

# Psychosocial Factors and Diabetes Mellitus: Evidence-based Treatment Guidelines

\*Frank Petrak<sup>1</sup>, Stephan Herpertz<sup>1</sup>, Christian Albus<sup>2</sup>, Axel Hirsch<sup>3</sup>, Bernhard Kulzer<sup>4</sup>, Johannes Kruse<sup>5</sup>

From the <sup>1</sup>Department of Psychosomatic Medicine and Psychotherapy, Westfälische Clinic Dortmund, Ruhr-University of Bochum; the <sup>2</sup>Department of Psychosomatic Medicine and Psychotherapy, University of Cologne; the <sup>3</sup>Hospital Bethanien, Hamburg; <sup>4</sup>Diabetes Clinic, Bad Mergentheim; <sup>5</sup>Department for Psychosomatic Medicine and Psychotherapy, Düsseldorf University Hospital; all in Germany.

**Abstract:** The aim of this project was to develop evidence-based guidelines regarding psychosocial aspects of diabetes mellitus in an effort to help the clinician bridge the gap between research and practice. Recommendations address the following topics: patient education, behavioural medicine, and psychiatric disorders of particular relevance to diabetes: depression, anxiety disorders, eating disorders, and dependence on alcohol and nicotine. The present guidelines were developed through an interdisciplinary process of consensus according to the specifications of evidence-based medicine and are recognized by the German Diabetes Association and the German College for Psychosomatic Medicine as their official guidelines.

**Keywords:** Diabetes mellitus; guidelines; psychosocial factors; mental disorders; patient education; behavioural medicine.

## INTRODUCTION

Somatic and psychosocial factors are important both for the treatment and long-term prognosis of diabetes mellitus. In diabetes care the patient assumes a crucial role since he or she must carry out the essential therapeutic measures in his or her daily life, in a responsible manner, and on a permanent basis. As a consequence, the prognosis for diabetes largely depends on how successful the patient is in this endeavour, against the background of his or her social, cultural, family, and work environment.

Therefore, a number of psychosocial factors are crucial to cope successfully with the recommended treatment strategies and maintain a good quality of life (QoL). These factors are the acquiring of knowledge about self-treatment and skills for its implementation in daily life; emotional and cognitive acceptance of one's illness; coping with diabetes and its possible consequences in all affected areas of life and in various phases of the illness (e.g., diabetes-specific burdens, acute and diabetes-related complications); identification and modification of behaviours that are obstacles to successful self-treatment; and dealing successfully with crises and/or problems associated with the illness (e.g., mental disorders such as depression, anxiety, and eating disorders).

A multiplicity of psychosocial interventions for patients with diabetes is available. Although there are sporadic recommendations in medical guidelines about diagnostic measures and psychosocial interventions [1-4] specific and systematic psychosocial guidelines are missing. Such

guidelines should provide evidence-based state-of-the-art knowledge about indication and efficacy of specific interventions targeted at psychosocial issues and problems for researchers as well as health care professionals who are engaged in diabetes care.

The development of this guideline was initiated by an interdisciplinary workgroup of the German Diabetes Association (Deutsche Diabetes Gesellschaft, DDG) and the German College for Psychosomatic Medicine (Deutsches Kollegium für Psychosomatische Medizin, DKPM). The objective of this expert group was a systematic analysis of the efficacy of different interventions according to the principles of evidence-based medicine, corresponding to the standards of the guideline commission of the DDG (see Table 1). Based on this analysis, the group established the present guideline "Psychosocial Factors and Diabetes" as an independent guideline, instead of integrating the recommendations into general guidelines about diabetes care. This guideline was reviewed and endorsed as the official guideline of the DDG and the DKPM. It refers only to adult patients with diabetes, as there is a DDG guideline about psychosocial care of children and adolescents [5].

At the beginning of the development of psychosocial guidelines, relevant topics were defined. The workgroup addressed the following topics: patient education, behavioural medicine, and psychiatric disorders of particular relevance to diabetes: depression, anxiety disorders, eating disorders, and dependence on alcohol and nicotine. The authors acknowledge that there are other important psychosocial issues (e.g., psychosis, social care) that were not addressed in this first step but will be integrated into the next revised edition of the guidelines in 2006.

\*Address correspondence to this author at the Westfälische Klinik Dortmund/Ruhr-Universität Bochum c/o Schulberg 7, D-65183 Wiesbaden, Germany; Tel: 0049-611-1747841; Fax: 0049-611-1747842; E-mail: frank\_petrak@web.de

## METHODS

The methodological approach in developing the guidelines follows the specifications of evidence-based medicine [6-9]. Due to space limitation a detailed description of the procedure including the following aspects is given elsewhere: composition of the working group, database search, determination of the keywords, and systematic search of the scientific literature [10]. Studies were classified by the authors of the working group according to their scientific evidence into levels of evidence I-IV corresponding to the AHCPR [6] and SIGN [8] (see Table 1). In cases of diverging opinions, classification was achieved according to consensus reached through discussion.

**Table 1. Classification of the published literature into levels of evidence according to their scientific evidence (modified after AHCPR [6] and SIGN [8]).**

Levels of Evidence (LE)	
Ia	Evidence from meta-analysis of randomized controlled trials
Ib	Evidence from at least one randomized controlled trial
IIa	Evidence from at least one controlled study without randomization
IIb	Evidence from at least one other type of non-randomized and uncontrolled clinical study (e.g., cohort study)
III	Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies, and case-control studies
IV	Evidence from expert committee reports or opinions and/or clinical experience of respected authorities

The weighting of the stated intervention recommendations (screening, prevention, diagnostics, therapy, and rehabilitation) with grades A through C was performed by the members of the working group according to the levels of evidence (LE) adapted from the US Agency for Health Care Policy and Research Classification [6] based on underlying evidence *and* clinical relevance (see Table 2). In areas in which clinical evidence had to be weighted differently from the scientific evidence, the grade of the recommendation was determined through an interdisciplinary consensus.

