Chapter 1

General introduction
Introduction

Physical symptoms without clear medical conditions induce a large number of people worldwide to attend a doctor.\textsuperscript{1, 2, 3} Healthy individuals in the general population also regularly experience physical symptoms, but they experience them as a normal phenomenon and not necessarily as pathological.\textsuperscript{4} These physical symptoms are often self-limiting and do not normally lead to impairments in daily life. A substantial number of patients, however, become severely disabled by their symptoms or repetitively search for medical attention. From a medical point of view, doctors do not have much to offer in the absence of a medical condition.\textsuperscript{5} This may explain why doctors often consider consultation for medically unexplained physical symptoms inappropriate illness behaviour. They feel frustrated and do not know how to deal with these patients effectively, often leading to the attribution ‘heart sink patient’.

This thesis focuses on patients bothered by medically unexplained physical symptoms that have been diagnosed as somatoform disorders. In this general introduction we will present the topic and give an overview of the terminology and classification as it is used in this field. We will describe the clinical problem, which has led to the aims, the study design and the structure of this thesis.

Terminology and classification

‘Medically unexplained physical symptoms’ is the most neutral term to describe patients presenting with physical symptoms that are not well explained by a medical condition. It does not indicate an underlying causal mechanism or interpretation. The term is wide-ranging and several more explicit terms have been used to describe this phenomenon. General practitioners and medical specialists describe patterns of symptoms as ‘functional somatic syndromes’, referring to the dysfunctioning of an organ in absence of structural damage. Diagnostic criteria are available for numerous syndromes whose aetiology is not clear. Typically, most medical specialities have their ‘own’ functional syndrome such as the irritable bowel syndrome in gastroenterology, fibromyalgia in rheumatology and tension-headache in neurology. Despite the variability in symptoms and definitions of these syndromes, some authors suggest the existence of an underlying common mechanism. In their view symptoms originate from a dysregulation of the central nervous system induced by somatic or psychosocial stress such as (previous) infectious disease or psychosocial stressors. Stress is taken here in the broad sense of ‘any influence threatening the homeostasis of the system’.\textsuperscript{6, 4}
A more general term to describe patients with medically unexplained physical symptoms is somatisation. Lipowski formulated the following definition of somatisation: ‘A tendency to experience and communicate somatic distress and symptoms unaccounted for by pathological findings, to attribute them to physical illness, and to seek medical help for them’. Other related terms are functional or nervous-functional symptoms and psychosomatic disorders. These terms are by no means neutral, suggesting the translation of mental distress into physical symptoms. They also imply that patients hold on to a somatic attribution of symptoms, and that symptoms may have a ‘function’ in the expression of psychological distress. Physical symptoms in this view serve as a signal for mental illness or psychosocial problems.

In psychiatry terms such as hysteria, neurasthenia or Briquet syndrome have traditionally been used to describe patients with medically unexplained physical symptoms. Over the years these concepts have evolved into more specific diagnoses for subgroups of patients, e.g. hypochondriasis or somatisation disorder. In the prevailing psychiatric classification of DSM-IV explicit criteria are given to classify medically unexplained physical symptoms as somatoform disorders, without assuming an underlying mechanism. The symptoms must cause clinically significant distress or impairment in social, occupational or other areas of functioning.

It is important to recognise that a patient with fatigue, for example, may be labelled differently by different professionals: as suffering from a functional somatic syndrome such as fibromyalgia by the rheumatologist, from an undifferentiated somatoform disorder by the psychiatrist or having nervous-functional symptoms by the GP.

Our starting point was to study medically unexplained physical symptoms from a clinical perspective and to rely on clinical assessment for the diagnosis. Although several options were available for a valid diagnosis, we chose the descriptive psychiatric classification of DSM-IV as a guideline, focusing on chronic symptoms with functional impairments. This does not imply or exclude any psychological mechanism as a possible cause or maintaining factor of the disorders. The classification offers a system to identify patients according to a fairly accepted set of criteria that can be applied in other populations as well.

