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CLINICAL PRACTICE GUIDELINE

Non-Specific, Functional, and Somatoform Bodily Complaints

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SUMMARY

Background: 4–10% of the general population and 20% of primary care patients have what are called "non-specific, functional, and somatoform bodily complaints." These often take a chronic course, markedly impair the sufferers' quality of life, and give rise to high costs. They can be made worse by inappropriate behavior on the physician's part.

Methods: The new S3 guideline was formulated by representatives of 29 medical and psychological specialty societies and one patient representative. They analyzed more than 4000 publications retrieved by a systematic literature search and held two online Delphi rounds and three consensus conferences.

Results: Because of the breadth of the topic, the available evidence varied in quality depending on the particular subject addressed and was often only of moderate quality. A strong consensus was reached on most subjects. In the new guideline, it is recommended that physicians should establish a therapeutic alliance with the patient, adopt a symptom/coping-oriented attitude, and avoid stigmatizing comments. A biopsychosocial diagnostic evaluation, combined with sensitive discussion of signs of psychosocial stress, enables the early recognition of problems of this type, as well as of comorbid conditions, while lowering the risk of iatrogenic somatization. For mild, uncomplicated courses, the establishment of a biopsychosocial explanatory model and physical/social activation are recommended. More severe, complicated courses call for collaborative, coordinated management, including regular appointments (as opposed to ad-hoc appointments whenever the patient feels worse), graded activation, and psychotherapy; the latter may involve cognitive behavioral therapy or a psychodynamic-interpersonal or hypnotherapeutic/imaginative approach. The comprehensive treatment plan may be multimodal, potentially including body-oriented/non-verbal therapies, relaxation training, and time-limited pharmacotherapy.

Conclusion: A thorough, simultaneous biopsychosocial diagnostic assessment enables the early recognition of non-specific, functional, and somatoform bodily complaints. The appropriate treatment depends on the severity of the condition. Effective treatment requires the patient's active cooperation and the collaboration of all treating health professionals under the overall management of the patient's primary-care physician.

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When the S2e guideline "Somatoform disorders" (1) expired, the German College of Psychosomatic Medicine (DKPM, Deutsches Kollegium für Psychosomatische Medizin) and the German Society of Psychosomatic Medicine and Medical Psychotherapy (DGPM, Deutsche Gesellschaft für Psychosomatische Medizin und Ärztliche Psychotherapie) determined to rework it comprehensively in an interdisciplinary way for the new edition. Under the coordination of these bodies, from 2008 to 2012, representatives of 28 medical and psychological specialist societies, the German Association for the Support of Self Help Groups (patient representative), and the Association of Scientific Medical Societies in Germany (AWMF, Arbeitsgemeinschaft medizinischer Fachgesellschaften) (*eBox 1*) developed the new S3 guideline "Management of patients with non-specific, functional, and somatoform bodily complaints" (NFS), of which the present article is the official short version (2–4).

Method

The guideline group included members from all areas of care and was balanced in terms of gender and seniority. At the inaugural meeting, key questions on all clinically relevant themes were formulated and divided up between nine working groups. Building on the 2002 S2e guideline, a seven-member steering group (*eBox 1*) carried out a systematic literature search of publications dating from 1 January 2000 to 1 January 2009 (for search terms see *eBox 2*), which was added to and brought up to date by the working groups up to May 2011 (3). After assessment of inclusion and exclusion criteria (*eBox 3*) and the quality and relevance of the studies (e1) (*eTable 1*), 761 publications were included for the guideline (*Figure 1*). The working groups analyzed the literature, evaluated the evidence levels (ELs) (e2) (*eTable 2*), and developed 148 recommendations, statements, and source texts. For the most important forms of therapy, examples of numbers needed to treat (NNTs) were calculated as a statistical measure of efficacy (*Table 1*). The guideline was modified in two online Delphi procedures and three consensus conferences, and finalized by consensus, in most cases strong consensus (e3) (*eTable 3*). The corresponding recommendation grades (RGs) were based on the evidence levels, but could be raised or lowered during the consensus procedure (e4) (*eFigure*). Recommendations

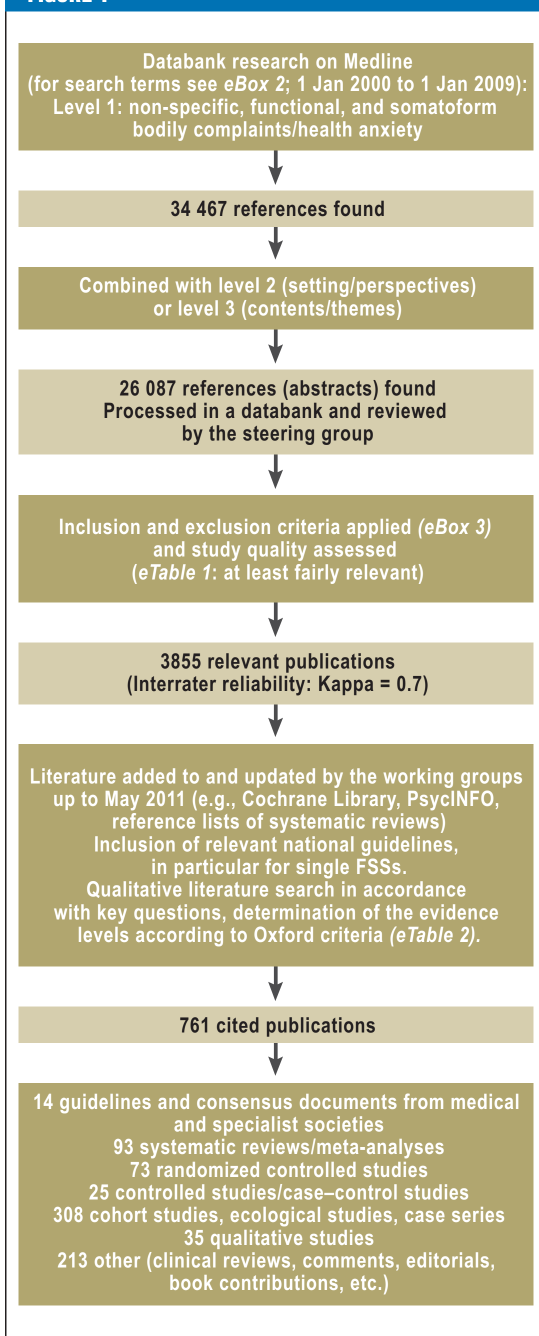


FIGURE 1

Systematic literature search and selection of relevant publications. FSS, functional somatic syndrome

regarded by the guideline group as representing a standard despite a lack of evidence were marked as "clinical consensus points" (CCPs) (e5). The guideline version passed by consensus was posted on the Internet in February 2012 for 4 weeks for public comment. It was reviewed by three external experts (*eBox 1*), approved by the participating medical societies and associations, and adopted by the AWMF on 15 April 2012 (register no. 051–001). It is valid for 5 years.

Terms and objectives

The plethora of terminology (e6) is a hindrance to care and to research (e7). With the aim of achieving an interdisciplinary perspective, the triple term "non-specific, functional, and somatoform bodily complaints" takes up the parallel classification of functional somatic syndromes (FSS) (somatic medicine) and somatoform disorders (psychosocial medicine), and complements the general medical perspective of non-specific bodily complaints (*eBox 4*). The guideline is concerned with what these disorders of adults have in common (5, 6, e8, e9). Its aim is to provide practical, interdisciplinary recommendations for all levels of care, to promote a biopsychosocial understanding of health and illness, to optimize early diagnosis, prevention, and treatment, to improve the quality of life and ability to function of those affected, and to reduce undertreatment and erroneous treatment.

