

Psychological Outcomes of Patients With Screen-Detected Type 2 Diabetes

The influence of time since diagnosis and treatment intensity

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OBJECTIVE — The objective of this study was to investigate how time since diagnosis and treatment intensity influence psychological outcomes in patients with screen-detected type 2 diabetes.

RESEARCH DESIGN AND METHODS — A 2 × 2 factorial cross-sectional design was used to examine psychological outcomes in 196 patients with screen-detected diabetes diagnosed 3–33 months previously who were receiving usual care or intensive multifactorial pharmacological treatment. Outcomes included anxiety, depression, diabetes-related distress, perceived seriousness and vulnerability, self-efficacy, and self-care. Multivariate analysis was used to examine variations in outcomes based on time since diagnosis (<1 vs. 2–3 years) and treatment intensity.

RESULTS — Most patients reported little distress, low perceived seriousness and vulnerability, high self-efficacy, and low self-care, but outcomes varied considerably across conditions. Time effects were found for perceived vulnerability, which increases significantly with time since diagnosis. Time × treatment interactions were found for anxiety, diabetes-related distress, and self-efficacy; notably, intensively treated patients showed more distress and less self-efficacy in the 1st year, and usual-care patients reported more distress and less self-efficacy 2–3 years after diagnosis.

CONCLUSIONS — Screen-detected patients generally do not experience much difficulty with their condition in the first few years, but early and intensive treatment can influence patients' psychological outcomes, leading to relatively more anxiety and less self-efficacy in the 1st year after diagnosis but not necessarily improving self-care. This suggests that intensive treatments confront patients with their diabetes earlier on whereas milder treatments may delay confrontation. This finding should be taken into account in the development and timing of psychological interventions for patients with newly diagnosed diabetes.

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There is an ongoing debate on screening for type 2 diabetes (1,2). Advocates emphasize the advantages of detecting diabetes in patients at an early stage of the disease, as an early and intensive treatment may reduce diabetes-

related morbidity and mortality (3). Opponents argue that the medical benefits of screening are not conclusive whereas the psychological consequences of early detection and treatment also remain unclear. Screening programs can

have negative side effects, including anxiety toward the procedure and negative feelings and labeling effects after a positive diagnosis (2,4). Furthermore, although early detection should result in earlier treatment, such treatments may be quite intensive for relatively asymptomatic patients, raising questions about the psychological consequences of intensive diabetes management. Understanding how patients with screen-detected diabetes adjust to their diagnosis and deal with their treatment is central to a discussion on the effectiveness of screening programs, as it is ultimately patients who must take responsibility for and manage their disease if they are to profit from earlier detection.

There is evidence that screening for type 2 diabetes has little psychological impact. Studies generally show that patients experience only short-term distress after screening (5,6). However, little is known about their cognitive or behavioral reactions, and no follow-up has gone beyond 1 year after diagnosis. In fact, concern has been expressed that patients with screen-detected diabetes have considerable difficulty in accepting their diagnosis and may tend to downplay their condition and treatment until the first signs and symptoms of the disease appear (7,8). With few symptoms and mild treatment, these patients may not yet recognize the seriousness of their condition or the need for or difficulties associated with sustained self-management.

With time, however, as their condition worsens and treatment intensifies, diabetic patients generally report more distress and feel more vulnerable (9,10). Complex treatments involving both lifestyle change and numerous medications can be very demanding, confronting patients with their disease on a daily basis while simultaneously making them more dependent on the health care system (11,12). As a result, many practitioners may be hesitant to treat patients with newly diagnosed diabetes intensively, despite the potential medical benefits. As of yet, no study has been conducted to investigate how treatment intensity may in-

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Abbreviations: ADDITION, Anglo-Danish-Dutch Study of Intensive Treatment and Complication Prevention in Type 2 Diabetic Patients Identified by Screening in Primary Care; HADS, Hospital Anxiety and Depression Scale; PAID, Problem Areas in Diabetes.

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

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fluence patients' adjustment to diabetes after diagnosis. In this study, we investigated psychological outcomes among patients with screen-detected type 2 diabetes, depending on the intensity of treatment (intensive medical treatment vs. usual care) and time since diagnosis (<1 year vs. 2–3 years).