**Epidemiology of somatoform disorders**

In the DSM-IV the following definition of somatoform disorders is given: ‘The common feature of somatoform disorders is the presence of physical symptoms that
suggest a medical condition and are not fully explained by a general medical condition. The symptoms must cause clinically significant distress or impairment in social, occupational or other areas of functioning.\textsuperscript{15,16}

Somatoform disorders in DSM-IV comprise the following disorders (subcategories):

- **Somatisation disorder.** For most clinicians somatisation disorder embodies the ‘prototype’ of the somatoform disorder although it is rarely encountered in general practice with prevalence rates below 0.5%.\textsuperscript{17} It is a polysymptomatic disorder that begins before the age of 30, extends over a period of years, and is characterized by a combination of pain, gastrointestinal, sexual, and pseudoneurological symptoms. In primary care several researchers used abridged somatisation criteria to construct a broader term of somatisation disorder, e.g. Somatic Symptom Index (SSI 4/6)\textsuperscript{18} or Multisomatoform Disorder\textsuperscript{19}.

- **Undifferentiated somatoform disorder.** Among all somatoform disorders, the undifferentiated somatoform disorder is most often encountered in general medical settings. This disorder is characterised by at least one medically unexplained physical symptom, causing impairment for a minimum of six months. Consequently, this definition covers functional syndromes and benign pain. Among primary care attendees, Fink reported a prevalence of undifferentiated somatoform disorder as high as 27%.\textsuperscript{20}

- **Pain disorder** is characterised by pain as the predominant focus of clinical attention. Psychological characteristics are judged to play an important role in the onset, severity, exacerbation, or maintenance of the symptoms.

- **Hypochondriasis.** The central symptom of hypochondriasis is the preoccupation with the fear of having a serious disease. The prevalence rates in primary care vary from 3% to 5%.\textsuperscript{21,20}

- Finally, the group of somatoform disorders comprises conversion disorder and body dysmorphic disorder. These are considered rare and are hardly ever studied in general practice.

The comorbidity of somatoform disorders with anxiety and depressive disorders is considerable\textsuperscript{22} and the burden of illness may be substantial.\textsuperscript{19} Few comprehensive studies have, however, focused on an accurate quantification of the separate or comorbid occurrence of somatoform, anxiety and depressive disorders. Most studies on somatoform disorders exclude the prevalent undifferentiated somatoform disorders and do not assess symptoms by means of self-report questionnaires combined with a clinical assessment.
Primary health care in the Netherlands

In the Netherlands the GP is the central gatekeeper for the provision of health care. All patients are listed with one GP and primarily consult him or her for all health problems. This system offers the GP the opportunity to have an overall insight in the patients’ demands for health care. In addition, most conditions are treated in general practice and the GP indicates whether a referral to secondary care is appropriate. The medical records of the GP cover all information, including reports from laboratories and specialists. As a consequence, GP records facilitate research on clinical assessment of reported symptoms.

Guidelines from the Dutch College of General Practitioners (NHG) support the GP with the scientific underpinning for diagnostic and therapeutic interventions. For most common mental disorders such as depressive disorder, anxiety disorder, alcohol dependence and sleep disorders guidelines are available. In addition, some functional somatic syndromes are covered by guidelines on headache, irritable bowel syndrome and low back pain. Still, guidelines that explicitly address medically unexplained physical symptoms or somatoform disorders are lacking. As a result the diagnosis and treatment of somatoform disorders may vary.

If a referral is indicated for a somatoform disorder, the Dutch GP has the option of a primary care mental health psychologist or a mental health service. However, considering the magnitude of the problem and the limited resources, most patients will be treated in primary care. It is not clear yet which patients can be treated by the GP and for which patients referral is indicated.

Treatment for medically unexplained physical symptoms

Treatment options vary with the diverse diagnostic views. Apart from the general approach of ‘wait and see’, more specific interventions will be described below.