**Table 2. Weighting of Recommendations**

Grade	Underlying Evidence
A	Evidence levels Ia, Ib or first-rate from a clinical perspective
B	Evidence levels IIa, IIb, III or second-rate from a clinical perspective
C	Evidence level IV or third-rate from a clinical perspective

This procedure ensures that recommendations for which external evidence is insufficient or unavailable can receive the highest grade A if experience has shown them to be indispensable for the clinical course. In contrast, interventions that otherwise might be assigned evidence levels Ia or Ib can receive the lowest grade due to their minimal clinical significance. Transparency is achieved by assigning both the underlying external evidence and the

grade of the recommendation to the individual recommendations.

The draft guidelines "Psychosocial Factors and Diabetes" were first presented to the interested public in a special issue of the journal of the German Diabetes Association *Diabetes und Stoffwechsel* [11] and as a virtual document on the DDG's website. All suggestions for alterations received before printing began were discussed by the expert group and incorporated when appropriate. The outcome of this process was presented as the long version of the diabetes guidelines, which was re-examined by the DDG Guideline Commission and approved by the DDG Executive Committee in May 2003. In the meantime, a short version

for clinical practice [12] and a patient version [13] were also published.

(Note: To improve readability, recommendations of the forthcoming section are displayed in italics).

## GUIDELINES: PATIENT EDUCATION

A diabetes education program is a systematic and goal-oriented process that imparts knowledge about the illness and skills for its treatment. It is a universally recognized, indispensable therapeutic measure for patients with diabetes (LE IV) [14-17]. The aim of patient education is to enable the patient to perform treatment strategies on his or her own authority.

- Within the framework of the patient education program, patients with diabetes have to be informed about the proper form of treatment and possible risks. This instruction will enable them to deal with the illness in a responsible manner and as independently as possible (LE IV, grade A) [18, 19].

A patient education program without adequate medical treatment of the diabetes is not successful (LE Ib) [20-22].

- The patient education program represents an integral part of the therapy of patients with diabetes and, therefore, must proceed in close coordination with the diabetes treatment (grade A).

Effectiveness and efficiency (cost-benefit analysis) of educational and treatment strategies must be secured empirically (LE Ib) [23, 24], (LE IV) [25]. Nevertheless,

there are a number of unanswered questions concerning the most effective and efficient forms of patient education, methods and didactics, specific target groups, and different measurements of success (LE Ia) [26] (LE IV) [27]. Despite sufficient evidence pointing to the effectiveness and efficiency of educational and treatment programs, deficiencies in patient education are common, especially among patients with type 2 diabetes. Only a minority of patients undergo a structured educational program shortly after the diagnosis is made. There are still a large number of patients who have never been trained in managing their diabetes (LE III) [28], (LE IV) [29].

Education programs with the primary goal of imparting knowledge about the origins of diabetes and its treatment have a proven influence on the patient's knowledge (LE Ib) [30, 31]. However, the increase in knowledge does not necessarily affect treatment-relevant behavior or glycaemic control and does not necessarily result in a reduction of diabetes-related complications (LE Ib) [32-35]. While diabetes-specific knowledge is necessary for successful self-treatment, it is not sufficient.

- Therefore, educational programs that primarily impart knowledge about the illness and its treatment should no longer be the sole component of diabetes education (grade A).

In contrast, educational programs that actively involve the patients in the educational process and motivate them to develop personal treatment goals have proved to be effective. As "self-management training," these programs offer concrete assistance in modifying behavior and transferring the content of the program into patients' daily living (LE Ia), [26] (LE Ib), [36, 37] (LE IV) [38, 39].

- Patients should be motivated to establish personal treatment goals. Moreover, they should be offered appropriate assistance to attain these goals (grade A).
- In addition to the type of diabetes, treatment strategies, and individual prognosis, the program must take into account the patients' individual problems, motivation levels and cognitive abilities. According to the patients' background knowledge, information, and needs, programs should be offered that are introductory or intermediate, refresher courses or problem-specific (LE IV, grade A) [40].

Both individual and group education programs have proven effective (LE Ia), [26] (LE Ib) [36, 41-43]. A group setting is more successful in achieving changes in fundamental living habits (LE Ia) [26].

#### **Patient Education (Type 1 Diabetes)**

The effectiveness of educational measures for patients with type 1 diabetes was verified in relatively few studies (LE Ib) [42] (LE III) [44, 45].

- Education of patients with type 1 diabetes represents an indispensable therapeutic measure (grade A).

#### **Patient Education (Type 2 Diabetes)**

The manifestation of type 2 diabetes is strongly linked to obesity and a lack of exercise (LE III) [46, 47]. Patients with

impaired glucose tolerance carry an increased risk of developing type 2 diabetes (LE III) [48, 49]. Obesity and lack of exercise can be positively influenced by a systematic, long-term treatment and education program (lifestyle modification) in order to prevent or delay the manifestation of the illness (LE Ib) [50-52].

- Early identification as well as behavioural and medical treatment of patients with an increased risk of developing type 2 diabetes are tasks of high priority in order to reduce the continually rising incidence of type 2 diabetes. Patient education programs that aim towards long-term assistance in modifying nutritional behavior and physical activity can be used for this purpose (grade A).

In the short and long term, patient education programs for patients with type 2 diabetes are able to improve patients' knowledge (LE Ib), [53] nutritional behaviour (LE Ib), [54] weight (LE Ib), [55] self-treatment (LE Ib), [56] lipids (LE Ib) [57] and glycaemic control (LE Ib) [37]. Despite a large number of randomized, controlled studies, at present it is difficult to point to well-founded conclusions regarding the differential indications and influencing factors of special educational strategies (LE Ia) [26].

Education of type 2 diabetes patients is an indispensable therapeutic measure (grade A).

### **GUIDELINES: BEHAVIOURAL MEDICINE**

Behavioural medicine in diabetology aims to improve patients' cognitive, emotional and behavioural abilities so that they can cope with typical problems related to the illness and diabetes treatment.