RESEARCH DESIGN AND METHODS

Participants were recruited from the Dutch arm of the Anglo-Danish-Dutch Study of Intensive Treatment and Complication Prevention in Type 2 Diabetic Patients Identified by Screening in Primary Care (ADDITION), a multicenter randomized controlled trial that evaluated a population-based screening program for type 2 diabetes and investigated the effectiveness of a target-driven approach to reduce cardiovascular risk of patients with screen-detected diabetes (13). The screening program was carried out in two phases between 2001 and 2002 and 2003 and 2004; 56,978 patients (aged 50–69 years) from 79 general practices in the southwest Netherlands were invited to participate (13). Patients with newly diagnosed diabetes were subsequently randomly assigned to receive either intensive multifactorial treatment (lifestyle advice and protocol-driven tight control of blood glucose, cholesterol, and blood pressure, including prescription of aspirin and ACE inhibitors) or usual care according to national guidelines.

In 2004, 468 patients included in ADDITION who did not have serious comorbidities were invited to participate in a self-management intervention, which included a psychological baseline assessment. At that point, patients could be divided into four groups depending on their time since diagnosis (<1 year vs. 2–3 years) and their treatment (intensive vs. usual care). In total, 227 patients ultimately agreed to participate, and 206 completed the questionnaire; 241 declined participation. To check for selection bias, we interviewed nonparticipants (B.J.T., D.T.D., J.M.B., K.J.G., G.E.R., unpublished observations). Major reasons for refusal were hesitancy to participate in more research (36%), practical difficulties (e.g., time and transportation; 36%), and personal circumstances (16%). The 206 participants were more educated and reported lower self-management than nonparticipants, but no other differences were observed with regard to patient characteristics or diabetes-related attitudes.

Participants received a questionnaire to gather information about sociodemographic characteristics (age, sex, and education), medical characteristics (time since diagnosis, BMI, and number of complaints) and seven measures covering the emotional, cognitive, and behavioral outcomes under study. Time since diagnosis was calculated by subtracting the screening date from the date on which the questionnaire was completed. BMI was calculated from self-reports of weight and height [weight/(height × height)]. Number of complaints was derived from self-reports in which patients listed their medical complaints.

Patients' emotional outcomes included general and diabetes-specific measures of distress. The Hospital Anxiety and Depression Scale (HADS) measures symptoms of anxiety and depression among patients with somatic complaints (14). It consists of seven items each for anxiety and depression, measured on a 4-point scale and totaled to two sum scores (0–21). Scores of ≥ 8 are considered clinically relevant; scores of ≥ 11 are considered clinically definite levels of anxiety and depression. The HADS has good validity and reliability (15).

The Problem Areas in Diabetes (PAID) scale was used because it is a widely recognized measure of diabetes distress, assessing the general emotional burden of diabetes and distress related to treatment, food choices, and social support. The 20 items are scored on a 5-point scale yielding a sum score (0–80), with higher scores representing higher distress. The Dutch PAID scale has good convergent and discriminant validity and high internal consistency (9).

Cognitive measures included patients' perceptions of the health threat and their self-efficacy. Perceptions of health threat were assessed using two scales measuring perceived seriousness of and vulnerability for diabetes, after recent studies showing that perceptions of seriousness do not necessarily translate into feelings of personal vulnerability (7,16). The perceived seriousness scale was based on the diabetes illness representations questionnaire (17) and used three items to explore patients' beliefs about the seriousness of diabetes in general. Patients were asked whether they agreed with each statements on a 5-point scale, ranging from strongly disagree to strongly agree, with a score of 3 as neutral. The perceived vulnerability scale asked patients to 1) estimate the seriousness of

their own diabetes (two items) and 2) indicate how much they worried about the consequences that diabetes could have for their health (two items). Cronbach's α values were 0.67 and 0.94 for the seriousness and vulnerability scale, respectively, whereas correlations between the scales were low (Spearman's $r = 0.27$, $P < 0.01$), supporting our use of these scales as independent measurements of health threat.