Characterization of the disorder

Clinical features

The main symptoms of NFS are pain in various locations, impaired organ functions (gastrointestinal, cardiovascular, respiratory, urogenital), including autonomic complaints, and exhaustion/fatigue (7). These are often accompanied by illness anxiety. If this anxiety dominates, a hypochondriac disorder is present (e10).

Multifactorial disorder model

Current etiopathogenetic models assume complex interactions between psychosocial factors, biological factors, iatrogenic factors or factors related to the medical system, and sociocultural factors, which can lead to neurobiological changes, and act together in disposition, triggering and maintenance of the complaints (7, 8, e11). A health system that focuses more on repair and care than on self-responsibility and prevention, and provides counterproductive financial incentives to illness-related behavior and technical measures rather than to healthy behavior, achievement through talking to the patient, and the avoidance of unnecessary treatment, has the effect of maintaining complaints (7, e11–e13). The iatrogenic chronification factors to be avoided (e14–e21) (CCP) are shown in *Box 1*.

Epidemiology, co-morbidity, and health care utilization behavior

NFS affect 4% to 10% of the population (2, 4, e22) and 20% of primary care patients (9, 10) (EL 1b), and are reported more frequently by women in all age groups (♀:♂ = 1.5–3:1) (e23, e24) (EL 2b). In specialized settings, such as specialist somatic medical outpatient

TABLE 1

Effectiveness of selected therapies in comparison to control groups (at the end of therapy) in patients with non-specific, functional, and somatoform bodily complaints; based on systematic review articles with meta-analyses of randomized controlled studies (2, 4)

NFS	Therapy form	No. of studies/ patients	Target variable	Statistical measure of effectivity: SDM, RR (95% CI)	NNT (95% CI)	Reference
MUS and somatoform disorders	CBT	11/832	Physical symptoms	SDM −0.25 (–0.38 to −0.12)	8 (6–17)*[1]	23
Fibromyalgia syndrome	CBT	12/568	Pain	SDM −0.28 (−0.59 to 0.03)	7 (4–68)*[1]	e85
	Hypnotherapy/guided imagery	5/166	Pain	SDM −1.40 (−2.59 to −0.21)	2 (1–9)*[1]	e85
	Aerobic exercise	32/1341	Pain	SDM −0.40 (−0.55 to −0.26)	5 (4–8)*[1]	e76
	Tricyclic antidepressants	10/520	Pain	SDM −0.53 (−0.78 to −0.29)	4 (3–7)*[1]	e82
	SNRI (duloxetine, milnacipran)	10/6012	Pain	SDM −0.23 (−0.29 to −0.18)	9 (7–11)*[1]	e82
	Pregabalin	5/4121	Pain	SDM −0.27 (−0.35 to −0.19)	8 (6–11)*[1]	e82
Irritable bowel syndrome	CBT	7/491	Persistent bowel-related symptoms	RR 0.59 (0.42 to 0.87)	3 (2–7)	e81
	Gut-directed hypnotherapy	2/40	Persistent bowel-related symptoms	RR 0.48 (0.26 to 0.87)	2 (1,5–7)	e81
	Psychodynamic therapy	3/211	Persistent bowel-related symptoms	RR 0.60 (0.39 to 0.93)	4 (2–25)	e81
	Aerobic exercise	2/134	Persistent bowel-related symptoms	SDM −0.49 (−0.84 to −0.15)	4 (3–14)*[1]	e74, e75
	Tricyclic antidepressants	9/575	Persistent bowel-related symptoms	RR 0.68 (0.56 to 0.83)	4 (3–8)	e81
	SSRIs	5/230	Persistent bowel-related symptoms	RR 0.62 (0.45 to 0.87)	4 (2–14)	e81
Chronic fatigue syndrome	CBT	6/373	Fatigue	SDM −0.39 (−0.60 to −0.19)	5 (4–11)*[1]	e84
	Aerobic training	5/286	Fatigue	SDM −0.77 (−1.26 to −0.28)	3 (2–7)*[1]	e73

NFS, non-specific, functional, and somatoform bodily complaints; SDM, standard deviation of the mean (therapy group versus control group at the end of therapy); RR, relative risk (therapy group versus control group at the end of therapy); NNT, number needed to treat; 95% CI, 95% confidence interval; MUS, medically unexplained symptoms; CBT, cognitive behavioral therapy; SNRI, selective serotonin and norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor

*[1] NNTs were calculated using the Wells Calculator Software of the Cochrane Musculoskeletal Group Editorial Office. A half standard deviation was chosen as the minimally important difference (MID) (e101).

units or practices, a percentage up to 50% may be assumed (2, 4, e25). In the general population, 10% of those affected with an FSS also fulfill the criteria of one or more other FSSs; in clinical populations this overlap may be as much as 50% (e8, e9, e26) (EL 2a). In both clinical and population-based samples, NFS show a comorbidity that increases with the severity of the NFS, including depressive, anxiety (11, e27, e28), and posttraumatic stress disorders (e29) as well as addiction disorders (medications, alcohol) (e30, e31). In severe cases (full-blown somatization disorder F45.0) there are often co-morbid personality disorders (e32, e33) (EL 2a). A majority show high, dysfunctional use of the health care system, especially in cases of psychological co-morbidity (9, e34) (EL 2b). The result is high direct (multiple diagnoses, overdiagnosis, inappropriate treatment) and indirect health costs (loss of productivity, long-term inability to work, early retirement) (13, e35). Also in older patients, NFS parts of the complaints should be considered, even if the differential diagnosis is more complex and uncertain because of multimorbidity and multimedication. (14, e36) (EL 2a, RG B).

Course and prognosis

Life expectancy for patients with NFS is presumably normal (e37, e38), but quality of life is more impaired than with somatic diseases (e39) (EL 2b). Suicide risk, especially among those in chronic pain, is greater than in the general population (e40, e41). In patients with fibromyalgia, the standardized mortality ratio for suicide was between 3.3 (95% confidence interval [95% CI] 2.2–5.1) (Danish retrospective cohort

BOX 1

Iatrogenic chronification factors/unfavorable physician behavior (e14–e21) (CCP)

- **Attitude and preconditions of treatment**
  - One-sided biomedical or psychologizing approach ("either/or" model)
  - Lack of cooperation between treating health professionals
- **Diagnostic investigations**
  - Overdiagnosis and multiple organic diagnostic investigations as pure exclusion diagnostics
  - Overestimation of non-specific somatic findings
  - Insufficient consideration of psychosocial factors and mental co-morbidity
  - Failure to take (adequately) into account social medical aspects (invalidity benefit, desire for pension) aand other relieving aspects of the "sick role" (secondary gain from being ill)
- **Communication skills**
  - Presenting findings in a way that causes anxiety; giving "catastrophizing" medical advice
  - Failure to give any diagnosis ("there's nothing wrong with you") or giving a stigmatizing diagnosis ("it's all in the mind")
  - Giving poor information about the clinical picture without adequately explaining the patient's complaints
  - Not involving the patient sufficiently (his or her ideas about causes and goals)
- **Treatment planning**
  - Unstructured proceeding with complaint-led or even emergency appointments
  - Insufficient treatment planning without setting therapy goals together with the patient
- **Treatment**
  - Promoting passive therapeutic approaches (e.g., passive physical procedures, injections, operations)
  - Preferring and inappropriately prescribing invasive or addiction-promoting therapies
  - Writing patients off sick for long periods without careful consideration
  - Not referring patients to psychosocial care, or referring them late, or with inadequate preparation and/or follow-up of the referral
  - Failing to initiate multimodal therapy that may be indicated
- **Medication**
  - Prescribing drugs without taking stock of whatever medications the patient may already be taking
  - Insufficient analgesic treatment for actue pain
  - Pain-contingent use of drugs "as needed" (especially analgesics)
  - Unreflecting prescription of addictive drugs, especially opioids and benzodiazepines
  - Non-indicated prescription of neuroleptics, e.g., "as a weekly/restaurative injection"
  - Prescribing long-term psychopharmacotherapy as a monotherapy without appropriate psychotherapy

study, n = 1269 women [e38]) and 10.5 (95% CI 4.5–20.7) (US retrospective case control study, n = 8186 [e37]).

