

Monitoring of Individual Needs in Diabetes (MIND)-2

Follow-up data from the cross-national Diabetes Attitudes, Wishes, and Needs (DAWN) MIND study

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OBJECTIVE—To test the effects of implementing computer-assisted Monitoring of Individual Needs in Diabetes (MIND) in routine diabetes care on psychological status and glycemic control, identify predictors of poor psychological outcomes, and evaluate care providers' experiences.

RESEARCH DESIGN AND METHODS—The MIND procedure was implemented as part of the annual review in diabetes clinics across eight countries in a prospective observational study with a 1-year follow-up. MIND encompasses well-being (World Health Organization Five Well-Being Index [WHO-5]), diabetes-related distress (Problem Areas in Diabetes [PAID]), a Life Event Inventory, and the patient's agenda for their consultation. Medical data and agreed case-management actions were retrieved from the charts.

RESULTS—Of the total 1,567 patients, 891 patients (57%) were monitored at a 1-year follow-up. Twenty-eight percent of the patients screened positive for depression and/or diabetes distress at baseline and considered cases, 17% of whom were receiving psychological care. Cases were significantly more often female and had type 2 diabetes and worse glycemic control compared with noncases. Clinically relevant improvements in WHO-5 and PAID were observed over time in cases, irrespective of referral (effects sizes 0.59 and 0.48, respectively; $P < 0.0001$). Glycemic control did not change. Female sex, life events, and concomitant chronic diseases were predictors of poor psychological outcomes. MIND was well received by patients and staff.

CONCLUSIONS—MIND appears suitable for screening and discussion of emotional distress as part of the annual review. Broader dissemination in diabetes care is recommendable, but sustainability will depend on reimbursement and availability of support services.

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A relatively large proportion of people with diabetes suffer from psychological distress that often stays unrecognized and untreated (1,2). To improve recognition of the psychological needs of diabetic patients, routine monitoring of emotional well-being has been advocated,

using validated screening tools (3,4). However, the act of screening by itself is unlikely to impact psychological outcomes, unless linked to discussion of outcomes with the patient, followed by a referral for those identified in need of additional psychological care (5,6). Previous studies have

demonstrated that monitoring of well-being and discussing outcomes as part of routine consultation help to improve psychological well-being in both youth and adults with diabetes (7,8). Based on this work, we set out to test the effects of implementing the Monitoring of Individual Needs in Diabetes (MIND) procedure as part of the cross-national Diabetes Attitudes, Wishes, and Needs (DAWN) program (9). Baseline data from this DAWN MIND study have been reported elsewhere (10).

In this study, we present the 12-month follow-up results testing the impact of implementing MIND on emotional well-being, diabetes-related distress, and glycemic control in routine secondary diabetes care in eight countries. In addition, we sought to identify predictors of poor psychological functioning at follow-up and evaluate the care providers' experience of implementing well-being monitoring as part of routine care.

RESEARCH DESIGN AND METHODS

The DAWN MIND study was designed as a multinational prospective observational study with measurements scheduled at baseline and 12 months' follow-up. The aim was to test the feasibility and effects of implementing monitoring of well-being as an integral part of the diabetes annual review in routine secondary care. Diabetes centers were self-selected from eight countries: Croatia, Denmark, Germany, Ireland, Israel, the Netherlands, Poland, and U.K. In line with the observational nature of the study, no additional clinical staff or funding was offered to the clinics. In the preparation phase, the participating centers received a 1-day MIND training from the VU University Medical Center (VUMC) team, providing instructions on logistics, use of the computer program, interpretation of scores, discussion of outcomes, and advising on referral to a mental health professional if so indicated. A short MIND manual was provided summarizing key points. During the project, MIND data (encrypted) were transferred to the coordinating research center (VUMC) and entered

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in a central database. Medical ethical approval for this study was obtained from the VUMC and all participating centers. Informed consent was obtained from the patients for use of anonymous MIND data for research purposes. After the project, all centers received a short questionnaire to evaluate the MIND implementation process and identify possible barriers and facilitating factors to adoption and maintenance of the MIND procedure in routine care.

Patients

All adult (>18 years) type 1 and type 2 diabetic patients were eligible, unless unable to read or complete questionnaires on the computer because of insufficient computer skills, language, reading, or cognitive problems. Patients were seen in an outpatient setting, with the exception of Germany, where patients were seen in an inpatient setting.