#### **Blood Glucose Awareness Training (BGAT)**

Approximately 17% of all type 1 diabetes patients in epidemiological studies are affected by severe, recurrent hypoglycaemia (LE III) [58]. Severe, recurrent hypoglycaemia can have various causes. The problem of disturbed perception of hypoglycaemia has been well investigated (LE III) [59-61]. In the treatment of disturbed perception of hypoglycemia, BGAT has proven to be effective. Proof of effectiveness is available for the following outcome variables: reduction of severe hypoglycemia, increase in knowledge about hypoglycemia-induced affective and mental alterations, and decrease in hypoglycemia-related driving violations (LE Ib); [62] improved perception of low blood glucose values and improved glycaemic control (LE Ib); [63] and improvement of the adrenalin response to a hypoglycaemic stimulus (LE Ib) [64].

- Patients with insufficient hypoglycaemia awareness and severe recurrent hypoglycaemia should be treated by means of BGAT (grade A).

#### **Interventions for Reducing Stress**

Stress has an influence on the metabolic control of patients with diabetes (LE III) [65] (LE IIa) [66]. However, the observable effects are not unidirectional; they show great intra-individual and inter-individual variance depending on situational factors, the type and amount of stress, personal

characteristics, and coping strategies (LE III) [67-69]. Increased stress can lead to treatment problems (LE III) [70] and poor glycaemic control (LE III) [71]. Studies of persons with an increased risk of manifesting type 2 diabetes (LE III) [72] and findings from animal experiments (LE III) [73] indicate that stress facilitates the manifestation of type 2 diabetes. In contrast, there is no convincing evidence for a direct influence of stress on the manifestation of type 1 diabetes (LE III) [74]. The effectiveness of stress reduction strategies (e.g., progressive muscle relaxation, biofeedback) in order to improve metabolic control has not yet been verified conclusively, despite isolated indications of effectiveness (LE Ib) [75-77, 78, 79], (LE IIa) [80].

- Therefore, interventions for reducing stress (e.g., relaxation) with the primary goal of improving blood sugar levels and metabolic control cannot yet be recommended unconditionally for clinical routine (grade B).
- In general, interventions for reducing stress (e.g., relaxation) are an effective procedure within the framework of basic psychosomatic care or psychotherapy (LE IIa) [e.g. 81]. There are no contraindications for implementation in persons with diabetes mellitus.

#### **Interventions to Facilitate Coping with Diabetes**

Adequate coping with illness is a decisive pre-condition for effective self-treatment behavior and for the long-term success of therapy. Diabetes-related negative emotions and other problems of coping behavior frequently arise over the course of the illness and can negatively influence glycaemic control and patients' compliance (LE III) [82-84]. Patients with diabetes-related complications and/or mental disorders have many difficulties in coping with the illness (LE III) [84, 85]. A number of various individual and group therapy interventions are available to improve patients' coping behavior, especially with regard to diabetes-associated psychosocial and medical problems. However, the majority of studies that have evaluated these types of interventions independent of educational programs could not verify a significant effect on glycaemic control or HRQoL (LE Ib) [86-91] (LE IIa) [37, 92].

- Available data do not support the general recommendation of psychotherapeutic strategies in diabetes care in order to improve coping behavior (grade B).
- Psychotherapeutic interventions should be considered in patients with severe coping problems, as the effectiveness of such interventions has been established for chronic illnesses in general (LE IV, grade B) [93].

#### **Interventions for Improving Interpersonal Problems**

Interpersonal problems and insufficient social support complicate therapy implementation and are associated with poor metabolic control. Social support contributes to improved glycaemic control (LE III) [94]. Psychotherapeutic group settings are effective in terms of altering dysfunctional locus of control and social competence (LE Ib) [95] (LE IIa);

[96] however, a positive effect on metabolic control has not been demonstrated consistently.

- Psychotherapeutic interventions are useful in patients with severe interpersonal problems that affect diabetes care negatively (grade B).

### **GUIDELINES: DEPRESSION**

#### **Epidemiology**

Compared with the normal population, persons with diabetes are roughly at twice the risk of developing depression. The prevalence of depression among individuals with either type 1 or type 2 diabetes ranges between 6% and 26.7% in controlled studies, depending on the population studied, the definition of the disorder, and the instruments implemented. Higher prevalences arise in clinical samples (LE III) [85].

#### **Interaction between Diabetes Mellitus and Comorbid Depression**

Patients with diabetes mellitus and comorbid depression have poorer metabolic control than patients who have diabetes without comorbid depression (LE III) [97]. This connection, however, is dependent on the type of diabetes, sex, and the population studied (LE III) [98]. Depressive patients with diabetes comply with the therapeutic and medical recommendations to a lesser extent than patients without comorbid depression (LE IIa) [99], in particular with regard to dietary recommendations (LE III) [100]. Overweight patients with both type 2 diabetes and a lifetime diagnosis of a depressive episode tend to break off from weight reduction programs more frequently than patients who never became depressed (LE III) [101]. Smoking and nicotine abuse are more frequent in depressive patients with diabetes (LE III) [101].

Depression is an independent risk factor for the development of not only diabetes, but also coronary heart disease (LE IIa) [102]. Depression influences the mortality rate following a myocardial infarction (LE IIa).[103] Depression and depressive mood considerably reduce HRQoL and satisfaction with therapy (LE III) [104, 105]. The costs of medical care are distinctly higher in patients with diabetes and comorbid depression as compared with patients who have diabetes but no depression (LE III) [100]. The risk of depression increases with the development and number of diabetes-related complications (LE III) [106]. Acute diabetes-related complications are associated with a higher depression rate compared with chronic diabetic lesions (LE III) [107]. During the first 30 days after a severe episode of hypoglycemia, patients show increased depressive symptomatology (LE III) [108]. Patients who suffer from depressive symptomatology show an increased risk of developing type 2 diabetes (LE IIb) [109]. The issue of whether depressed patients with diabetes experience a less favorable course of the depression (higher rate of relapse, longer phases of illness) than patients who have depression but no diabetes is controversial. (LE III) [110, 111].