Irrespective of clinical setting, a less severe course with improvement of functioning and quality of life is seen in 50% to 75% of those affected, and a more severe course (usually marked functional/ somatoform disorders, with deterioration of functioning and quality of life is seen in 10% to 30% (15) (EL 1b).

Principles and preconditions of diagnosis and treatment

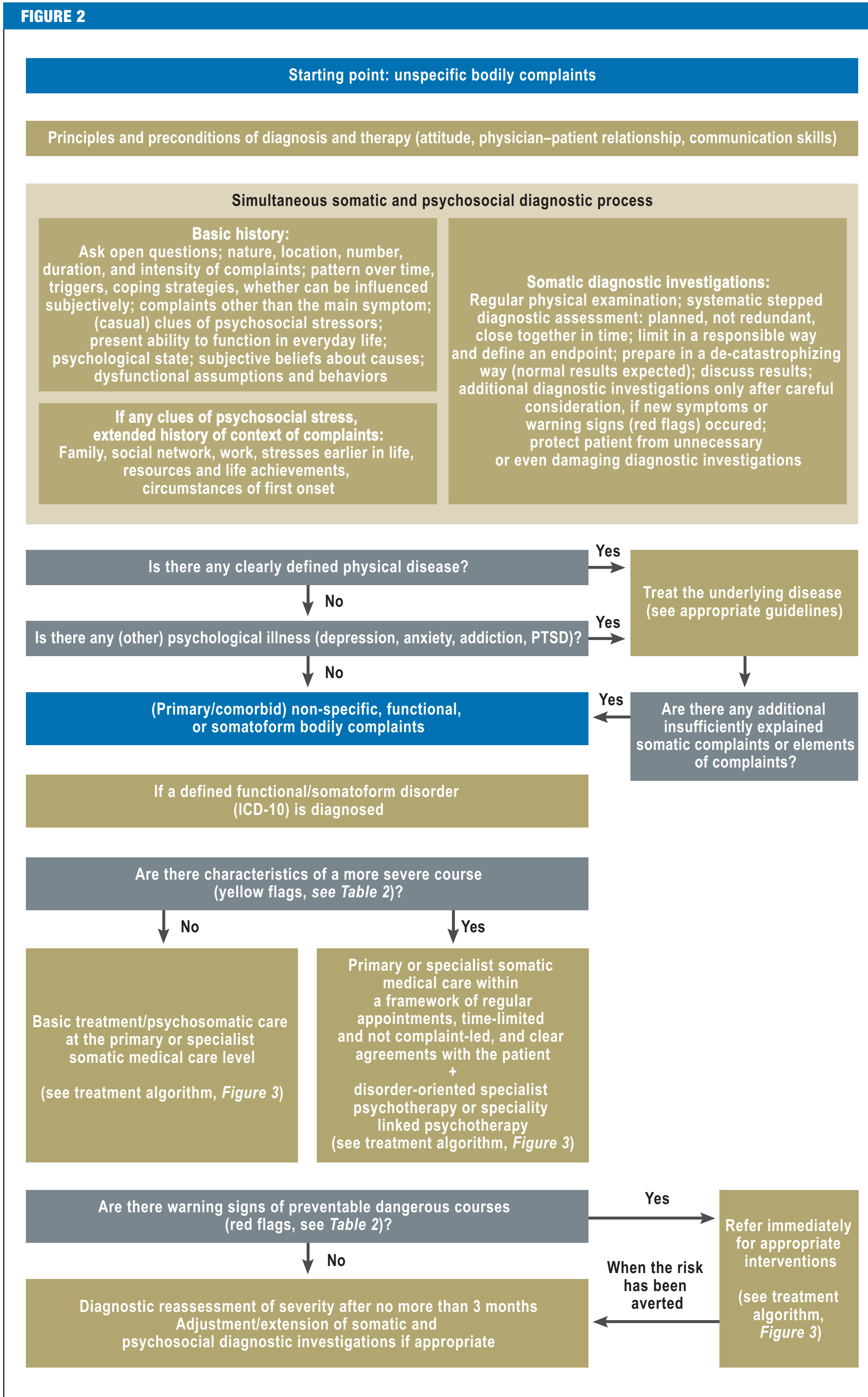
Attitude and physician–patient relationship

Since the physician–patient relationship is often felt to be difficult on both sides (e42–e45), building up a sound working alliance on a partnership basis is of central importance (7, e46–e48). An active, supportive and biopsychosocial attitude ("as well/as attitude") is recommended, focusing on symptoms and on coping with them. It is characterized by situational consistency; that is the right balance between reticence and authenticity ("I'm not going to say everything that would be authentic, but what I do say should be authentic") (e52) (RB B).

Communication skills

First, the physician should allow the patient to describe the complaints spontaneously and explicitly ("accepting the complaint") (e53) (EL 4, EG B), signaling attention, interest, and acceptance in both verbal and nonverbal ways ("active listening") (EL 4, EG B). Psychosocial themes should be handled casually and indirectly rather than by confronting them, e.g., by accompanying the patient's report switching to and fro between hinting at psychosocial stressors and returning to the complaints description ("tangential conversation") (e51). Clues to psychosocial problems and

FIGURE 2



Diagnostic algorithm: Stepped simultaneous diagnostic assessment depending on symptom severity (modified from 2, 4); PTSD, post-traumatic stress disorder

TABLE 2

Guide to green, yellow, and red flags and clinical characteristics of severe courses (modified from 7, e62, e63)

Possible protective/prognostically favorable factors (green flags)	Clinical characteristics of more severe courses (yellow flags)	Warning signs of preventable severe courses (red flags)
• Active coping strategies (e.g., physical exercise, positive attitude, motivation for psychotherapy) • Healthy life style (enough sleep, balanced diet, exercise and relaxation) • Secure relationships, social support • Good work conditions • Sustainable physician-patient relationship • Biopsychosocial, decatastrophizing approach, avoiding unnecessary investigations and treatments • Health care system that is freely accessible but emphasizes self-responsibility and prevention	• Several complaints (polysymptomatic course) • Frequent or persistent complaints (complaint-free intervals non-existent or rare or brief) • Dysfunctional perception of health/illness (e.g., catastrophizing thoughts, substantial health-related anxiety) • Dysfunctional health/illness behavior (high use of health services, resting and avoidance behavior) • Markedly reduced ability to function; inability to work > 4 weeks, social withdrawal, physical deconditioning, possibly with physical sequelae • Moderate to severe psychosocial stress (possibly biographical stressors) (e.g., low spirits, anxiety about the future, few social contacts) • Psychological co-morbidity (especially depression, anxiety, post-traumatic stress disorder, substance dependence disorders, personality disorders) • Physician-patient relationship experienced (by both) as “difficult” • Iatrogenic “somatizing” factors *(Box 1)*	• Very severe complaints • Occurrence of known warning signs of a somatically defined disease • Indications of serious self-harming behavior • Suicidality • Physical sequelae (e.g., faulty posture becomes fixed, limitation of movement up to severe restricted mobility of spared joints, contractures, serious weight gain, patient stays in bed) • Particularly severe psychological co-morbidity (e.g., development of severe depression; anxiety that keeps the patient confined in the home) • Frequent change of treating physicans and therapists and frequent discontinuation of therapy • Indications of severe iatrogenic damaging behavior

needs shall be picked up empathetically and spoken of as meaningful (e54) (EL 1b, RG A). In constructing the contextual interdependencies, phrases from the vernacular can help (“Is something making you heavy hearted?”) (EL 5, RG 0). The patient should be offered to make a joint decision together with the physician once enough information has been given (“shared decision making”) (e55) (EL 2b, RG A).