Self-efficacy was assessed using a questionnaire adapted from Lorig et al. (18) and Kuijer and de Ridder (19), which measures self-efficacy in performing both general and domain-specific self-care behaviors. The scale includes 12 items, with answers ranging from not at all (1) to totally confident (7). Scores of 5 and above reflect high self-efficacy. Cronbach's α was 0.84 in this sample.

Self-care behavior was assessed using the revised summary of diabetes self-care activities measure (20), which includes 10 items covering diet, exercise, blood glucose testing, foot care, and medication. For each domain, patients were asked "Over the last 7 days, how often did you. . .," which was summarized in a mean score of 0–7. The scale shows moderate interitem correlations and relatively low overall and test-retest reliability. Nevertheless, given the difficulty of measuring self-care, the scale is considered a valid alternative, particularly because of its brief and lucid format. Cronbach's α was 0.63.

Analyses

Primary analyses included an investigation of overall scores and variations on the seven key variables (anxiety, depression, diabetes-related distress, perceived seriousness and vulnerability, self-efficacy, and self-care behavior), using a 2×2 factorial design based on patients' time since diagnosis (<1 year vs. 2–3 years) and their treatment intensity (usual care vs. intensive).

Patients' sociodemographic characteristics and medical characteristics were first explored to examine variations between groups based on treatment intensity and time since diagnosis, using χ^2 tests and univariate analyses. A preliminary analysis across groups examined scores on the key dependent variables and explored potential associations with patient characteristics, using descriptive statistics. A MANOVA with two factors (time since diagnosis and treatment intensity) was used to examine possible differences

Table 1—Patient characteristics

	Intensive <1 year	Intensive 2–3 years	Usual care <1 year	Usual care 2–3 years	P values for group differences	
					Time	Treatment
n (% response)	58 ± 46	35 ± 36	41 ± 50	62 ± 59		
Age (years)	61 ± 5.9	61.9 ± 5.3	61 ± 5.5	62.1 ± 5.0	0.49	0.55
% male	50	57	71	63	0.96	0.07
Education*	3.0 ± 1.4	3.0 ± 1.7	3.0 ± 1.6	3.4 ± 1.6	0.35	0.20
No. of medical complaints	1.3 ± 1.2	1.7 ± 1.4	1.1 ± 1.2	1.5 ± 1.2	0.06	0.29
BMI (kg/m ²)	29.4 ± 4.7	30.0 ± 4.9	29.0 ± 4.3	30.0 ± 4.9	0.23	0.69
Duration (months)	8.6 ± 2.0	26.4 ± 2.1	8.7 ± 2.9	26.8 ± 2.0	<0.001	0.69

Data are means ± SD unless otherwise indicated ($n = 196$). P values reflect χ^2 test and univariate tests for group differences. Time × treatment effects were never significant and therefore are excluded from the table. *Level of education was measured on a 6-point scale (1 = primary to 6 = higher education).

between patients, based on the seven dependent variables described above, looking for effects of time, treatment, and time × treatment interactions. If significant, univariate statistics were examined and subsequent post hoc comparisons were done (Bonferroni correction). Sex was controlled for in an additional analysis due to marginal differences between groups. BMI and number of complaints were also controlled for in additional analyses, as variations in psychological outcomes may also reflect physical health status. An additional MANOVA was carried out among nonparticipants based on outcomes measured in the nonresponse interview (including perceived seriousness, vulnerability, self-efficacy, and self-management).

RESULTS— Table 1 gives an overview of patient characteristics on the basis of patients' time since diagnosis and treatment intensity. Diabetes was diagnosed in 10 patients between 1 and 2 years previously and could not be included, which left 196 patients for comparisons. Participation rates varied between groups, but no clear selection bias was observed; there were no significant differences on any patient characteristic, except, of course, for time since diagnosis. There were some marginal differences, however: usual-care patients were more often female, and patients with longer disease duration had more medical complaints.