## Diagnostics

Patients who suffer from depressive symptomatology often consult a physician for unspecific physical ailments and play down the psychological symptomatology. Weakness, increased fatigue, apathy, irritability, anxiety, sexual problems, sleep disorders, loss of appetite, and weight loss (in addition to the more characteristic complaints of depression) all can be symptoms of depression.

When presented with these unspecific complaints, depression should be taken into consideration in terms of differential diagnostics. In cases of severe ketoacidosis or hypoglycemia, differential diagnostic procedures should check whether these conditions stem from an attempted suicide or other expressions of depressive disorders or self-destructive behavior (grade A).

The general practitioner plays a key role in the early recognition of the depressive disorder. Fifty percent to seventy percent of depressive disorders are not recognized in primary care; an even larger number of patients are not adequately treated (LE III) [112]. The central diagnostic instrument is the physician-patient dialogue. The sensitivity of the diagnostic judgment grows as the physician-patient interaction becomes more patient-oriented (LE III) [113-115].

- As part of the screening questions for depressive disorders, the physician should inquire about depressive mood (despondency, hopelessness), loss of interest and pleasure in activities, and reduction in drive. If signs of depression are present, the physician always should ask about suicidal thoughts and impulses (grade A).

Questionnaires on depressive symptomatology allow depression screening based on the patient's own responses. Especially valuable questionnaires include the "Hospital Anxiety and Depression Scale, HADS", [116] the "Patient Health Questionnaire, PHQ", [117] the "Center for Epidemiologic Studies-Depression Scale, CES-D", [118] and the "Beck Depression Inventory, BDI" [119]. These measures have proved to be valid and reliable instruments that can be implemented as screening instruments and also to evaluate effects of therapies for depression. Structured clinical interviews such as the CIDI [120] and SCID [121] provide a reliable diagnostic assessment of depressive disorders. Due to the considerable amounts of time involved, they are suitable primarily for scientific studies and for monitoring the course of psychotherapies.

## Therapy

There are few studies that specifically examine the therapy of depression in patients with diabetes mellitus. Cognitive behavioural therapy reduces the depressive symptomatology of patients with type 2 diabetes and leads to an increase in the rate of remission of the depression. These results are accompanied by improved metabolic control (LE Ib) [122]. Antidepressants have been shown to be effective among patients with diabetes in reducing the depressive symptomatology (LE Ib) [123, 124] (LE IIb) [125]. Tricyclic antidepressants can lead to a deterioration of metabolic control and a considerable gain in weight (LE Ib) [123] while therapy with Selective Serotonin Reuptake Inhibitors

(SSRI) can lead to hypoglycemia, which can necessitate an adjustment in the insulin therapy (LE Ib) [124] (LE IIb) [125] (LE III) [126]. There is some evidence that stress management and stress reduction programs reduce depressive symptoms of patients with diabetes mellitus (LE Ib) [75, 127, 128]. Also, regular telephone calls by a nurse within the framework of "automated telephone disease management" might reduce the depressiveness of patients (LE Ib) [129].

## Treatment in Primary Care

If the patient is not suicidal, there is no acute crisis, and prior attempts at therapy were not a failure, then the attending physician can administer basic psychosomatic treatment in order to reduce symptoms.

1. This treatment encompasses the following: building a trusting relationship with the patient; providing information about depression, conveying encouragement, relieving feelings of blame; accepting the patient's behavior (including complaining); positively reinforcing non-depressive cognitions; anticipating the patient's vulnerability; activating and motivating the patient without overwhelming him or her; and taking notice of and addressing suicidal tendencies (grade A).
- If the symptoms are not alleviated within a certain time or if the pre-conditions are not met, then specialized psychotherapy and/or pharmacological therapy should be introduced (grade A).

## Psychotherapy

The following psychotherapeutic procedures are scientifically and empirically based and recommended for the treatment of depression: Interpersonal Psychotherapy, Cognitive Behavioural Therapy, and Psychodynamic Psychotherapy (LE IV) [130].

- The above-mentioned psychotherapy also should be implemented according to a differential indication in patients with diabetes (grade A).

## Pharmacological Therapy

The following antidepressant drugs are used in the acute treatment of unipolar depressive disorders: tricyclic and tetracyclic antidepressants, SSRI's, MAO inhibitors, atypical and new antidepressants, adjuvant administration of benzodiazepine and low-potency neuroleptics (LE IV) (according to the guidelines of the German Society for Psychiatry and Psychotherapy and Nervous Diseases, DGPPN) [130].

- The psychopharmacological treatment of depression in patients with diabetes should comply with the guidelines of the DGPPN, taking into account side effects relevant to diabetic metabolic control (grade A).
- When selecting an antidepressant for patients with diabetes, SSRI's should be preferred because tricyclic antidepressants can lead to weight gain and hyperglycemia, thereby worsening metabolic control (grade A).

## GUIDELINES: ANXIETY DISORDERS

### Epidemiology

Point prevalence of anxiety disorders in the general population is 9% (LE III) [131]. There is no convincing evidence of an increased prevalence of anxiety disorders in patients with diabetes as compared with the normal population (LE III) [132-134]. Injection phobias rarely occur (LE III) [135, 136]. Only one study reported a high rate (28%) of injection-related anxieties (LE IV) [137]. Anxiety about diabetes-related complications and fear of hypoglycaemia are the two most important diabetes-associated psychological burdens. These two hardships may lead to considerable emotional impairment and problems with coping with the illness (LE IIb), [138] (LE III), [83, 84] (LE IV) [139, 140].

### Interaction between Diabetes Mellitus and Comorbid Anxiety Disorders

Anxiety disorders or subclinical anxieties can cause poor metabolic control (LE III), [132, 134, 141] although study results are inconsistent (LE III) [142-144]. Patients who have diabetes and an anxiety disorder are not only impaired by their mental disorder, but also have an above-average burden with regard to coping with the diabetes and generic HRQoL (LE III) [105].