Simultaneous biopsychosocial diagnostic assessment

For early diagnosis of NFS, stepped simultaneous diagnostic assessment of both somatic and psychosocial conditioning factors should be carried out. If necessary further medical and/or psychotherapeutic specialists should be consulted (e56–e58) (EL 1b, RG A) (*Figure 2*). For patients with a chronic course, the first thing is to take stock of the results of previous diagnostic and therapeutic procedures (EL 5, RG 0). Waiting for the exclusion of somatic disease despite the presence of psychosocial stressors is contraindicated.

Biopsychosocial history taking

First, the bodily complaints should be recorded precisely (nature, location, number, frequency, duration, intensity) (e53) (EL 3b, RG B). Because accompanying complaints are often not reported spontaneously, history taking should be extended beyond the main symptoms, e.g., by systematic questioning about the different organ systems (2, 4) (EL 2b, RG A). The number of symptoms is an important predictor of the presence of NFS and of an unfavorable course (15) (EL 1b). For all bodily complaints, everyday functioning and psychological state should be assessed even at the first consultation (e59) (EL 2b, RG B). The patient’s subjective theory of the illness and illness/health behavior should be explored, including, if there are cues about psychosocial stressors or functional impairment, the context of the complaints (family, social network, work, biographical stressors, and resources) (CCP).

Somatic diagnostic investigations

Basic organic diagnostic investigation including physical examination is always necessary. Depending on the pattern of symptoms, specialist diagnostic procedures may also be required (e58) (EL 5, RG B). In the absence of “red flags” and so long as any dangerous illness appears unlikely, a “watchful waiting” approach is recommended, which will not increase the patient’s anxiety (e60) (EL 1b, RG B). Any tests should be discussed with the patient before and after they are carried out in a “de-catastrophizing” way (“normal results

BOX 2

Stepped, collaborative, and coordinated care model

- **Stepped:**
  - Patients with less severe courses should if possible be cared for by their primary care physician (21, e96) (EL 2b, RG B).
  - Patients with more severe courses should be referred for early psychotherapeutic assessment and, if appropriate, concurrent psychotherapy (7, 22–24, e80) (EL 1a, RG A).
  - Patients with particularly severe courses require a multimodal therapeutic approach, i.e., interdisciplinary treatment including at least two specialties, one of them psychosomatic, psychological, or psychiatric, following a fixed treatment plan led by a qualified physician; because of lack of outpatient facilities, this often requires treatment to be on an inpatient or day clinic basis (for indications see *Box 3*) (CCP).
- **Collaborative:** Close collaboration between all contributing physicians and therapists is important, ideally within the framework of a mutually agreed treatment approach, which may be multimodal (e97) (EL 1b).
- **Coordinated:** The collaborative care should be coordinated by the primary care physician following a structured overall care plan (e71) (EL 1b, RG B).

expected") and the reasons for doing them clearly explained (transparency) (e61). A reasonable endpoint for the somatic diagnostic pathway should be agreed and adhered to (EL 1b, RG A).

Severity assessment

Characteristics of more severe cases ("yellow flags") and red flags for more severe, complicated courses including suicidality should be repeatedly evaluated (7, e62, e63) (EL 2b, RG B). Some protective factors ("green flags") presumably have a favorable effect on the prognosis (e64) (EL 4) and should be recorded and supported (RG B) (*Table 2*).

Treatment

Treatment should adhere to a severity-staged, collaborative and coordinated model of care (7, 16, 17, e65) (RG A) (*Box 2, Figure 3*).

Basic treatment in primary care and specialist somatic medicine

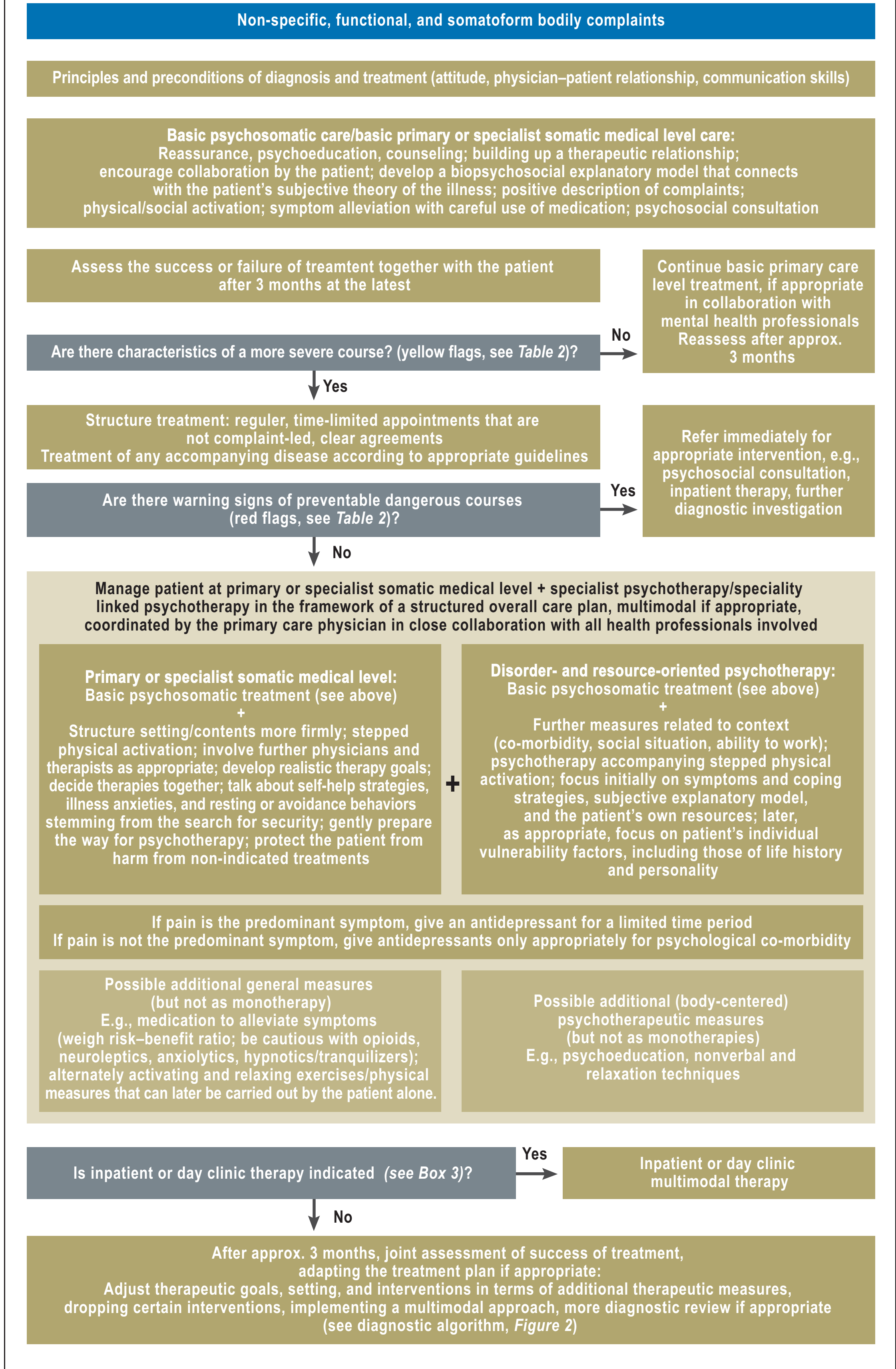
The basis of treatment should be "Basic Psychosomatic Care" (CCP). Both complaints and findings should be explained clearly and reassuringly, and psychophysiological relationships should be explained (psychoeducation: e.g., vicious circles of resting, somatosensory amplification etc.) (17, e66) (EL 2a). This should connect with the patient's subjective theory of the illness, so that a biospychosocial explanatory model can be built up (RG B). The physician should offer a positive description of the complaints (e.g., "non-specific," "functional," "bodily distress," with a corresponding diagnosis if appropriate), but should not belittle ("There's nothing wrong with you,") or use stigmatizing terms ("hysteria") (e66, e67) (EL 2b, RG B). Important elements are reassuring the patient that dangerous disease is unlikely (17, e56, e60) (EL 2b, RGA) and no unnecessary steps should be taken ("first, do no harm", "quaternary prevention") (e68) (EL 5, RG B), and furthermore long-term support with physical and social activation (7, e69, e70) (EL 2b). Medication (e.g., symptomatic medication for patients with irritable bowel syndrome, pain alleviation, treatment of psychological co-morbidity) should be discussed with the aim of alleviating symptoms within the framework of an overall treatment plan, carefully weighing the risks and benefits, and for a limited period (4) (CCP). Physicians should not be too quick to certify patients as unable to work, and should weigh the *advantages* (rest, relief from stress) against the *disadvantages* (avoidance, increased weakness due to rest, loss of participatory activity) early on (e83) (EL 4–5). Short-term sick notes (7 days, patient to attend again, another 7 days if appropriate) may be considered, in order to support spontaneous improvement of symptoms and promote the therapeutic relationship and/or adherence to treatment (RG B). Psychotherapy may be considered, e.g., if the patient wants to discuss psychosocial stressors or when the bodily complaints are incidental findings in, for example, a patient with depression (CCP).

