

Summary

This thesis describes the results of the Somatisation study of the University of Leiden, SOUL. The main goal of this study was to investigate the epidemiology and treatment of somatoform disorders in primary care to establish the clinical relevance of somatoform disorders in relation to the other common psychiatric disorders in primary care: anxiety and depressive disorders. It comprised a prevalence study with a prospective follow-up and a subsequent treatment study.

General introduction

Chapter 1 provides a general introduction of the topic and an overview of the terminology and classification used for medically unexplained physical symptoms, somatisation and somatoform disorders. It goes on to describe the clinical problem, which led to the aims, the study design and the structure of this thesis.

Many patients attend their general practitioner with physical symptoms that are not adequately explained by a medical condition: medically unexplained physical symptoms. Frequently these symptoms, such as fatigue, back pain, headache or gastrointestinal symptoms, lead to functional disability in daily life. When impairments last for at least 6 months a somatoform disorder can be diagnosed according to DSM-IV, the prevailing psychiatric classification system. Besides having physical symptoms, patients with somatoform disorders are often bothered by anxiety or depression. Few comprehensive studies have, however, focused on an accurate quantification of the separate or comorbid occurrence of somatoform, anxiety and depressive disorders. Cognitive-behavioural therapy proved effective in reducing medically unexplained physical symptoms in earlier studies in secondary care. Evidence on the most appropriate treatment in primary care is however limited.

Our first aim was to quantify the prevalence of strictly defined DSM-IV somatoform disorders and their comorbidity with anxiety and depressive disorders in primary care (chapter 2). In addition, the relationship between the reporting of physical and mental symptoms was evaluated to explore comorbidity on the level of mere symptoms (chapter 3).

Our second aim was to examine the contribution of a mental and physical symptom count to the detection of anxiety, depressive and somatoform disorders (chapter 4).

Our third aim was to evaluate the clinical and prognostic implications of somatoform disorders in primary care. To this end we evaluated the consequences of somatoform disorders on symptoms and functional limitations (chapter 2), its consequences on use of healthcare (chapter 5), and the natural course of somatoform symptoms (chapter 6).

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. The need for treatment was quantified in a study in general practice among attendees with persistent symptoms (chapter 6). We investigated the feasibility of two forms of treatment; an individual intervention carried out by the GP (chapter 6) and group therapy with professional psychotherapists (chapter 7). Lastly, we examined whether 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 (chapter 9).

Design and patients

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 standardized psychiatric diagnostic interview to assess DSM-IV psychiatric disorders. All patients received a follow-up questionnaire at 6 months. Use of primary health care was monitored prospectively for one year through the central database of the general practice registration network Leiden RNUH-LEO. Patients with persistent symptoms of somatoform disorders were invited to take part in the treatment study. In a controlled trial care as usual was compared with care as usual plus a cognitive-behavioural intervention by a trained GP. The primary end-points were the self-reported recovery of symptoms and the severity of the symptoms after 6 and 12 months.

SOUL included three cohorts between April 2000 and July 2002. A cohort of 1046 attendees (response 59%), aged 25 to 80, was drawn from eight university-affiliated general practices from urban areas in the western part of The Netherlands. These attendees were selected after a contact with their GP, and can be referred to as the 'consulting population'. Of the attendees 473 were interviewed (response 80%) and for 400 patients data from RNUH-LEO were available at one-year follow-up. A cohort of listed patients was followed using the same methods. Prior to the SOUL-study, a pilot study among consulting patients of one general practice in Leiderdorp had been carried out from January to March 1999 to investigate the acceptance and

feasibility of a group cognitive-behavioural therapy. Given the results of the pilot study, we anticipated we would need more patients for the treatment study. Therefore, a third cohort of 915 listed patients, aged 25 to 70, 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. For the third cohort an extra telephone screening was performed. Finally, 65 patients were included in the treatment study from all three cohorts.

Main findings

In [chapter 2](#) we quantified the prevalence and functional impairment of DSM-IV somatoform disorders and the comorbidity with anxiety and depressive disorders at baseline among attendees.

In a consulting population in general practice the prevalence of somatoform disorders was 16.1%. Most common was the undifferentiated somatoform disorder, with a prevalence rate of 13.1%. These patients suffer from one or more medically unexplained physical symptoms, causing clinically significant distress or functional impairment for at least 6 months. When disorders with only mild impairment were included the prevalence of somatoform disorders increased from 16.1% to 21.9%. The prevalence of anxiety or depressive disorders was 4.0% and 5.5%, respectively. Comorbidity of somatoform disorders and anxiety/depressive disorders was 3.3 times higher than could have been expected by chance. More than half the patients with an anxiety or a depressive disorder met the criteria of a co-morbid somatoform disorder. Of all the patients with a somatoform disorder 26% also had an anxiety and/or depressive disorder. In patients with comorbid disorders physical symptoms, symptoms of depression and functional limitations increased proportionally. These findings underline the importance of a comprehensive diagnostic approach to common psychiatric disorders in general practice.