### Diagnostics

Because the symptomatology usually lacks specificity, diagnosis of anxiety disorders in patients with diabetes is rather complex. For this reason, the physician's interview is of considerable importance.

- According to the DGPPN guidelines, [145] the following questions should be clarified: Are somatic or psychological symptoms of anxiety present? Are anxiety attacks or chronic anxiety involved? Do the anxiety attacks manifest themselves unexpectedly? To what extent do anticipation anxiety, avoidance behavior, or social impairments exist? (LE IV, grade A).
- Questions about diabetes-related anxieties, such as excessive anxiety about the consequences of diabetes or hypoglycemia, should be asked as screening strategies (grade A).

The German version of the Beck Anxiety Inventory is suitable to attain an initial orienting assessment (LE IV) [146]. For screening purposes, the complete German version of the "Patient Health Questionnaire" (PHQ-D) is appropriate (LE III) [117, 147]. This comprehensive inventory provides screening for the most frequent mental disorders in primary care, in addition to a specific screening of anxiety disorders. Furthermore, screening instruments for the occurrence of fear of hypoglycemia, for example, the "Hypoglycaemia Anxiety Inventory" (LE III) [148] proved to be effective in clinical practice. The "Questionnaire on Stress in patients with diabetes" (QSD-R) (LE III) [149] can provide clues to excessive diabetes-associated stress. Standardized psychiatric interviews, such as the Diagnostic Interview for Mental Disorders (DIMD), [150] Muenchner Composite International Diagnostic Interview (M-CIDI),

[151] or Structured Clinical Interview for DSM-IV (SCID), [152] provide a precise differential diagnostic classification according to the ICD-10 criteria.

Anxiety symptoms may be of varying origins and have to be distinguished from one another. They may result from psychological stress associated with diabetes; however, they also may be due to different illnesses (e.g., hyperthyreosis, pheochromocytoma, vestibular syndrome, seizures, arrhythmia, and supraventricular tachycardia) (LE IV) [145].

- If a comorbid anxiety disorder needs to be taken into consideration in a patient with diabetes, adequate diagnostic procedures must be performed; established diagnostic procedures and differential diagnostics should be performed. In cases of doubt or in cases with severe symptomatology, diagnostic clarification and possibly continued treatment by a specialist should be arranged (psychologist, physician who specializes in psychosomatic medicine or psychiatry) (grade A).
- Suitable laboratory tests (blood count, electrolytes, blood glucose, transaminases, gamma-GT, TSH, FT<sub>3</sub> and FT<sub>4</sub>) should be performed (including ECG and EEG).
- So as not to foster hypochondriacal anxieties, additional diagnostic procedures should proceed only upon founded suspicion of certain physical illnesses or in the event of treatment resistance (LE IV, grade A) [145].

### Therapy

There are very few specific, methodically sound research findings with regard to psychotherapy of anxiety disorders in adult patients with diabetes. These findings do not allow definite statements to be made regarding specific intervention strategies and effects in order to reduce anxiety symptoms. Four case studies reported successful psychotherapeutic treatments of insulin injection phobia (LE IV) [153-156]. Nonetheless, the number of studies is too small for any generalizations or treatment recommendations to be made. Nor has the effectiveness of behavioural therapy or blood-glucose awareness training been verified sufficiently for the reduction of fear of hypoglycaemia or anxiety about diabetes-related complications (LE Ib) [157] (LE IIa), [158] (LE IIb) [62, 138].

- Anxiety treatment interventions are generally an effective procedure within the framework of psychotherapy. There is no counter-indication for their use in patients who have diabetes (grade A).

### TREATMENT IN PRIMARY CARE

- For subclinical anxieties or low-grade symptomatology, basic psychosomatic treatment strategies may be performed: diagnostics and differential diagnostics of the anxiety disorder, clarification of diabetes-specific anxieties, Counselling and psychoeducation. For mild phobias, encouragement and guidance for exposure to feared situations, and self-help manuals (grade A) may be utilized.
- If the symptoms are not alleviated within a certain time or if the pre-conditions are not met, then specialized

psychotherapy and/or pharmacological therapy should be introduced (grade A).

- If evidence arises that points to diabetes-specific anxieties (e.g., hypoglycaemia anxiety, insulin injection phobia), then treatment with a psychotherapist who is experienced in the area of diabetes should proceed, whenever possible (grade A).

### Psychotherapy

If a patient with diabetes has a moderate or severe anxiety disorder or a satisfactory improvement was not achieved within the bounds of the described basic psychotherapeutic interventions, procedures should be implemented that have been scientifically validated for patients with anxiety disorders and no diabetes.

- Such procedures include cognitive behavioural therapy, psychodynamic psychotherapy, and, possibly in combination with these procedures, pharmacological interventions. The guidelines of the DGPPN should be consulted [145] (LE IV, grade A).
- If there is evidence of diabetes-specific anxieties (e.g., fear of hypoglycemia, insulin injection phobia), then the method of first choice should be behavioural therapy with a psychotherapist who is experienced in treating patients with diabetes. If this treatment remains unsuccessful, then psychodynamic therapy should be recommended as second choice (grade A).

### Pharmacological Therapy

In the treatment of anxiety disorders, the following drugs are primarily used, according to the guidelines of the DGPPN (LE IV): [145] benzodiazepine, beta-blockers, MAO inhibitors, Bupropion, neuroleptics, SSRI's, and tricyclic antidepressants.

Of all the antidepressants, the SSRIs are preferred over the tricyclic antidepressants due to the former's better profile of side effects for patients with diabetes (grade A).