Additional steps in severe courses

Even in severe courses, care at the primary level and specialist somatic medical level is at the center of management. Within the framework of a clear treatment plan, there should be a stronger structuring of the framework and content of treatment (e71) (EL 2a, RG B). Essential elements are regular appointments that are time-limited and are not complaint-led (e48, e71) (EL 2b) along with treatment of comorbid disorders in accordance with guidelines (RG B). Specific, realistic therapy goals should be developed with the patient (18, e72) (EL 2b, RG A), in the process of which the importance of self-responsibility and collaboration should be conveyed (EL 4). Physical activation (especially

Therapeutic algorithm: Stepped, collaborative, and coordinated care model according to severity level (modified from 2, 4)

FIGURE 3



aerobic exercise [endurance training] and strength training of low to moderate intensity) should be carried out in stages, with slowly increasing work alternating with rest (7, e73–e76) (EL 2b, RG A) (*Table 2*) and should be accompanied by sustained encouragement. Similarly, the patient should be encouraged towards social activation (7, e69, e70). Some body-centered or nonverbal therapy elements and relaxation techniques (e.g., biofeedback, progressive muscle relaxation, autogenic training, tai chi, qi-gong, yoga, Feldenkrais, mindfulness training, meditation, writing as therapy, music therapy) may be recommended as additional elements within an overall treatment plan, but not as monotherapies (e77–e79) (EL 2a). In severe cases where pain predominates, low-dose, short-term antidepressant treatment should be given (7, 19, e80–e82) (EL 1a, RG A) (*Table 1*). In severe courses where pain does not dominate, treatment with antidepressants according to guidelines should be given only where there is relevant psychological co-morbidity (e5) (EL 2a, RG B). Referrals, especially psychosocial referrals, should be well organized and carefully discussed both before and after they take place (CCP).

Psychosocial co-assessment

Requesting a specialist psychosocial assessment will reduce health service utilization (20) (EL 1a, RG A). A consultation/care recommendation letter provided to the primary care physician (information about the patient's illness and specific recommendations for treatment including assessment wether inpatient or day clinic treatment is indicated [*Box 3*]), which may if necessary be repeated, leads to improvement in the level of functioning and saves costs when used as an additional measure, but not on its own (21, 22) (EL 1a, RG A).

Disorder-oriented psychotherapy

In severe courses, psychotherapeutic interventions should be disorder-/ or symptom-oriented-focused, context-related (co-morbidity, social situation, ability to work), and resource-oriented (CCP). Wider evidence is available for various NFS – with low to moderate effect sizes – especially for cognitive behavioral therapy (22–24, e80, e81, e84, e85) (EL 1a), and also for psychodynamic (interpersonal) (7, 25, e81, e86) (EL 1b) and hypnotherapeutic/imaginative approaches (e81, e85, e87, e88) (EL 1a, RG A) (*Table 1*). Follow-up studies showing positive effects are available for psychotherapy and physical activation, but not for medications (e74, e75, e81, e89).

Particularly severe courses: multimodal treatment, if necessary on an inpatient/day clinic basis

In particularly severe and chronic cases, multimodal treatment should already be initiated at the primary care and specialist somatic medical level (*Box 2*). Multimodal treatment has been shown to be effective especially for chronic pain syndrome (e90) (EL 1b, CCP). It should be assessed wether inpatient/day clinic treatment at a facility offering multimodal therapy at a clinic offering multimodal therapy is indicated, including when there are few or no options for treatment on an outpatient basis (*Box 3*) (e91, e92) (CCP).

Rehabilitation

Rehabilitation should also follow a multimodal approach (e93). The main goals are improvement in ability to function and to work, and to prevent (further) chronification. The sociomedical baseline situation (e.g. duration of inability to work) appears essential for success (e94) (CCP). In suitable facilities (e.g., day clinics with the appropriate range of indications/treatments), rehabilitation measures should be done at first on an outpatient basis, in close collaboration between primary care physician/somatic medical specialist and psychotherapist, and only after that on an inpatient or partly inpatient basis.

Reassessment after 3 months at the latest

To prevent cases become dangerous or chronic when this could have been prevented, complaints, diagnostic

BOX 3

Indications for full or inpatient/day clinic treatment (clinical decision) (2, 4)

- Self-endangerment or endangerment of others, including suicidality (absolute indication), requirement for constant presence of a physician in case of possible crises
- Severe physical symptoms or strong somatic co-morbidity, severe psychological symptoms or pronounced psychological co-morbidity
- Long-term inability to work (at least 4 weeks) that risks becoming permanent, low level of social support or major conflicts at home or at work, or other relevant sociomedical factors
- Insufficient motivation for treatment, or insufficient resilience for the outpatient treatment process, purely somatic understanding of the illness
- Severe biographical stressors
- Major interactional problems in the physician–patient relationship
- Failure of outpatient treatment after 6 months (treatment on an inpatient/day clinic basis should be considered when two of the recommended 3-monthly assessments have shown treatment failure)
- Logistical problems or problems of availability make it difficult to provide multimodal/multiprofessional (differential) diagnosis and treatment
- Treatment plan needs change or adjustment within a multiprofessional team led by a specialist physician; inpatient setting needed to observe the patient or to provide a practice space for the patient (e.g., for exposure therapy)
- Patient preference

BOX 4

What is new in comparison to the S2e guideline "Somatoform disorders"?

