, Tansman M: Promoting psychology in diabetes primary care. *Prof Psychol* 30:14–21, 1999
13. Glasgow RE: Behavioral and psychosocial measures for diabetes care: what is important to assess? *Diabetes Spectrum* 10:12–17, 1997
14. Bradley C: The well-being questionnaire. In *Handbook of Psychology and Diabetes.* Bradley C (Ed). Chur, Switzerland, Harwood Academic, 1994, p. 89–109
15. Pouwer F, Snoek FJ, Van der Ploeg HM, Adèr HJ, Heine RJ: The Well-being Questionnaire (W-BQ): evidence for a 3-factor structure with 12 items. *Psychol Med* 30: 455–462, 2000
16. Pouwer F, Van der Ploeg HM, Adèr HJ, Heine RJ, Snoek FJ: The 12-item Well-being Questionnaire: an evaluation of its validity and reliability in Dutch people with diabetes. *Diabetes Care* 22:2004–2010, 1999
17. Pouwer F, Snoek FJ, Van der Ploeg HM, Heine RJ, Brand AN: A comparison of the standard and the computerised versions of the Well-being Questionnaire (W-BQ) and the Diabetes Treatment Satisfaction Questionnaire (DTSQ). *Qual Life Res* 7:33–38, 1998
18. Shillitoe R: *Counselling People With Diabetes*. Leicester, U.K., British Psychological Society, 1994
19. Nichols KA: Psychological care by nurses, paramedical and medical staff: essential developments for the general hospitals. *Br J Med Psychol* 58:231–240, 1985
20. Ware JE: *SF-36 Health Survey: Manual and Interpretation Guide*. Boston, MA, The Health Institute, New England Medical Center, 1993
21. Pouwer F, Snoek FJ: The patient's evaluation of the quality of diabetes care: development and validation of a new instrument (PEQD). *Qual Health Care*, in press
22. Hollis S, Campbell F: What is meant by intention to treat analysis? Survey of published randomised controlled trials. *BMJ* 319:670–674, 1999
23. Kazis LE, Anderson JJ, Meenan RF: Effect sizes for interpreting changes in health status. *Med Care* 27: S178–S189, 1989
24. Jadad AR: Bias in RCTs: beyond the sequence generation. In *Randomised Controlled Trials*: *A User's Guide*. London, BMJ, 1998
25. Thompson C, Kinmonth AL, Stevens L, Peveler RC, Stevens A, Ostler KJ, Pickering RM, Baker NG, Henson A, Preece J, Cooper D, Campbell MJ: Effects of a clinical-practice guideline and practice-based education on detection and outcome of depression in primary care: Hampshire Depression Project randomised controlled trial. *Lancet* 355:185–191, 2000
26. Welch GW, Jacobson AM, Polonsky WH: The Problem Areas in Diabetes Scale: an evaluation of its clinical utility. *Diabetes Care* 20:760–766, 1997
27. Snoek FJ, Pouwer F, Welch GW, Polonsky WH: Diabetes-related emotional distress in Dutch and U.S. diabetic patients: cross-cultural validity of the Problem Areas in Diabetes Scale. *Diabetes Care* 23: 1305–1309, 2000
28. Rubin RR: Psychotherapy and counselling in diabetes mellitus. In *Psychology in Diabetes Care*. Snoek FJ, Skinner TC (Eds), Chichester, U.K., John Wiley & Sons, 2000, p. 235–263