In [chapter 3](#) we studied the comorbidity on symptom level, thus without using preset diagnostic concepts. We hypothesised that a non-specific elevation of all sorts of self-reported physical symptoms on the Physical Symptom Checklist (PSC-51) would be present in relation to mental distress. Mental distress was rated as present on the basis of a self-report questionnaire for symptoms of anxiety and depression, the Hospital Anxiety and Depression Scale (HADS). We tested this within the samples of consulting and listed patients, aged 25 to 70.

The presence of mental distress had a major effect on the reporting of all types of physical symptoms in both men and women. Multivariate analyses in women showed the pattern to be independent of the presence of somatic disease. This implies that mental distress is a much stronger predictor for the reporting of any physical symptom than somatic disease. We found no specific stress-related physical symptoms, except fatigue and forgetfulness. Odds ratios were particularly high (> 6) for 'feeling tired/ having low energy', 'fatigue without exertion' and 'forgetfulness'. For these symptoms the classification 'physical' rather than 'mental' is somewhat ambiguous, e.g. bodily fatigue is difficult to distinguish from mental fatigue or decreased energy.

In [chapter 4](#) the contribution of a mental and physical symptom count to detect DSM-IV anxiety, depressive and somatoform disorders is examined. The diagnostic value of two questionnaires, the Hospital Anxiety and Depression Scale (HADS) and the Physical Symptom Checklist (PSC-51), was examined within the sample of consulting patients with ROC-analyses.

There was a substantial correlation between the symptom count on the PSC-51 and the total score on the HADS ($r=0.6$; $p<0.01$). The discriminative power of PSC-51 and HADS to detect DSM-IV disorders was highest for patients with both a somatoform disorder and an anxiety or depressive disorder, with area under curve (AUC) of 0.86 and 0.91 respectively (for AUC 1.0 is optimal). Using both symptom counts together did not increase the diagnostic value for the detection of psychiatric disorders. We concluded that the diagnostic value of the number of physical symptoms was similar to that of mental symptoms. The fact that a mental symptom count predicts the presence of a somatoform disorder suggests a close relationship. We found that this predictive value was partly due to the comorbidity with anxiety and depressive disorders. Both symptom counts preferentially detected patients with comorbid psychiatric disorders.

In [chapter 5](#) results from the follow-up study are presented. The contribution to primary health care consumption of undifferentiated somatoform disorders, other somatoform disorders, anxiety and depressive disorders was investigated prospectively (within the sample of consulting patients).

In the follow-up year patients with psychiatric disorders had more face-to-face contacts with the GP than patients without a psychiatric disorder. The impact on primary care by patients with somatoform disorders was comparable to that of patients with depressive or anxiety disorders. Undifferentiated somatoform disorders had an independent impact on use of primary care after adjustment for anxiety and depressive disorders, resulting in 40% more consultations (incidence rate ratio, IRR, 1.4 (95% CI:

1.0-1.9)). Other somatoform disorders and depressive disorders also showed this tendency, although not significantly. The presence of an anxiety disorder did not contribute independently to the consultation rate.

We concluded that health care should focus equally on recognition and treatment of somatoform and depressive disorders.

In [chapter 6](#) the course of the disorder and the need for treatment are examined. All patients in the consulting population with an initial diagnosis of a somatoform disorder were checked for persistence of somatoform symptoms after a follow-up period of six months. For each patient with an initial diagnosis of a somatoform disorder the need for treatment was evaluated by assessing recovery, contraindications, current psychotherapy, and acceptance of the treatment.

After six months 70% of the patients were still bothered by the presence of somatoform symptoms, corresponding with a weighted prevalence of 12.3 % of persisting somatoform disorders. In addition to the 30% of the patients that recovered, 20% was not eligible for starting cognitive-behavioural therapy; they either had a contraindication for psychotherapy or were already receiving long-term psychological treatment for a psychiatric disorder. Another 23% of the initial selection of patients was not motivated to enter cognitive-behavioural therapy for their problems. Most patients indicated that they had accepted the symptoms as a part of their lives. Thus, despite the high initial prevalence in primary care, only 26% of all the patients with a diagnosis of a somatoform disorder had a need for treatment and enrolled in the trial for a brief cognitive-behavioural treatment. Still, these figures suggest an additional need of cognitive-behavioural therapy for somatoform disorders of nearly 5% of the consulting population in primary care.