- Consensus between 29 medical and psychological specialist societies and one patient representative that bridges the usual divisions between the psychosocial and the somatic disciplines and between the various levels of care
- As a meta-guideline using the triple term "non-specific, functional, and somatoform bodily complaints, the new guideline emphasizes the common elements in managing the multifarious manifestations of burdensome bodily complaints in a symptom-focused, comprehensive way
- S3 level of evidence and consensus base
- Educative approach with detailed recommendations regarding the principles and preconditions for simultaneous diagnostic investigations and treatment (attitude, physician–patient relationship, communication skills)
- Takes account of interactional aspects and iatrogenic factors in patient's illness perception, illness behavior, and the maintenance of complaints
- De-emphasizes the unreliable criterion of being "medically unexplained"
- Identifies clinical characteristics of more and less severe courses, of warning signals (red flags) for preventable dangerous courses, and of protective factors
- Stepped recommendations for diagnosis and treatment according to severity level (stepped care)
- Detailed recommendations for primary and specialist somatic medical care levels and for dfor disorder-oriented specialist or speciality linked psychotherapy and for their collaboration (collaborative care)
- Practical recommendations for all relevant topics and all health professional groups
- Emphasizes the value of the filtering, collaborative, steering, and integrating function of the primary care physician
- After 3 months at the latest, reassessment of the severity of the course and the patient's response to treatment, with adjustment or extension of treatment measures is recommended
- Strong focus on clinical implementation, with algorithms for diagnosis and treatment, tips for practical use with specific suggestions for formulations, and a coat pocket edition
- Associated guideline for patients and their relatives

categorization, and the severity of illness and the outcome of treatment should be reassessed after 3 months at the latest (e56, e95) (EL 2b, RG B). If appropriate, and in agreement with the patient and collaborating physicians and therapists, both somatic and psychosocial diagnostic investigations and treatment should be adjusted. Basic medical diagnostic investigations including physical examination should be regularly repeated, especially where complaints persist. In this way, changes in symptoms will be recognized, organic disease will be identified, the patient will be given a feeling of being looked after and taken seriously, and unnecessary tests will be avoided (EL 5, RG B). After 6 months, if treatment on an outpatient basis fails, treatment on an inpatient or day clinic basis should be considered (*Box 3*).

Discussion

In the S3 guideline "Management of patients with nonspecific, functional, and somatoform bodily complaints," a broad group of medical and psychological societies together with a patient representative have for the first time achieved an evidence-based consensus on terminology and care of these patients that is interdisciplinary and bridges the borders of health care sectors as well as psychosocial and somatic disciplines. The innovations are summarized in *Box 4*. To date, randomized controlled studies, reviews, and meta-analyses are available on only a few aspects (*Figure 1*), so that in places the present guideline has to rely on weaker evidence or clinical consensus. Overall, a very strong need is evident for fundamental research as well as research in treatment and health services. Guideline texts and practice materials may be downloaded from the AWMF website (www.awmf.org/ leitlinien/detail/ll/ 051–001.html) and from the project website (www.funktionell.net). An important complement to this guideline is the *Evidence-Based Guideline on Psychotherapy of Somatoform Disorders and Associated Syndromes* by the Group for Clinical Psychology and Psychotherapy of the German Society of Psychology (24). This is primarily aimed at psychotherapists as an aid to choosing effective psychotherapeutic interventions.

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P. Henningsen has received lecture fees from Lilly.

W. Häuser has been on an advisory board of Daiichi Sankyo, has had conference and travel expenses reimbursed by the Falk Foundation and Eli Lilly, and has received non-product-related lecture fees from the Falk Foundation and from Janssen-Cilag.

R. Schaefert, C. Hausteiner-Wiehle, M. Herrmann und J. Ronel declare that no conflict of interest exists according to the guidelines of the International Committee of Medical Journal Editors.

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CLINICAL PRACTICE GUIDELINE

Non-Specific, Functional, and Somatoform Bodily Complaints

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eBOX 1

Participating medical and psychological societies, patient organizations, representatives of other involved bodies, and experts (2, 4)

- Association of Scientific Medical Societies in Germany (AWMF, Arbeitsgemeinschaft medizinischer Fachgesellschaften): Prof. Ina Kopp
- German College for Psychosomatic Medicine (Deutsches Kollegium für Psychosomatische Medizin, DKPM) (coordinator): Prof. Peter Henningsen
- German Society of Psychosomatic Medicine and Medical Psychotherapy (Deutsche Gesellschaft für Psychosomatische Medizin und Ärztliche Psychotherapie, DGPM) coordinator: Prof. Peter Henningsen
- German College of General Practitioners and Family Physicans (Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin, DEGAM): Prof. Markus Herrmann, MPH
- German Society for Behavioural Medicine and -Modification (Deutsche Gesellschaft für Verhaltensmedizin und Verhaltensmodifikation, DGVM): Prof. Winfried Rief
- German Association for Psychiatry and Psychotherapy (Deutsche Gesellschaft für Psychiatrie, Psychotherapie und Nervenheilkunde, DGPPN): Prof. Volker Arolt
- German Psychological Society, Group for Clinical Psychology and Psychotherapy (Deutsche Gesellschaft für Psychologie, DGPs): Prof. Alexandra Martin
- German Society for Surgery (Deutsche Gesellschaft für Chirurgie, DGCH): Prof. Marcus Schiltenwolf
- Society of Hygiene, Environmental and Public Health Sciences (Gesellschaft für Hygiene, Umweltmedizin und Präventivmedizin, GHUP): Prof. Caroline Herr
- German Society of Internal Medicine (Deutsche Gesellschaft für Innere Medizin, DGIM): Prof. Hubert Mönnikes
- German Society for Occupational and Environmental Medicine (Deutsche Gesellschaft für Arbeitsmedizin und Umweltmedizin, DGAUM): Prof. Dennis Nowak
- German Society of Psychosomatic Obstetrics and Gynaecology (Deutsche Gesellschaft für Psychosomatische Geburtshilfe und Gynäkologie, DGPFG): Dr. Friederike Siedentopf
- German Society of Obstetrics and Gynaecology (Deutsche Gesellschaft für Gynäkologie und Geburtshilfe, DGGG): Dr. Friederike Siedentopf
- German Society of Oto-Rhino-Laryngology, Head and Neck Surgery (Deutsche Gesellschaft für Hals-Nasen-Ohren-Heilkunde, Kopf- und Hals-Chirurgie, DGHNO: Dr. Astrid Marek
- German Society of Rheumatology (Deutsche Gesellschaft für Rheumatologie, DGRh): Prof. Wolfgang Eich
- German Urology Society, Working Group Psychosomatic Urology and Sexual Medicine (Deutsche Gesellschaft für Urologie, DGU) AK Psychosomatische Urologie und Sexualmedizin: Dr. Dirk Rösing
- German Society for Digestive and Metabolic Diseases (Deutsche Gesellschaft für Verdauungs- und Stoffwechselkrankheiten, DGVS): Prof. Hubert Mönnikes
- German Society of Dentistry and Oral Medicine (Deutsche Gesellschaft für Zahn-, Mund- und Kieferheilkunde, DGZMK) AK Psychologie und Psychosomatik: Dr. Anne Wolowski
- German Society of Orthopedics and Orthopedic Surgery / Working Group Psychology and Psychosomatics (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie, DGOOC): Prof. Marcus Schiltenwolf
- German Cardiac Society (DGK, Deutsche Gesellschaft für Kardiologie): Prof. Karl-Heinz Ladwig
- German Dermatologic Society (Deutsche Dermatologische Gesellschaft, DDG): Prof. Uwe Gieler
- German Neurological Society (Deutsche Gesellschaft für Neurologie, DGN): Prof. Marianne Dieterich
- German Society for Allergology and Clinical Immunology (Deutsche Gesellschaft für Allergologie und Klinische Immunologie, DGAKI): Prof. Uwe Gieler
- German Society for Psychoanalysis, Psychotherapy, Psychosomatics and Depth Psychology (Deutsche Gesellschaft für Psychoanalyse, Psychotherapie, Psychosomatik und Tiefenpsychologie, DGPT): Prof. Gerd Rudolf
- German Society of Pediatrics and Adolescent Medicine (Deutsche Gesellschaft für Kinder- und Jugendmedizin, DGKJ): Dr. Kirsten Mönkemöller
- German Psychoanalytical Association (Deutsche Psychoanalytische Vereinigung, DPV): Prof. Ulrich Schultz-Venrath
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- German Pain Society (Deutsche Schmerzgesellschaft, DGSS)[*1]