Measures

The computer-assisted MIND program was developed by the VUMC team using the Health Quest software (Tilburg University) and was adapted for the purpose of the study. Patient instructions were translated by the participating centers. The computerized assessment procedure took, on average, 5–10 min and was scheduled prior to the consultation with the diabetes nurse specialist or physician. At completion, the computer instantly generated two copies of a report summarizing the results and using standardized scores (bars 0–100) for the psychological measures, indicating means and clinical cutoff values above or below which special attention is warranted. The patient brought two copies of the report to the consultation, and outcomes were discussed (~5–15 min) with the health care professional. Further actions were agreed as appropriate (e.g., referral) and documented by the care provider. Referral pathways for mental health care were not predefined and differed by country. Some clinics had access to a psychiatrist or psychologist in their center; others referred to a network of psychological services in primary care.

The time between baseline and follow-up assessment was set at 12 months, with an acceptable range of ± 3 months.

The choice of questionnaires included in MIND was based on proven validity, clinical utility (brief, noninvasive), availability in a multitude of languages, and following International Diabetes Federation recommendations (3). The MIND protocol includes a short questionnaire on sociodemographics and self-reported clinical data,

including severe hypoglycemic episodes in the previous 6 months, and further covers the following three domains:

1. Emotional well-being measured with the World Health Organization Five Well-Being Index (WHO-5), which was developed from the WHO-10 Well-Being Index and has shown good validity (11,12). The WHO-5 contains five positively worded items, scored on a six-point Likert scale ranging from 0 (not present) to 5 (constantly present) and is transformed to a score from 0 (worst thinkable well-being) to 100 (best thinkable well-being). A score of ≤ 50 suggests suboptimal well-being and is a sign for further testing, whereas a score < 28 represents likely depression. Cronbach's α at baseline for the WHO-5 across the eight countries ranged from 0.81 (Germany) to 0.89 (U.K.).
2. Diabetes-related distress was measured with the Problem Areas In Diabetes scale (PAID), a widely used instrument with proven validity (13). It consists of 20 statements capturing common negative emotions related to living with diabetes and its treatment. Each item can be rated on a five-point Likert scale ranging from 0 (not a problem) to 4 (serious problem). An item score of 3 or 4 indicates moderate to serious distress regarding a particular topic. To facilitate interpretation, total PAID scores are transformed to a 0–100 scale, with higher scores indicating greater emotional distress. A cutoff of 40 was used to indicate high diabetes-related distress. Cronbach's α for the PAID across the eight countries ranged from 0.91 (Germany) to 0.94 (the Netherlands and U.K.) at baseline.
3. Life events were reported on a self-developed scale, derived from the Social Readjustment Rating scale (14). Six items were included, representing six major categories of possible negative stressful events: loss of loved one, loss of job or income, divorce or family conflicts, financial problems, severe illness of oneself or loved one, and other (stressful) life event. Patients were invited to confirm if one or more of the mentioned events had occurred in the past 6 months.
4. A patient agenda question concluded the assessment procedure, as a means of activating the patient and help set the agenda. The patient is invited to tick one or more of the following topics: medication/treatment, symptoms/complaints, lifestyle, mood/stress, sexual problems, other topic, or indicate no specific topic.

In addition to the patient-reported outcomes, clinical characteristics were collected from the medical records, including type and duration of the diabetes, most recent HbA_{1c}, treatment regimen, complication status, and comorbidity.

Statistical analyses

SPSS 15.0 (SPSS Inc, Chicago, IL) was used to carry out statistical analyses. Descriptive statistics and independent *t* tests were used to explore and compare the sociodemographic characteristics, clinical status, and psychological outcomes of the groups with and without a follow-up measurement. Subsequently, these analyses were used to compare the identified cases at baseline (patients with likely depression and/or high diabetes-related distress) and patients with average to good well-being and distress. Significance level was set at $P < 0.05$. Sociodemographic and clinical variables that were shown to be significantly different between these groups were included as covariates in the repeated measures analyses for well-being (WHO-5), distress (PAID), and glycemic control (HbA_{1c}). To measure the effect sizes of these outcomes, Cohen's *d* was calculated (15). An effect size of 0.2 to 0.3 is regarded as a small effect, ~0.5 a medium effect, and ≥ 0.8 a large effect. The same analyses were performed within the subgroup of cases with and cases without an agreed referral.