In [chapter 7](#) the feasibility of group cognitive-behavioural therapy is explored. In a pilot study in one general practice we found 104 patients with medically unexplained physical symptoms through systematic selection. We estimated the prevalence to be 18% in this consulting primary care population. After applying in- and exclusion criteria, only 12 patients out of the 104 were eligible for treatment, of which only 7 were willing to accept group cognitive-behavioural therapy for their symptoms. We concluded that group cognitive-behavioural therapy does not appear suitable and acceptable to most patients in primary care.

In [chapter 8](#) the consequences model is discussed. The central idea of the cognitive-behavioural approach is to focus on consequences rather than on causes of symptoms. The general practitioner should give a plausible logical explanation for symptoms whenever possible and acknowledge that the symptoms are real for the patient,

providing an opportunity to treat physical symptoms without fruitless discussions of causes. Cognitive and behavioural techniques in the consequences model aim at changing the consequences of the symptoms and thus to achieve changes in illness behaviour. In fact, the consequences model may be useful in all situations in which the symptoms experienced by the patient are not in keeping with medical findings.

In [chapter 9](#) we assessed the effectiveness of cognitive-behavioural therapy on somatoform disorders in a controlled study in primary care. Intervention patients (n=31) were offered five 45-minute sessions of cognitive-behavioural treatment by their GP as an additional intervention to care as usual. In the control condition patients (n=34) received care as usual.

We found no advantage of a brief cognitive-behavioural treatment added to care as usual. In general, during the follow-up period most symptoms and impairments remained stable or improved slightly. The average severity score of the main physical symptom on a visual analogue scale (0-10) decreased from 7.6 at baseline to 6.0 for controls and 6.0 for intervention participants after 12 months. According to their self-reported recovery, 12 out of 34 controls (35%) and 13 out of 31 intervention patients (42%) indicated improvement of symptoms, which was not significantly different. Secondary outcome measures did not show significant differences in outcome either. The prescription of psychotropic drugs was associated with better recovery. Regarding the actual treatment that patients received in the year following baseline, 17 out of the 31 intervention patients (55%) did not complete all five sessions of the cognitive-behavioural treatment and 8 of them even withdrew before the start of the intervention (26%). There were no differences in utilisation of care as usual between intervention and control group.

Our findings in primary care are in contrast with a previous similar study we conducted in secondary care, in which cognitive-behavioural therapy was superior to optimised medical care. Although we aimed at using the same treatment model, tailored to use by the general practitioner, and applied similar inclusion and exclusion criteria, we could not confirm the beneficial effects of additional cognitive-behavioural treatment as we did in secondary care. We considered several factors in our study that might have contributed to the lack of additional effect of cognitive-behavioural treatment to care as usual. Firstly, the GP carried out the abbreviated form of cognitive-behavioural treatment and consequently the professional level and the intensity of our intervention are not comparable with secondary care treatment. Secondly, with our emphasis on severity and persistence of symptoms we mainly selected patients who had reached a chronic stage with little tendency to recovery and no explicit need for treatment. Thirdly, it may well be that the control participants also

received effective treatment with cognitive-behavioural techniques or pharmacological interventions.

General discussion

Chapter 10 provides a general discussion on the results of this thesis and its implications. SOUL is among the first to study DSM-IV somatoform disorders including undifferentiated somatoform disorders. The magnitude of the problem is evident, since one in six patients consulting his GP suffers from medically unexplained symptoms with serious impairments. The overlap with anxiety and depressive disorders is substantial, and this amplifies the severity of the burden of disease. Considering health care use, patients with somatoform and depressive disorders had more face-to-face contacts with the GP than patients who had no psychiatric disorder. These findings underline the importance of a comprehensive diagnostic approach to psychiatric disorders in general practice. The number of symptoms, whether physical or mental, might be a helpful tool to identify the most severe patients.

The treatment study was nested in a population-based cohort, allowing us to evaluate the generalisability towards the entire primary care population. The implications for treatment ensue from the finding that three-quarters of all patients with a somatoform disorder had persisting symptoms. However, we could not demonstrate that the extra training of GPs and the cognitive-behavioural intervention that we offered in this study are more effective than the clinical improvements realized by care as usual. Considering the differences between primary care patients in terms of the range in severity of the symptoms and motivation for therapy, it is not likely that one single treatment approach will be appropriate for somatoform disorders. Instead, a stepped-care treatment model could provide more efficient care, ranging from a simple “upgrading” of the care as usual by GPs to intensive interventions by specialised professionals for chronic patients.

Our findings underline the need for the development of feasible and effective treatment options for primary care patients with somatoform disorders. Since somatoform disorders show a considerable overlap with depression and anxiety disorders, an integrative approach for all three disorders could be advantageous for patient and doctor.