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[*1] The DGSS was involved in the development of the guideline in the persons of several DGSS members and pain experts representing other professional societies, but did not have its own representative. After the guideline had been finished, it was explicitly approved by the governing board of the DGSS.

eBOX 2

Search term list*[1] (3)

Level 1: Clinical symptoms

a) Non-specific, functional, and somatoform bodily complaints:

(somatoform disorder OR somatiz* OR somatis* OR conversion disorder* OR multisomatoform OR medically unexplained* OR organically unexplained* OR psychogenic OR nonorganic OR psychosomatic syndrom* OR functional somatic syndrom* OR functional syndrom* OR functional disorder* OR functional illness* OR functional symptom* OR irritable bowel* OR functional bowel* OR functional gastrointestinal* OR functional dyspepsia* OR nonulcer dyspepsia* OR food intolerance* OR fibromyalgia* OR chronic widespread pain* OR widespread musculoskeletal pain* OR myofascial pain syndrome* OR tension-type headache* OR chronic pain* OR atypical chest pain* OR nonspecific chest pain* OR non-specific chest pain* OR atypical face pain* OR facial pain* OR chronic low back pain* OR back pain* OR panalges* OR (psychogen* AND pain) OR idiopathic pain* OR idiopathic pain disorder* OR fatigue/*psychology OR chronic fatigue syndrome* OR Fatigue Syndrome, Chronic* OR myalgic encephalomyelitis* OR myalgic encephalopathy* OR chronic epstein barr virus* OR chronic mononucleosis* OR chronic infectious mononucleosis like syndrome* OR chronic fatigue and immune dysfunction syndrome* OR effort syndrome* OR low natural killer cell syndrome* OR neuromyasthenia OR post viral fatigue syndrome* OR postviral fatigue syndrome* OR post viral syndrome* OR postviral syndrome* OR post infectious fatigue* OR postinfectious fatigue* OR royal free disease* OR royal free epidemic* OR *royal free hospital disease* OR chronic lyme disease* OR candida hypersensitivity* OR candida syndrome* OR (mitral valve prolapse* AND psychology) OR hypoglycaemia/*psychology OR sleep disorder/*psychology OR nonorganic Insomnia* OR Multiple chemical sensitivit* OR idiopathic environmental intolerance* OR electromagnetic hypersensitivity OR electrohypersensitivity OR electrosensitiv* OR IEI-EMF OR environmental illness* OR Sick Building Syndrome* OR Persian gulf syndrome OR Amalgam hypersensitivity* OR Dental Amalgam/* toxicity OR dental amalgam/*adverse effects OR silicone breast implant* OR implant intolerance* OR burning mouth* OR glossalg* OR glossodyn* OR glossopyr* OR bruxism OR temporomandibular joint disorder* OR temporomandibular disorder* OR temporomandibular joint dysfunction* OR temporomandibular joint dysfunction* OR craniomandibular disorder* OR atypical odontalgia* OR prosthesis intolerance* OR (psychogen* AND gagging) OR chronic rhinopharyngitis* OR globus syndrome* OR globus hystericus* OR hyperventilation syndrome* OR dysphonia OR aphonia OR tinnitus OR Vertigo OR Dizziness OR repetitive strain injury *OR chronic whiplash syndrome* OR tension headache OR pseudoseizures OR hysterical seizures* OR (psychogen* AND dystonia) OR (psychogen* AND dysphagia) OR functional micturition disorder* OR functional urinary disorder* OR urethral syndrome* OR micturition dysfunction* OR (urinary retention* AND (psychogen* or psychology)) OR irritable bladder* OR painful bladder syndrome* OR interstitial cystitis* OR enuresis diurnal et nocturnal* OR anogenital syndrome* OR sexual dysfunction* OR chronic pelvic pain* OR (skin disease* AND (psychology OR psychogen*)) OR (pruritus AND (psychology OR psychogen* OR somatoform)) OR culture-bound disorder* OR ((reduced OR impaired) AND well-being*)

b) Health anxiety: A term for health anxiety was added to the bodily complaints, since this feature is frequent and characteristic in non-specific, functional, and somatoform physical complaints, and is important for their differential diagnosis:

(OR hypochondria* OR illness phobia* OR health anxiet*)

Level 2: Level of medical care/setting and perspectives

a) Primary and secondary level medical care:

(ambulatory care* OR primary health care* OR physicians, family* OR (specialties, medical* NOT psychiatry*) OR general pract* OR family pract* OR family doctor* OR family physician* OR family medicine* OR primary care*)

b) Psychosomatic medicine, psychiatry, psychology:

(mental health services* OR Psychosomatic Medicine OR Psychiatry OR Psychology)

c) Workplace:

(workplace OR occupational health* OR occupational health physicians* OR occupation*)

d) Physician perspective:

(physician OR doctor* OR clinician* OR general practit* OR family pract*)

e) Patient perspective:

(patient OR self-report* OR subjective*)

Level 3: Contents and themes

a) Relationship/own attitude:

(attitude of health personnel* OR communication OR empathy OR professional-patient relations* OR physician's practice patterns* OR role OR medical history taking* OR decision making* OR countertransference OR disease attributes* OR emotions OR interact* OR encounter* OR disposition* OR setting* OR approach* OR engag* OR deal* OR exposure* OR experience* OR handl* OR function* OR attitud* OR declin* OR prejud* OR reject* OR rigid* OR belie* OR concept* OR critic* OR legitim* OR motivat* OR stigma*)

b) Communication skills:

(communicat* OR counsel* OR talk*)

c) Relationship/patient's attitude:

(attitude to health* OR physician-patient relations* OR role OR self-disclosure* OR disease attributes* OR transference OR personality OR social behavior* OR interpersonal relations* OR communication OR utilization OR relation* OR resistance* OR balint OR enactment OR psychodynamic* OR mirror* OR interact* OR attitud* OR belie* OR concept* OR criticism OR legitim* OR motivat* OR percept* OR perspect* OR stigma* OR reporting OR encounter*)

d) Positive criteria, characteristics of non-specific, functional, and somatoform bodily complaints:

eBOX 2 – CONTINUED

(disease attributes* OR attitude to health* OR physician-patient relations* OR behavior OR attitude OR health behavior* OR sick role* OR cognition OR emotions OR body image* OR personality OR motivation OR defense mechanisms* OR attention OR perception OR memory OR health services misuse* OR utilization* OR utili* OR abnormal illness behavior* OR illness percept* OR health anxiety* OR illness phobia* OR health related concern* OR fear of disease* OR attribut* OR explanat* OR attachment OR alexithym* OR reporting OR reassur*)

e) History/diagnosis/differential diagnosis/co-morbidity/somatic diagnostic investigations:
(psychological tests* OR questionnaires OR personality assessment* OR psychometrics OR interview, psychological* OR diagnosis OR diagnosis, differential* OR differential diagnosis* OR diagnostic techniques and procedures* OR medical history taking* OR unnecessary procedures* OR workup* OR diagnosis OR differential* OR diagnostic OR comorbidity OR overlap OR association OR associated OR Diagnostic and Statistical Manual of Mental Disorders* OR depression OR anxiety OR eating disorder* OR personality disorder*)

f) Referral:
(referral and consultation* OR hospitalization OR disease management *OR patient care OR referral OR consult*)

g) Practice organization and collaboration with other health professionals:
(organization and administration* OR practice management, medical* OR practice OR triage OR schedule* OR appointment* OR practice nurse* OR team approach* OR team conferenc* OR cooperat* OR network OR medical billing system*)

h) General therapy (including pharmacotherapy):
(therapy OR therapeutic* OR complementary therapies* OR treatment outcome* OR counseling OR education OR long term care)

i) Specialist psychotherapy:
(psychotherapy OR psychopharmacology OR psychotherap* OR drug therapy*)

j) Epidemiology:
(epidemiology OR public health* OR demography OR socioeconomic OR population OR gender* OR cultur*)

k) Prevention, rehabilitation, prognosis:
(risk assessment* OR risk factors* OR disease susceptibility* OR health promotion* OR prevention and control* OR disease progression* OR chronic disease* OR rehabilitation OR predict* OR iatrogen* OR somatic fixation* OR maintaining factor* OR exacerbating factor* OR prevent* OR prophyla* OR susceptibility)

l) Delivery of health care/economics:
(delivery of health care* OR health services* OR economics OR utilization OR medical billing system* OR pharmacoeconom* OR cost-benefit analysis* OR cost control* OR cost of illness*)

m) Medicolegal aspects:
(legislation and jurisprudence* OR insurance benefits* OR workers compensation* OR Jurisprud* OR disability evaluation* OR malpract* OR medical errors* OR litig* OR compensat* OR disabilit*)