Multilevel backward regression analyses were performed twice using MLwiN 1.1 to determine prediction models of lower well-being (WHO-5) and higher diabetes-related distress (PAID) while correcting for between-country and time differences. First, multilevel analyses were performed on the total baseline data. Variables that were identified as predictors at baseline were included for the second multilevel analyses concerning the follow-up data. For lower well-being, the identified predictor variables at baseline were: sex, age, work status (unemployed or employed), severe hypoglycemic episodes (none versus one or more), comorbidity (none versus one or more), major life events (none versus one or more), and diabetes-related distress (PAID < 40 or ≥ 40). For higher diabetes-related distress, the predictor variables at baseline were: sex, age, type of diabetes, depression score (WHO-5 > 28 or ≤ 28), HbA_{1c}, severe hypoglycemic episodes (0 or ≥ 1), comorbidity (0 or ≥ 1), diabetes complications (0 or ≥ 1), and major life events (0 or ≥ 1).

RESULTS

Baseline characteristics

In total, 891 patients (57%) of the 1,567 patients monitored at baseline underwent an assessment at follow-up within the time range set for this study. Median time for follow-up monitoring was 14 months. Compared with the patients with a follow-up measurement, those not included in the analyses were better educated ($P = 0.021$), more often single ($P = 0.001$), more likely to have other chronic disease(s) ($P = 0.0001$), and less likely to have diabetes complications ($P = 0.002$). Mean levels of baseline well-being and diabetes-related distress were comparable in both groups. Sociodemographic, clinical, and psychological characteristics of the patients included in the analyses across countries at baseline and follow-up are displayed in Table 1.

Overall changes

For the group as a whole, mean well-being scores (WHO-5) did not change significantly between baseline and follow-up (Table 1). However, significant improvements were observed in diabetes-related distress (PAID) and glycemic control ($P = 0.013$ and $P = 0.0001$, respectively).

Caseness

At baseline, 27.5% of the patients screened positive, having either likely depression (WHO-5 ≤ 28) or high diabetes-related distress (PAID ≥ 40) and were identified as a case. Of these cases, 17% were receiving psychological care of some sort.

Patients identified as a case were significantly more often female ($P = 0.0001$), not in a relationship ($P = 0.004$), more often reported stressful life events ($P = 0.0001$), had type 2 diabetes ($P = 0.034$), a higher mean HbA_{1c} ($8.1 \pm 1.5\%$ vs. $7.8 \pm 1.4\%$; $P = 0.03$), and ≥ 1 concomitant chronic diseases ($P = 0.01$) than those reporting to feel psychologically well.

Within the group of identified cases, a significant improvement in emotional well-being ($P = 0.0001$) and diabetes-related distress ($P = 0.0001$) was observed at follow-up, with medium to large effect sizes (WHO-5 score 36.7 ± 21.9 at baseline and 49.5 ± 21.7 at follow-up; Cohen's $d = 0.59$; PAID score 46.7 ± 18.2 at baseline and 37.3 ± 20.7 at follow-up; Cohen's $d = 0.48$).

Among the patients who were no longer a case at follow-up ($N = 97$), a decreased wish to discuss mood/stress as indicated on the patient agenda was observed (from 32 to 11.3%). In contrast,

among patients that continued to be a case at follow-up ($N = 108$), the percentage that wished to talk about their mood/stress did not change from baseline to follow-up (32.4 vs. 31.6%). Changes in HbA_{1c} were not different between patients who showed improved mental health and those who did not ($P = 0.09$).

At follow-up, MIND identified 105 new cases (i.e., screened positive for the first time) on WHO-5 (mean 36.8 ± 20.8) and/or PAID (mean 44.2 ± 19.8). Added to the 108 remaining cases, 213 of the total 891 patients (24%) monitored at 12 months follow-up thus had clinically relevant symptoms of depression or diabetes distress. Glycemic control among the newly identified cases was significantly worse compared with the negatively screened patients (HbA_{1c} $8.1 \pm 1.5\%$ vs. $7.8 \pm 1.4\%$; $P = 0.007$).

Cases with and without referral

In view of the importance of linking psychological screening to action, we separated out patients identified at baseline as a case into those with and without a referral, as documented by the health professional. For 2.9% ($N = 6$) of the total number of identified cases ($N = 205$), agreed actions were not documented and considered missing. Of the remaining 199 identified cases, 34 patients (17%) were already receiving psychological care. Of the remaining 165 cases, a referral was agreed in 39.3% ($N = 65$). Comparing patient characteristics of cases with and without an agreed referral, the first group had significantly lower education ($P = 0.0001$), more often reported diabetes complications ($P = 0.037$), and had worse glycemic control ($8.4 \pm 1.5\%$ vs. $7.9 \pm 1.5\%$; $P = 0.001$). Interestingly, referred cases did not show more improvement in well-being, diabetes-related distress, or glycemic control at follow-up compared with cases without a referral.