Functional somatic syndromes are considered to be the result of the dysfunction of an organ. Therefore, many medical specialists adopt a neurobiological model as it comes to treatment of e.g. irritable bowel syndrome. From this point of view, medication that interferes with neurotransmitters or the motility of the gut plays an important role in the treatment of symptoms. Reviews indicate that antidepressants may be effective in irritable bowel syndrome, fibromyalgia and tension headache. Health psychologists have also been successful in treating functional somatic syndromes with cognitive behavioural therapy in secondary care. As a result, a
recent report of the Dutch Health Council considers cognitive behavioural therapy as the treatment of choice for the chronic fatigue syndrome. The concept of somatisation or nervous-functional symptoms often implies that physical symptoms are an expression of underlying mental distress. Therefore, the treatment is focused on this psychological process or the communication with the physician. Studies on somatisation as a form of mental distress are mostly situated in primary care settings. Interventions primarily consist of training GPs to recognise depression or psychosocial distress. Further, reattribution is often added as a cognitive technique to change the patient’s misconception that the symptoms are caused by a physical disease. If reattribution is successful, the patient will accept a psychological explanation. Underlying depressions or psychosocial problems can then be treated more effectively, leading to an improvement of the physical problems. Most research in this field has considerable limitations. In general, patient selection is not based on a clinical assessment of the symptoms, but e.g. on the previous consultation rate or the number of symptoms reported in screening questionnaires. The effectiveness of treatment is mostly evaluated by GP-outcomes, such as recognition of somatisation and doctor-patient communication, or by patients’ illness behaviour, such as use of medical services. Only few authors have reported on the effectiveness of treatment by evaluating patients’ symptoms.

Physical symptoms also feature largely in many psychiatric disorders. Consequently, psychiatric classification in the DSM-IV emphasises the importance of diagnosing depressive and anxiety disorders when medically unexplained physical symptoms are present. It is apparent that comorbidity needs to be recognised since most studies on the overlap of physical symptoms and depression confirm their association. Hence, successful treatment of comorbidity should improve the outcome of physical symptoms. Despite the plausibility of this hypothesis, clinical evidence on the decrease of physical symptoms after antidepressant treatment is scarce.

**Cognitive-behavioural treatment**

Several authors have reported on the successful treatment of a range of medically unexplained physical symptoms with cognitive-behavioural therapy. A group from the Leiden University Medical Center (LUMC) conducted a randomised controlled trial at a general medical outpatient clinic, which demonstrated that cognitive-behavioural treatment was also effective in patients with more heterogeneous medically unexplained physical symptoms. Many of the patients
included in these studies would have qualified for a diagnosis of undifferentiated somatoform disorder.

If all patients with somatoform disorders in primary care were offered cognitive-behavioural therapy this would result in a substantial increase in the need for treatment. However, all the available studies were conducted in secondary care and it therefore remains unclear whether treatment is acceptable and effective for each and every patient in primary care that is identified with a somatoform disorder. Studies on the prognosis of medically unexplained physical symptoms mostly report a substantial improvement of the symptoms in the majority of the patients within one year or even a complete recovery. In comparative treatment studies recovery in the non-treatment condition is usually also considerable. For instance, in the LUMC trial the recovery rates for intervention and control patients were 73% and 57% respectively after one year. It is as yet unclear to which extent patients with somatoform disorders are willing to accept psychological treatment, especially when they did not actively seek help. In one study in secondary care we found that most patients accepted psychological treatment, but it is not known whether the same applies to patients in primary care. A meta-analysis by Raine indicated that, in general, interventions for common mental disorders that are effective in secondary care have smaller effect sizes in primary care. This discussion about the most appropriate treatment for somatoform disorders is all the more relevant since GPs and mental health professionals have expressed the need for more expertise on cognitive-behavioural treatment in primary care. Recently, the Dutch College of General Practitioners has developed a training for GPs on cognitive-behavioural techniques, and local initiatives are focusing on implementing this treatment in general practice. The question remains, though, whether and in what form cognitive-behavioural treatment is effective for the treatment of somatoform disorders in primary care. In addition to effectiveness, an important prerequisite for an intervention in general practice is its wide applicability and availability.