*[1] Results were filtered using the following conditions: Humans, English, German, all; adult: 19+ years, adolescent: 13–18 years; publication date from 2000/01/01 to 2009/01/01.

eBOX 3

Inclusion and exclusion criteria for selection of evidence (3)

Inclusion criteria:

- Study of a non-specific, functional, or somatoform bodily complaint including a defined diagnostic description
- Studies of treatment procedures: randomized studies with a control group, controlled studies without randomization, or case–control studies
- Etiological and pathophysiological studies: prospective cohort studies or systematic reviews of cross-sectional studies (level 3 case–control studies, ecological studies, case series)
- Study reports in English or German

Exclusion criteria:

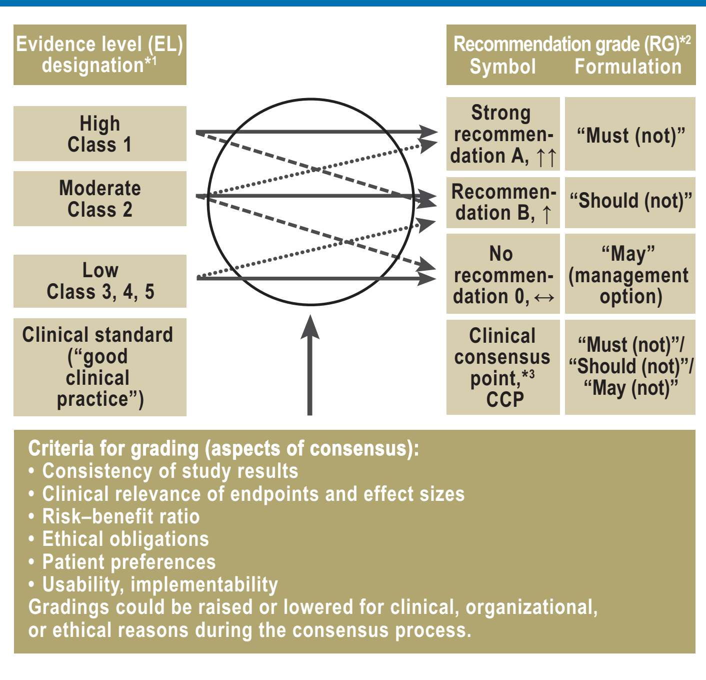
- Study of a non-specific, functional, or somatoform bodily complaint without a defined diagnostic description or with a diagnosis described as a sequela of a defined organ pathology
- Experimental studies (duration < 1 week and/or use of a procedure once or twice, e.g., experimental studies of medication or hypnotherapy)
- Treatment studies without randomization or without control groups
- For pathophysiological studies: case–control studies, ecological studies, case series
- Incomplete publication (e.g., abstract)
- Case reports, reader letters, duplicate publication

eBOX 4

Definition of terms: non-specific, functional, and somatoform bodily complaints

- **"Non-specific":** Emphasizes the way in which many complaints cannot be categorized as belonging to a specific disease. Intended to prevent over-hasty labeling as "disease" and hence prevent medicalization.
- **"Functional":** Assumes that it is principally the function of the affected organ or organ system that is impaired; the single medical specialities define a variety of functional somatic syndromes for particular complaints (e.g., irritable bowel syndrome, fibromyalgia syndrome).
- **"Somatoform disorder" in the narrow sense:** Is present when insufficiently explained bodily complaints persist for at least 6 months, leading to a significant impairment of the ability to function in everyday life. If any physical disorders are present, they do not explain the nature and extent of the symptoms or the distress and preoccupation of the patient. (do not change, ICD-10 definition). The ICD-10 criteria have been criticized for inconsistencies, limited validity, failure to cover the range of severity, and lack of positive psychobehavioral criteria (e98, e99). The revised definition of terms emphasizes the association with psychosocial stressors, which increases with the severity of the bodily complaints (e100).

eFIGURE



Association between evidence level (EL) and recommendation grade (RG) (from e4);
*1 evidence level according to Oxford Centre of Evidence-Based Medicine (eTable 2);
*2 recommendation grade in the Program for National Care Guidelines (Programm für Nationale Versorgungsleitlinien);
*3 clinical consensus point, by analogy to the National Care Guideline for Unipolar Depression (e5)

eTABLE 1

Global assessment of the study's methodological quality (guided by the "summary assessment of risk of bias" of the Cochrane Collaboration [e1]), relevance for the guideline (3)

Assessment	Methodological quality	Influence on validity of study results
Most relevant	Bias can be largely ruled out or cannot be identified	Low risk of bias; any bias will have at most a small effect on study results
Relevant	Bias can be largely ruled out, slight errors may exist in some areas or cannot be assessed	Low risk of bias; any bias will have at most a small effect on study results
Fairly relevant	Identifiable but not serious bias present in some areas	Uncertain risk of bias; study results may be affected
Relevance doubtful	Slight bias identified in several areas, or some areas cannot be assessed with sufficient certainty because of inadequate description	Risk of bias; study results probably affected
Not relevant	More than slight bias identified in several areas, or such bias cannot be ruled out with sufficient certainty because of inadequate description	High risk of bias; an effect on study results must be assumed

eTABLE 2

Evidence levels (EL) according to the Oxford Centre for Evidence-Based Medicine (e2)

Evidence level	Studies on diagnosis	Studies on treatment/etiology/prevention
1a	Systematic review of level 1 diagnostic studies or clinical decision rules, based on 1b studies, validated in different clinical centers	Systematic review of randomized controlled trials (RCT)
1b	Validating cohort study with good reference standards; or clinical decision rule validated within one clinical center	Individual RCT (with narrow confidence interval)
1c	Absolute SpPins und SnNouts*[1]	All-or-nothing principle*[2]
2a 2b 2c	Systematic review of well-designed cohort studies Individual well-designed cohort study or low quality RCT "Outcomes" research; ecological studies	
3a 3b	Systematic review of level 3 diagnostic studies Non-consecutive study; or without consistently applied reference standards	Systematic review of case-control studies Individual case-control study
4	Case-control study, poor or nonindependent reference standard	Poor-quality case series or cohort and case-control studies
5	Expert opinion without explicit critical appraisal, or based on physiology, or laboratory research	

*[1] "absolute SpPin," test specificity is so high that a positive result rules the diagnosis in with certainty;
"absolute SnNout," test sensitivity is so high that a positive result rules the diagnosis out

*[2] Dramatic effects: this is the case if all patients died before the treatment was available, but after the introduction of the treatment some patients survive; or if some patients died before the treatment was available, but after introduction of the treatment no patient dies

eTABLE 3

Grading of consensus strength (e3)

Consensus strength	Agreement from . . . % of participants*[1]
Strong consensus	>95 %
Consensus	>75%–95%
Majority agreement	50%–75%
No consensus	<50%

*[1] A minority vote with an explanatory statement was a possible option but was not used