Predictors of poor psychological status

Using multilevel analyses to correct for between-country differences, the following predictors for likely depression at follow-up (WHO-5 ≤ 28) were identified: being female ($B = -4.4$; $P < 0.001$), having high diabetes-related distress at baseline (PAID ≥ 40) ($B = -16.5$; $P < 0.001$), having experienced one or more major life events ($B = -7.5$; $P < 0.001$), and having ≥ 1 concomitant chronic disease ($B = -5.8$; $P < 0.001$). For high diabetes-related distress (PAID) at follow-up, the following predictors were

identified: being female ($B = 4.6$; $P < 0.001$), being likely depressed at baseline (WHO-5 ≤ 28) ($B = 8.9$; $P < 0.001$), having experienced one or more major life events ($B = 3.8$; $P < 0.001$), and having ≥ 1 concomitant chronic disease ($B = 2.8$; $P < 0.01$) and elevated HbA_{1c} ($B = 1.8$; $P < 0.001$). Predictors for both indices of poor emotional well-being thus largely overlap, with the exception of poor glycemic control at baseline that was found to be a predictor of high diabetes-related distress at follow-up, but not for likely depression.

Evaluation

All health care teams were satisfied with MIND as part of the annual review that was well received by patients. No major problems with the computer software were encountered, and data were easily retrieved. Barriers to offering MIND to all patients as part of the annual review brought forward by the participating teams were: lack of resources (staff), logistical issues (planning, documentation), and time constraints. Shortening the MIND procedure was suggested to reduce assessment and consultation time. In addition, it was proposed to make technical changes like larger characters and touch screen to simplify use for diabetic patients who are older or have visual difficulties.

CONCLUSIONS—We found monitoring of psychological well-being and discussion of outcomes with the patient as part of routine diabetes care across countries to be feasible and well-accepted by patients and staff. The monitoring procedure helped to identify roughly a quarter of the patients as a case at baseline (i.e., reporting low mood and/or high diabetes-related distress). Less than 20% of these cases were already receiving psychological care. In the total group, the mean level of well-being over the 12-month period did not change, whereas a small but significant improvement in glycemic control was observed. Patients with a poor psychological status at baseline showed clinically meaningful improvements in well-being and diabetes distress, following MIND, yet mean scores on measures of depression and diabetes-related distress were still suboptimal, suggesting a need for follow-up and psychological treatment. Patients with a documented referral on average were in worse medical condition compared with those not referred for mental health services. Interestingly, the observed psychological improvements following MIND were similar for

Table 1—Baseline and follow-up characteristics of the international DAWN MIND study

	Baseline	Follow-up	P value
Sociodemographics			
Sex (male/female)	50.7/49.3	—	—
Age (years)	54.7 ± 14.0	—	—
Education (≥11 years)	64.4	—	—
Work status (employed)	50.7	—	—
Marital status (with partner)	76.7	—	—
Major life events* (≥1)	53.0	44.0	0.675
Personal agenda			
No specific topic	53.9	49.8	0.119
Treatment/medication	26.2	23.4	0.054
Symptoms/complaints	11.9	9.1	0.060
Lifestyle	13.0	8.7	0.017
Mood/stress	14.3	12.2	0.521
Sexual problems	6.5	4.1	0.021
Other topic	6.8	4.6	0.035
Clinical characteristics			
Type diabetes (1/2)	44.0/56.0	—	—
Diabetes duration			
0 to 1 year	6.5	—	—
2–5 years	16.0	—	—
6–10 years	19.8	—	—
≥11 years	57.7	—	—
Type 2 insulin treated	61.7	—	—
Mean HbA _{1c}	7.9 ± 1.4	7.7 ± 1.4	0.0001
Poor glycemic control (>8.0%)	41.6	39.4	0.361
Good glycemic control (≤7%)	28.9	32.1	0.265
Severe hypoglycemic episodes* (≥1 episode)	21.1	22.6	0.345
Psychological status			
Well-being (WHO-5)	61.3 ± 22.2	61.4 ± 21.9	0.914
Diabetes-related distress (PAID)	22.7 ± 18.3	21.4 ± 18.4	0.013
Caseness			
Likely depression (WHO-5 ≤28)	9.9	10.9	0.432
High diabetes distress (PAID ≥40)	13.1	13.6	1.0
Depressed/distressed (WHO-5 ≤28, PAID ≥40)	4.5	4.4	1.0
Change in psychological status of identified cases			
WHO-5	36.7 ± 21.9	49.5 ± 21.7	0.0001
PAID	46.7 ± 18.2	37.3 ± 20.7	0.0001