Psychological outcomes

Table 2 gives an overview of patients' emotional, cognitive, and behavioral outcomes, describing mean scores for the entire sample and for the four groups separately, as well as summarizing the outcomes of the multivariate analyses. Looking at overall scores, the majority of

patients reported low subclinical anxiety, depression, and diabetes-related distress. However, a significant number experienced high clinically relevant anxiety (HADS score >8; 27%) and depression (score >8; 22%). Patients generally did not perceive diabetes to be a serious health threat; only one-half considered diabetes to be serious (48% scored >3) whereas only one-third felt vulnerable for diabetes-related consequences (30% scored >3). Finally, most patients reported high self-efficacy (76% scored >5) but low self-care (mean [\pm SD] 3.6 ± 1.0). Self-care was very high with regard to medication (6.8 ± 0.8) and lower for diet (5.1 ± 1.3) and physical exercise (3.4 ± 2.0).

There were strong associations between the psychological outcomes, notably, between the distress measures (range $r = 0.38$ – 0.56 , $P < 0.01$) and between distress and perceived vulnerability ($r = 0.16$ – 0.45 , $P < 0.01$) and self-efficacy ($r = -0.28$ to -0.43 , $P < 0.01$). Psychological outcomes were not associated with sociodemographic variables but were associated with BMI and medical complaints. BMI was negatively associated with self-efficacy and self-care ($r = -0.19$ and -0.20 , respectively, $P < 0.01$), and the number of complaints was positively associated with distress and perceived vulnerability ($r = 0.20$ and 0.22 , respectively, $P < 0.01$) and negatively associated with self-efficacy ($r = -0.15$, $P < 0.01$).

Comparisons between groups revealed considerable variations in the emotional, cognitive, and behavioral outcomes, reflected in mean differences and SDs. The MANOVA showed a significant multivariate effect of time [$F(8,188) = 2.45$, $P < 0.05$] and time × treatment [$F(8,188) = 2.70$, $P < 0.01$],

but no effect for treatment. Including sex, number of complaints, and BMI as covariates had no significant effects on the original MANOVA and only slightly altered univariate effects.

The main effect of time was significant for perceived vulnerability ($F = 14.3$, $P < 0.001$). Patients in whom diabetes was diagnosed between 2 and 3 years previously considered their diabetes to be more threatening than patients with a more recent diagnosis (means 2.4 and 2.9, respectively). This effect remained standing regardless of patients' number of complaints or BMI. Diabetes-related distress was also marginally higher among patients with a longer disease duration ($F = 3.0$, $P = 0.08$), but this difference disappeared when number of complaints was taken into account.

Time × treatment effects were significant for anxiety ($F = 5.8$, $P < 0.01$), diabetes-related distress ($F = 4.6$, $P < 0.05$), and self-efficacy ($F = 7.1$, $P < 0.01$). Controlling for sex, number of complaints, and BMI increased time × treatment effects on both the HADS ($F = 7.8$, $P < 0.01$) and PAID scale ($F = 5.6$, $P < 0.05$). Figure 1 portrays the time × treatment interactions, illustrating the fact that intensively treated patients showed relatively more distress and less self-efficacy in the short term, whereas usual-care patients showed relatively more distress and less self-efficacy in the long term (Fig. 1). Post hoc analysis revealed that on the HADS anxiety subscale, the difference between the intensive and usual-care patients with a diagnosis of diabetes of <1 year was significant ($P < 0.01$). Nearly one-third of the intensively treated patients with a more recent diagnosis were experiencing clinically relevant anxiety levels (score >8) compared with one-fifth in the other groups. On the

Table 2—Psychological outcomes: total scores, group differences, and multivariate analysis of time, treatment, and time × treatment interactions

	Total sample	Intensive <1 year	Intensive 2–3 years	Usual care <1 year	Usual care 2–3 years	Time	Treatment	Time × treatment
Anxiety (0–21)	5.6 ± 4.2	6.8 ^a	5.0	4.5 ^a	5.5	F = 0.3, NS	F = 2.3, NS	F = 5.8, P < 0.01
Depression (0–21)	4.8 ± 3.7	4.9	5.4	4.2	4.8	F = 1.2, NS	F = 1.5, NS	F = 0.0, NS
Diabetes distress (0–80)	18.3 ± 17	19.2	18.2	12.2 ^a	21.5 ^a	F = 3.0, NS	F = 0.7, NS	F = 4.6, P < 0.05
Perceived seriousness (1–5)	3.2 ± 1.0	3.2	3.3	3.0	3.2	F = 1.8, NS	F = 1.0, NS	F = 0.0, NS
Perceived vulnerability (1–5)	2.6 ± 1.0	2.5	3.0 ^a	2.2 ^{ab}	2.8 ^b	F = 14.3, P < 0.001	F = 2.0, NS	F = 0.2, NS
Self-efficacy (1–7)	5.6 ± 1.0	5.4	5.8	5.9	5.5	F = 0.2, NS	F = 0.5, NS	F = 7.1, P < 0.01
Self-management (0–7)	3.6 ± 1.0	3.6	3.7	3.9	3.5	F = 0.0, NS	F = 1.4, NS	F = 2.2, NS