## GUIDELINES: EATING DISORDERS

### Epidemiology

The prevalence of anorexia nervosa (AN) varies between 0.2 and 0.8% [159]. Therefore, the comorbidity of diabetes mellitus and AN is judged to be extremely rare in patients with type 1 diabetes mellitus (LE IIa), [160-165] (LE III) [166]. The prevalence of bulimia nervosa (BN) in patients with type 1 diabetes mellitus is higher than that of AN, varying between 0.0% [162-164] and 3.0% [161] (LE IIa). However, in a systematic review of all controlled studies, (LE Ia) [167] the assumption of a higher prevalence of BN in type 1 diabetic patients as compared with the general population could not be confirmed. In controlled studies among patients with type 1 diabetes, atypical eating disorders ("eating disorders not otherwise specified," EDNOS) varied between 3.0% [161] and 9.0% [165] (LE IIa).

Regarding self-care behavior, omission or intentional underdosing of recommended levels of self-administered

insulin is one of the most serious adherence problems. Omission of insulin in type 1 diabetes leads to hyperglycemia, excessive urination, volume depletion, and ketoacidosis. Some young patients with diabetes omit or underdose insulin in order to reduce their weight, thus inducing glucosuria. This highly risky attempt to lose weight, called "insulin-purging," is considered to be a diabetes-specific method of preventing weight gain. According to research studies, the prevalence of insulin purging varies from 5.9% (LE III) [168] to 39.0% (LE III) [169]. The large variation can be explained neither by the different age groups nor by the different survey instruments (questionnaires, interviews).

Despite the greater epidemiological importance of type 2 diabetes mellitus, the comorbidity of diabetes mellitus type 2 and eating disorders has been the subject of little empirical research. According to a controlled study, the prevalence of binge eating disorder (BED) in patients with type 2 diabetes was not higher than that of healthy controls (LE IIa) [170]. In a comparison of samples of patients with type 1 diabetes vs. those with type 2 diabetes, no difference in the prevalence of eating disorders could be observed, although the BED predominated in patients with type 2 diabetes (LE III) [168].

### Interaction Between Diabetes Mellitus and Comorbid Eating Disorders

Regarding the question as to whether an eating disorder in a patient with diabetes is accompanied by deterioration in metabolic control, the majority of controlled studies have compared eating-disturbed patients who have type 1 diabetes mellitus with non-eating-disturbed ones. In comparison with non-eating-disturbed patients who have diabetes, the metabolic control of eating-disturbed patients with diabetes was significantly poorer in all studies (LE IIa) [161, 162, 165] (LE III) [171, 172] with the exception of two (LE III) [168, 173]. Pathological eating behavior that fulfils the criteria of neither a clinical eating disorder (AN, BN) nor a subclinical eating disorder (EDNOS) but is characterized by frequent "feeding attacks" also goes hand in hand with poorer metabolic condition (LE IIa) [174].

Regarding diabetes-related complications in patients with eating disorders, results of a meta-analysis (LE Ia) [167] indicate a three-fold increased risk of retinopathy in patients with type 1 diabetes mellitus and BN. Pathological eating behavior that does not exhibit the full picture of an eating disorder according to the ICD criteria [175] likewise represents an increased risk of diabetic microangiopathy (LE IIa) [174]. If a patient with type 1 diabetes mellitus develops AN, there is a significant rise in mortality (LE IIb) [176]. In light of the rarity of this coincidence, there is a paucity of empirical investigations into the cause of death.

### Diagnostics

The comorbidity of diabetes mellitus and AN is extremely rare; due to the poor nutritional condition of the anorexic patient, it is generally easy to diagnose.

- In every instance of diabetes mellitus that requires insulin and remains difficult to bring under control –

particularly among adolescent girls and young female adults – one should consider early on whether a combination with BN and/or “insulin purging” possibly might be present (grade A).

- What points to this kind of comorbidity is above all the frequent, seemingly inexplicable decompensation of the diabetes mellitus (LE IV) [177]. To diagnose an eating disorder, a biographical case history is often necessary, as it helps the patient overcome the threshold of shame and a longstanding tendency to deny the eating disorder.
- In obese patients who have type 2 diabetes as well as considerable fluctuations in weight and highly variable blood glucose values, the differential diagnosis of a BED should be considered early on (grade A).

Various standardized questionnaires are available that screen for eating disorders. Questionnaires such as the Eating Disorder Inventory (EDI), [178] in particular, have proven to be valid and reliable instruments that can be implemented as screening instruments and as a therapy control. With the aid of the Structured Interview for Anorexia and Bulimia nervosa (SIAB) or clinical interviews such as the DIMD, [150] M-CIDI, [151] or SCID, [152] reliable and valid diagnoses of eating disorders can be performed.

### Therapy of Patients with Type 1 Diabetes Mellitus

Results of case studies showed predominantly positive therapeutic effects, primarily in inpatient treatment of anorexic and bulimic patients with type 1 diabetes (LE IV) [179-182]. Up to now, three treatment intervention studies [183-185] have been carried out on eating-disturbed patients with type 1 diabetes mellitus. Short-term group psychoeducation programs improved dysfunctional cognitions associated with eating disorders [184]. However, they seem to be ineffective with regard to disordered eating, purging by insulin omission, general psychopathology, adherence to diabetes treatment, and metabolic control (LE IIb) [183, 184]. Inpatient psychotherapy of type 1 diabetes patients with BN has a positive impact both on the eating disorder symptomatology and the diabetes; this positive impact is reflected in improved glycaemic control, depressiveness, anxiety, and psychological/behavioural disturbances related to bulimia nervosa (LE IIb) [185].

- Specialized psychotherapeutic treatment of these patients is urgently needed because of the increased risk of mortality, the danger to health from the eating disorder, the frequently encountered comorbid depressive disorder, as well as the negative effect on the diabetes therapy. Psychoeducational approaches alone are not sufficient, nor will they help to achieve their objective (grade A).
- Psychotherapeutic interventions for the treatment of eating disorders are effective. There is no counter-indication for their use among patients with diabetes mellitus. Consequently, the treatment of eating-disturbed patients with type 1 diabetes mellitus should proceed according to the internationally widely accepted NICE guidelines [186] (LE I). For psychotherapy to be successful, it is necessary to understand patients' life situations in general and that of the diabetes mellitus

patient in particular. Therefore, the attending psychotherapist needs to know about the therapy regime and any possible association with the eating behavior/eating disorder (grade A).