Data are percent or mean ± SD. *In the past 6 months.

patients with and without a documented referral. In previous trials, we did find evidence to support the notion that monitoring and discussion of well-being as part of routine outpatient consultations help to improve patients' emotional status, irrespective of referral (7,8). The MIND procedure can indeed be considered a minimal intervention and a previous randomized controlled trial by our group was for that reason included in the first systematic review and meta-analysis of psychological therapies in diabetes by Winkley et al. (16). Moreover, in adolescents with type 1 diabetes, withdrawing the monitoring procedure in the follow-up phase of a trial resulted in a loss of beneficial effects and worsening of outcomes (17). Of course, we

should keep in mind that documentation of referrals in the charts may not have been complete, and we cannot rule out the possibility that patients identified as in need of psychological help but not referred may at a later stage have decided to seek psychological support. Unfortunately, we have no data on how patients and doctors came to (dis)agree on a referral, nor on mental health services offered to patients identified as a case. Future studies should further investigate the consultation process following psychological assessment and document patients' health seeking behaviors as a result of the MIND procedure. Such process evaluations will also be helpful to inform us on the role of professionals' competencies, such as active listening, use of open-ended

questions, avoidance of negative labeling, and promoting active patient participation in the decision-making process.

Importantly, we observed a 12% incidence of clinically relevant psychological distress in the patient population remaining in the study, whereas persistent psychological distress was found to be also 12%. These findings are in line with recent findings in primary care (18) and underscore the need of continued monitoring and management of comorbid psychological problems in routine diabetes care.

Some strengths and limitations of this study should be noted. First, our findings were derived from an observational study and should therefore be interpreted with caution, given the lack of a control group. We cannot exclude the possibility of regression to the mean, although the observed changes in psychological status corroborate earlier findings from randomized controlled trials using similar approaches (7,8). Second, the fact that this relatively large and multinational study was conducted in a real-life setting without financial incentives adds to the external validity. In contrast, clinics were self-selected, and the participating staff could be qualified as early adopters (19), motivated to implement MIND in their practice. Third, approximately one-third of the patients were lost to follow-up, which might have caused selection bias. Patients lost to follow-up did not have dissimilar psychological profiles but were more likely to have comorbid diseases and less likely to suffer from diabetes-related complications, which may hint at a lesser involvement in their diabetes care.

Health care teams indicated they were not always able to schedule the second assessment in time due to logistical difficulties, high caseload, and limited staff. This points to the importance of a reimbursement schedule to support routine monitoring of well-being in diabetes care as part of the annual review and access to mental health referral networks. Without reimbursement, the sustainability of integrated psychosocial care is likely to be limited. Although the total time spent on MIND per patient does not exceed 30 min on average, it may also be worthwhile to explore possibilities to shorten the assessment procedure (20) and simplify scoring algorithms and interpretation. Future applications could be Web-based, which may also facilitate tracking of patients over time as part of stepped care, including online depression treatment (21,22).

It is of note that the patients with a poor mental health status had significantly worse glycemic control, which did not change

following MIND. Most likely, more intensive, combined therapies are called for to improve diabetes outcomes in those with psychological comorbidity. Collaborative care has recently shown to be effective both in terms of clinical outcomes and depression in primary diabetes care (23). These findings underscore the importance of developing integrative models of care that can effectively address the psychosocial, educational, and medical needs of diabetic patients.

In conclusion, implementing systematic monitoring and discussion of psychological distress in the context of routine diabetes care is appreciated by patients and professionals and appears to have beneficial effects, irrespective of further referral. Further research should focus on developing successful strategies for disseminating MIND in routine diabetes care and effective care pathways to impact on both psychological and glycaemic outcomes.

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F.J.S. conceptualized the study and wrote and edited the manuscript. N.Y.A.K. and M.d.W. researched the data and reviewed and edited the manuscript. E.E., I.H.-B., N.H., A.K., D.R.M., B.E.M., M.P.-O., and J.S. collected data, reviewed the manuscript, and contributed to the discussion. S.E.S. assisted in designing and organizing the study and reviewed and edited the manuscript. F.J.S. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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