Data are means ± SD or means. Means with different superscripts in a row differ significantly from each other at P < 0.05 (Bonferroni test). Pooled within correlations between dependent variables ranged from 0.16 to 0.52.

PAID scale, the difference between the two groups of usual-care patients was significant (P < 0.05) with patients with a more recent diagnosis experiencing considerably less distress than patients with diagnosis 2–3 years previously. An additional post hoc analysis on the PAID subscales (data not shown) indicated that usual-care patients with a recent diagnosis scored significantly lower than other groups on treatment-related problems and dietary issues (P < 0.05).

With regard to self-efficacy, among intensively treated patients, those with a more recent diagnosis reported less self-efficacy. Vice versa, among usual-care patients, those with longer duration showed less self-efficacy. Post hoc analyses between groups did not reveal specific differences. Finally, whereas emotional and cognitive outcomes varied by both treatment and time since diagnosis, there were no differences with regard to self-care behavior. The MANOVA as applied in the group of nonparticipants showed a significant main effect for time and a time × treatment interaction with the direction of results identical to that of participants (data not shown).

CONCLUSIONS— A number of conclusions can be drawn from this study. First, patients with screen-detected type 2 diabetes generally reported low emotional distress, low threat perceptions, and high self-efficacy but low self-care behavior. Second, and more importantly, we found that patients with screen-detected diabetes vary considerably in their emotional and cognitive outcomes, depending on the time since diagnosis and treatment intensity. Notably, intensively treated patients reported more distress and less self-efficacy in the 1st year, whereas usual-care patients showed relatively more distress and less self-efficacy 2–3 years after diagnosis. Finally, intensively treated patients did not report better self-management than patients receiving usual care. These findings will be discussed in more detail below.

Our first finding agrees with previous studies: most patients with screen-detected diabetes do not experience much distress after diagnosis (5–8,22). That said, many patients in our study reported clinically relevant depression and anxiety. Distress was particularly high among recent intensively treated patients, which suggests that intensive treatment is not without costs, at least not in the short term.

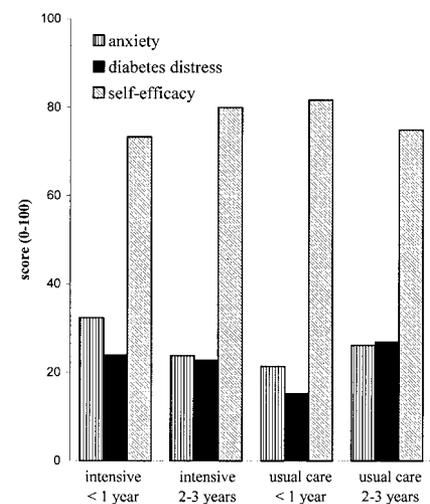


Figure 1—Anxiety, diabetes-related distress, and self-efficacy by treatment intensity and disease duration. Scores for anxiety, distress, and self-efficacy have been transformed to a scale of 0–100.

We also found that many patients with screen-detected diabetes do not consider the disease to be threatening to their health. As with previous studies, we found that perceived vulnerability is higher with longer disease duration and positively associated with distress and the number of medical complaints (21). This finding suggests that asymptomatic patients tend to downplay their illness as an attempt to alleviate distress and will continue to do so until signs and symptoms of the disease appear (22). Increasing confrontations with diabetes-related complaints and the realities of living with a chronic illness apparently make patients more aware of the threat that diabetes poses to their health. The finding that most patients reported low self-management but high self-efficacy suggests that many patients with screen-detected diabetes were overly confident in their ability to manage their disease, further supporting our suggestion that these patients do not yet fully recognize the difficulties that living with diabetes presents. This finding is important, as most psychological theories consider adequate representations of health threats and high but realistic self-efficacy to be important prerequisites for actually engaging in self-care (23).