- Specialized psychotherapeutic treatment should be given particular consideration in the presence of the diagnosis “insulin purging,” which is a highly risky procedure to control weight gain that is found often in young female patients with type 1 diabetes. Insulin purging is commonly accompanied by poor metabolic control and very often represents an expression of self-destructive behavior (grade A).
- Early start of therapy and sufficient duration are important for treating eating-disturbed patients (grade A).

### Therapy of Patients with Type 2 Diabetes Mellitus

Only one small study with a short follow-up period showed that binge eating in type 2 diabetes is responsive to cognitive behavioural therapy; the study also demonstrated that reduction in binge eating improves glycaemic control [187] (LE IIb). Psychotherapeutic interventions are generally effective for the treatment of patients with eating disorders [186] (LE I). There are no counter-indications for their implementation in patients with diabetes mellitus.

- As a consequence, patients with type 2 diabetes mellitus and eating disorders should be treated according to the NICE guidelines [186] (LE I, grade A).
- As a rule, patients with type 2 diabetes who suffer from BED and obesity require that considerations about all three illness entities are taken into account for their treatment. Consequently, a multimodal treatment concept is necessary, whose integral parts comprise psychotherapy and weight management (grade A).

According to the guidelines of the German Obesity Society (LE IV), [188] the basic program for weight management rests on three foundations: nutrition therapy, behavioural therapy, and physical activities [189]. One should bear in mind, though, that the medical demand for weight reduction and the unavoidable, restrictive eating behavior it requires pose obstacles to the treatment of the BED. The hunger attacks involved in this disorder are discussed as being a consequence of pronounced cognitive control behavior and its collapse (loss of control), among other factors (LE IIa) [190].

- In terms of weight management in patients with BED, emphasis should be placed initially on normalizing eating behavior, as opposed to restricting eating behavior, in order to break the vicious circle of cognitive loss of control (binging) followed by fasting (grade A).

## GUIDELINES: ALCOHOL-RELATED DISORDERS

### Epidemiology

Alcohol abuse currently exists among 2.65 million persons (4% of the population aged 18 and older) in Germany; 1.6 million persons (2.4% of the population aged 18 and older) are acutely alcohol dependent. Ten to twelve

percent of German citizens consume alcohol to a degree (men > 40g pure alcohol/d; women > 20g pure alcohol/d) that may not be acutely dangerous but carries with it a high long-term risk of damage to the individual's health (LE IV) [191, 192]. Alcohol dependence does not occur with any greater frequency among individuals with diabetes than among the general population (LE IIb) [193] (LE III); [194] in fact, some studies showed lower prevalence rates (LE III) [195, 196].

### Interaction between Diabetes and Alcohol-Related Disorders

Alcohol abuse increases the risk of manifestation of type 2 diabetes through an alcohol-related pancreatitis (LE IIb) [197] (LE III) [198]. In addition to the general physical and psychosocial consequences of alcohol dependency, metabolic control is negatively influenced by the direct effect of alcohol on glucose metabolism and indirectly by the negative effect of alcohol consumption on self-treatment behavior [199, 200]. There is a specifically increased risk for diabetes-associated secondary illnesses, such as high blood pressure (LE IIb), [201] hyperlipidemia (LE IIb), [202] and/or diabetes-related complications, for example, the development of polyneuropathy (LE IIb), [203] diabetic foot syndrome (LE III), [204] erectile dysfunction (LE III), [205] or severe hypoglycaemia and ketoacidoses, which may result in death (LE IIb) [206, 207] (LE III) [208] (LE IV) [209, 210]. Poor results of the diabetes therapy of patients with alcohol abuse arise largely from a lack of motivation for treatment, faulty self-treatment, and chronic effects on health (e.g., gastrointestinal disorders) from the alcohol abuse (LE IIb) [207] (LE IV) [211].

### Diagnostics

Early diagnosis is important because of the negative effects substance dependencies have on diabetes therapy.

- Diagnosis requires a thorough review of the drinking habits and attendant physical and psychological problems, a physical examination, and special laboratory tests (LE IV) [39]. Due to the problems of dependency, patients often exhibit a tendency to deny their alcohol dependency; such denial should be taken into consideration during the diagnostic process (grade A).

Frequently those affected have additional psychological disorders (e.g., depression, anxiety disorders) and cognitive impairments that likewise require in-depth diagnosis and treatment (LE III) [131]. Questionnaires on alcohol-related dependency allow screening for alcohol dependency based on self reports. Suitable are valid and reliable German-language instruments such as the "Luebeck Alcohol Dependency and Abuse Screening Test" (LAST), [212] the Trier Alcoholism Inventory, [213] and the "Munich Alcoholism Test" (MALT) [214]. Structured clinical interviews, such as DIMD, [150] M-CIDI, [151] and SCID, [152] allow reliable diagnoses of alcohol dependence.

### Therapy

There are no studies of the treatment of alcohol-dependent patients with diabetes mellitus.

- Therefore, the interventions recommended in the guidelines of the American Psychiatric Association (LE IV) [39] should be applied for the treatment of alcohol dependency (grade A).

Because of the increased danger to health resulting from dependency and its negative effect on diabetes therapy, the treatment of the dependency illness in patients with diabetes carries special importance.

- Thus, every alcohol-dependent patient should undergo a structured therapeutic program to treat his or her dependency (grade A).
- The diabetes therapy must be oriented toward the dependency as long as the patient is unsuccessful in breaking the habit or the prospect of doing so seems unrealistic (LE IV) [215]. The demands of therapy should be adapted to the abilities of the patient. Relatives should be involved in the diabetes care of the patient as much as possible (grade A).