The conceptual frame of the treatment, as chosen in this thesis, was based on the same biopsychosocial model as used by Speckens in the LUMC secondary care study (see figure 1). This model for the treatment of medically unexplained physical symptoms was a further elaboration on the treatment as described in the practical guide by Sharpe e.a. The central idea of this approach is to focus on consequences rather than on causes of symptoms, providing an opportunity to treat physical symptoms without fruitless discussions on causes. Cognitive and behavioural techniques in the consequences model aim at changing the consequences of the symptoms. Many patients believe that bodily sensations always signify danger; this cognition can induce emotional, behavioural and new physical responses. Changing these dysfunctional cognitions may relieve anxiety and improve adequate coping. Many patients will have reduced their activities or are avoiding certain circumstances,
thus needing explicit advice about the planning of activities. In addition, many patients are not aware of an increased muscle tension and have to be instructed on how to relax. In fact, the consequences model we propose may be useful in all situations where symptoms experienced by the patient are not in keeping with medical findings. In line with this assumption, cognitive-behavioural therapy has brought about clinically relevant improvements in physical and psychological outcomes, also in established chronic conditions such as rheumatoid arthritis.\textsuperscript{53}

Figure 1. General treatment model based on the physical symptoms and their various consequences by Speckens (1995).
Chapter 1

Aims

Our main goal was to investigate the epidemiology and treatment of somatoform disorders in primary care: the SOmatization study of the University of Leiden (SOUL).

Our first aim was to quantify the prevalence of strictly defined DSM-IV somatoform disorders and comorbidity with anxiety disorders and depressive disorders in a consulting general practice population, with special emphasis on functional impairment. To obtain a better understanding of the comorbidity and to avoid arbitrary interpretations, we chose not to apply the hierarchic rules of DSM-IV. This implies that in the diagnostic interview no judgement was made whether the disturbance was primarily caused by the somatoform disorder or by the anxiety or depressive disorder. In addition, we studied the comorbidity on symptom level. In this way, comorbidity was explored without preset diagnostic concepts. We hypothesised that a non-specific elevation of all sorts of physical symptoms would be present in relation to emotional symptoms.

Our second aim was to evaluate the value of questionnaires measuring symptoms. To this end we compared the discriminative value of a physical and a mental symptom count to detect somatoform disorders with or without comorbid anxiety or depressive disorders. Symptoms expressing emotional distress, such as depressed mood and anxiety, are essential components of screening instruments for anxiety or depressive disorders. Questionnaires with unexplained physical symptoms, such as the Screening for Somatoform Symptoms (SOMS) or the 15-item list from the Primary Care Evaluation of Mental Disorders patient questionnaire (PRIME-MD PQ), are used to screen for somatoform disorders. Considering the wide overlap of somatoform, anxiety and depressive disorders, both mental and physical symptom counts may contribute to the detection of each disorder. To gain more insight into the relationship between symptoms and disorders, comorbidity was taken into account.

Our third aim was to evaluate the clinical and prognostic implications of somatoform disorders in primary care. Especially the clinical relevance of the DSM-IV undifferentiated somatoform disorder had not been given much attention in research, despite its high prevalence in primary care. We aimed at demonstrating that in primary care the diagnosis of a somatoform disorder adds significant information to the more common evaluation of anxiety and depression. To this end we evaluated the consequences of somatoform disorders on symptoms and functional limitations, the consequences on use of healthcare and the natural course of somatoform symptoms.
Our fourth aim was to establish the need for treatment, the feasibility and the effectiveness of cognitive-behavioural therapy for somatoform disorders in primary care. We investigated two forms of treatment; group therapy with professional psychotherapists and an individual intervention carried out by the GP. Firstly, we quantified the need for treatment in a study among attendees with persistent symptoms in general practice. Secondly, in a pilot study, we explored if a group intervention in primary care were feasible. Group cognitive-behavioural therapy would offer a more efficient use of resources than individual treatment. This pilot might provide information on the number of patients with an indication for cognitive-behavioural treatment. Thirdly, we hypothesised that a cognitive-behavioural intervention provided by the GP in addition to care as usual, would be more effective in reducing somatic symptoms and functional impairment than care as usual. If such an intervention were successful in reducing symptoms and health care use, it would provide an underpinning for further implementation of cognitive-behavioural treatment by the GP. The treatment protocol for the GP intervention was an adaptation of a protocol for cognitive-behavioural therapy that had proven to be successful in the LUMC-trial in secondary care and was tailored to use in primary care. The same cognitive-behaviour therapist as the secondary care LUMC-trial supervised the training and treatment, with a detailed manual for the GP and self-help materials for the patients.