Ultimately, the difference between patients on the basis of their time since diagnosis and their treatment intensity is the major outcome of this study. The higher emotional distress and lower self-efficacy among intensively treated pa-

tients with a recent diagnosis suggests that they have more difficulty adjusting to their illness in the 1st year after diagnosis. Of course, increased distress does not necessarily mean less adaptive. In fact, many self-regulation theories consider a certain amount of negative arousal to be necessary in the appraisal of and coping with problem situations (24). In that sense, heightened distress and lower self-efficacy could also reflect a reality check, which intensively treated patients undergo as their rigorous treatment makes them face the day-to-day realities of living with diabetes. Apparently this reality is delayed among usual-care patients, perhaps because these patients do not begin to experience distress until symptoms appear and treatment intensifies. Indeed, usual-care patients with a recent diagnosis scored lowest on both anxiety and diabetes-related distress and particularly on treatment-related items. These findings remain stable when controlling for medical characteristics such as BMI and medical complaints. The overall picture is that intensively treated patients already experience emotional distress shortly after diagnosis, as they must immediately face a barrage of treatments, whereas distress in usual-care patients is delayed and primarily related to increased treatment as their illness progresses.

Finally, in contrast with our expectations, intensively treated patients were not showing better self-management, regardless of time since diagnosis. It appears that neither intensive medical treatment nor experience alone will help patients engage in and maintain their self-management. That said, all patients reported high medication adherence, and, in that sense, they are essentially adhering to the intensive pharmacological treatments under study in ADDITION. Regardless of the potential long-term medical benefits, this early and intensive treatment also comes at a cost, being associated with more distress and less self-confidence in the 1st year after diagnosis. If medical professionals consider lifestyle changes to be an essential part of diabetes self-management, then patients apparently need more support. The fact that patients with screen-detected diabetes vary in their emotional distress and illness cognitions suggests that they may profit to various degrees from such support. Indeed, it has been suggested that understanding how such psychological outcomes vary will help us know when and how to intervene (25,26). This study

indicates treatment and disease duration as two important parameters.

The present study has some limitations. First, these findings rely on cross-sectional data; as such, we were not able to examine the course of adjustment over time. A second limitation is the potential selection bias; as this study involved patients who signed up for a behavioral intervention, it might have attracted only patients who take their disease more seriously. The results of a nonresponse survey, however, demonstrated that nonparticipants did not take their disease less seriously than participants whereas they also showed similar variations in psychological outcomes related to their treatment intensity and disease duration. Furthermore, the differences in participation rates between groups also supports our findings, as the group with the highest distress and lowest self-efficacy also showed the highest inclination to participate (i.e., intensively treated patients with a diagnosis of <1 year and usual-care patients with a diagnosis 2–3 years previously). The fact that patients are open to behavioral interventions at different times, depending on their treatment intensity, strengthens our conclusion.

Finally, this study focused on patients with screen-detected diabetes. Whether our findings hold true for patients in whom diabetes is diagnosed via routine care remains to be determined. That said, studies comparing patients with newly diagnosed diabetes and patients with screen-detected diabetes showed that they have similar reactions to their diagnosis (6,8), suggesting that the manner of diagnosis is not that important. Our study reveals that patients' treatment intensity may play a more decisive role in how they adjust to their disease in the first few years.

This study emphasizes the importance of taking variations between patients into account in the development and implementation of (self-care) programs for patients with a recent diagnosis of type 2 diabetes during a screening trial. It also suggests that clinicians should be more attuned to patients' psychological needs when they first prescribe (more) intensive treatments, when acknowledging the distress that strict regimens may produce, when assessing their illness cognitions, and when actively addressing problems with regard to their self-care. Additional research needs to be done to investigate whether patients do, in fact, profit differently from such psychological

support, depending on their disease duration and their treatment intensity.

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