## GUIDELINES: SMOKING-RELATED DISORDERS

### Epidemiology

Nicotine dependence is the most widespread form of substance dependence in Germany. Altogether, 28.3% of the population over 15 years of age smokes in Germany. Eighty-seven percent of the cigarette smokers are regular smokers who consume 15.4 cigarettes a day on average. Roughly 70% to 80% of the smokers are nicotine dependent, so that a total of approximately 8-9 million men and 5-6 million women can be classified as tobacco dependent in Germany (LE III) [216] (LE IV) [217, 218].

The prevalence of tobacco dependence in patients with diabetes does not differ, on average, from that of the general population, despite an increased risk for developing diabetes-related effects and complications (LE III) [196, 219, 220]. In fact, several studies found higher rates of tobacco dependence in patients with diabetes (LE IV), [221] especially in younger patients (LE III), [219, 220, 222] and patients with low levels of education (LE III) [220].

### Interaction between Diabetes and Tobacco-Related Disorders

Tobacco consumption increases the risk of manifestation of type 2 diabetes (LE IIb) [197, 223-225] (LE III) [226]. Smoking is an important additional risk factor for developing diabetes-related complications. It is well established that smoking increases the risk of cardiovascular diseases, diabetes-related neuropathies, peripheral vascular disease, erectile dysfunction, strokes, and high blood pressure (LE IIb) [227] (LE III) [228] (LE IV) [221]. Smoking significantly increases the risk of diabetic nephropathy (LE IIb) [229-231] (LE III) [232-235]. Nicotine abstinence can improve an existing proteinuria (LE III) [236]. In the case of terminal kidney disease, smoking is an important risk factor for increased mortality (LE IIb) [237, 238]. The findings on diabetic retinopathy are controversial (LE IIb) [239] (LE III) [229, 240]. Patients who have diabetes and smoke have an increased risk of mortality as compared with persons who have never smoked; this risk depends on the duration of

smoking and the number of cigarettes smoked (LE IIb) [241, 242]. Increasingly, nicotine dependence has been associated with problems in carrying out diabetes therapy (LE III) [194]. Broadly, one can assume a negative association between smoking and metabolic control (LE IIb) [229, 243] (LE III); [244] however, the data on this connection are contradictory (LE IIb) [245] (LE III) [246, 247]. Smoking can represent a predictor variable for poor self-treatment behavior (LE IIb) [243] (LE III) [248]. Patients with diabetes who are tobacco dependent have an increased comorbidity with depression (LE III) [194] (LE IV) [249].

### Diagnosics

Those affected by nicotine dependency often deny the dependency (LE III) [250, 251] and underestimate the negative effects in terms of the risk of developing diabetes-related complications (LE III) [219].

In addition to a general case history survey, inquiries should be made specifically about secondary illnesses and complications. The degree of dependency is contingent on the number of cigarettes (or cigars or pipes) smoked daily, the time when the morning cigarettes are smoked, and the smoker's daily profile, depth of inhalation, and brand of cigarette smoked, among other factors (LE IV) [252]. To determine nicotine dependence, the Fagerstrom Test is recommended (LE IV); [253] this test can evaluate the degree of dependency based on six questions. Structured clinical interviews such as the DIMD, [150] M-CIDI, [151] and SCID [152] allow reliable diagnoses of nicotine dependency.

### Therapy

Smoking cessation counseling is given in different forms, generally derived from behavior therapy. Five steps that can be implemented to ensure a patient's capacity for successful smoking cessation (the "five A's") are: ask about smoking, advise the patient to stop smoking, assess readiness to quit, aim interventions, and arrange follow-up. Randomized studies have shown varying rates of success for the therapy of tobacco-dependent patients who have diabetes (LE Ib) [232, 254]. Various authors indicate that the treatment of tobacco dependency is particularly difficult among young adults (LE III) [251, 255-257]. Very heavy smokers rarely achieve nicotine abstinence (LE IIb) [245].

- For treatment of tobacco dependency in patients with diabetes, the interventions recommended by the evidence-based guidelines of the WHO (LE IV), [258] the American Psychiatric Association (LE IV), [39] and the American Diabetes Association (LE IV); [259] and the therapeutic recommendations of the Drug Commission of the German Board of Physicians (LE IV) [252] should be implemented (grade A).

Treatment of tobacco dependency takes on particular importance in patients with diabetes due to the increased danger to health caused by the dependency and its negative effects on diabetes therapy (LE III) [259].

- Consequently, the problem of the relationship between smoking and risk of diabetes-related complications should be adequately addressed in a structured diabetes

education program. Every nicotine-dependent patient with diabetes should undergo a structured therapy program to treat his or her dependency within the framework of that person's diabetes therapy (grade A).

If patients reject smoking cessation programs, short interventions should be performed, because they have proven to be effective in increasing motivation to stop smoking (LE IV) [215, 260].

- As a consequence, measures for increasing motivation to abstain from smoking should be implemented repeatedly within the framework of diabetes treatment (grade A).

### CONCLUSION

In summary, these psychosocial guidelines are a first step toward a systematic analysis of the published literature that has addressed psychosocial issues in diabetes. Principles of evidence-based medicine were applied to define standards of diagnosis and treatment of common psychosocial problems of patients with diabetes. These guidelines also provide the state-of-the-art knowledge about patient education and behavioural interventions. By following the methodology used to develop these guidelines, the reader can reconstruct easily the empirical evidence supporting specific recommendations.

Besides the scientific guidelines, the versions for clinical practice and for patients may help to improve routine diabetes care with regard to psychosocial issues. Updates of these guidelines are planned at 2-year intervals to guarantee that the recommendations stay up-to-date. Apart from the problem-focused aspects of these guidelines, in future versions we will enlarge the view to include a resource-oriented perspective as well (e.g., inclusion of prevention aspects). Also, psychosocial issues that have been neglected in this version (e.g., psychoses, drug dependencies other than alcohol- and smoking-related ones, and cognitive impairment) could be addressed as part of this revision process.

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