Design

The SOUL study consisted of three parts: prevalence, follow-up and treatment. The design of the treatment study, embedded in a population-based cohort, also provided detailed information on the selection of patients for treatment.

At baseline a two-stage prevalence study was set up. In the initial stage screening questionnaires were used to identify high-risk patients. In the second stage all high-risk patients and a sample of 15% of the low risk patients were invited for the WHO-SCAN 2.1 standardised psychiatric diagnostic interview to assess DSM-IV psychiatric disorders.

In the follow-up study we assessed the natural course of somatoform disorders and the need for treatment with cognitive-behavioural therapy. Patients were followed for 6 months after the initial diagnostic assessment of somatoform disorders. We estimated the proportion of patients in primary care with persistent symptoms of somatoform disorders that would accept treatment. Use of primary health care was monitored prospectively for 12 months.
In the treatment study we tested the hypothesis that cognitive-behavioural treatment provided by the GP is more effective in reducing somatic symptoms and functional impairment than usual care. In a controlled trial we compared the recovery of symptoms in patients who received a cognitive-behavioural intervention in addition to care as usual to patients who only received care as usual. The primary end-points were the self-reported recovery of symptoms and the severity of the symptoms after 6 and 12 months.

Prior to the start of the SOUL study, a pilot study with a separate data collection was performed among consulting patients in a single general practice. The aim was to investigate the acceptance and feasibility of a group cognitive-behavioural intervention.

Patients

The SOUL study included three cohorts between April 2000 and July 2002. A cohort of consulting patients and a cohort of listed patients were drawn from eight university-affiliated general practices from urban areas in the western part of The Netherlands. The electronic medical records of all patients were available through the central database of the family practice registration network Leiden RNUH-LEO. In this way, data on morbidity and health care use were (efficiently) accessible for the large group of patients selected for the prevalence study and follow-up study.

Given the results of the pilot study, we anticipated we would need more patients for the treatment study. Therefore, a third cohort of listed patients from four of the eight university affiliated practices and from four regular general practices in the Leiden area was followed to recruit additional patients for the treatment study.

Structure of the thesis

In chapter 2 the prevalence of somatoform disorders and the comorbidity with anxiety and depressive disorders is described, with particular emphasis on functional impairment. In chapter 3 we explore whether patients report specific physical symptoms in the presence of mental distress, taking into account the presence of somatic disease.

In chapter 4 the contribution of physical and mental symptom counts to the detection of psychiatric disorders in primary care is explored.
In chapters 5 and 6 results from the follow-up study are presented. In chapter 5 the contribution to primary health care consumption of undifferentiated somatoform disorders is investigated prospectively, as well as the contribution of other somatoform disorders, anxiety and depressive disorders. The natural course of somatoform disorders and the need for treatment in general practice is described in chapter 6. A realistic estimate of the additional need for treatment for somatoform disorders is made.

In chapter 7 a pilot study reports on the feasibility of a group intervention with cognitive-behavioural therapy. Group therapy has the potential of treating greater numbers of patients with limited staff. Patients with medically unexplained physical symptoms were offered a cognitive-behavioural therapy group intervention. Chapter 8 provides the conceptual frame for the intervention protocol. The consequences model for somatoform disorders with its cognitive and behavioural techniques is described. The effectiveness of a cognitive-behavioural intervention performed by the GP is reported in chapter 9. Intervention patients received 5 sessions of cognitive-behavioural treatment by their own GP. Patients in the control practices received care as usual. The effects of the intervention on symptoms, functional limitations and health care were evaluated.

Chapter 10 provides a general discussion with the main findings, the clinical implications of the study and suggestions for further research.

References


