Chapter 10

General discussion

The main goal of the SOmatization study of the University of Leiden (SOUL) was to establish the clinical relevance of somatoform disorders in relation to anxiety and depressive disorders in primary care. It comprised a prevalence study with a prospective follow-up and a subsequent treatment study.

Discussion of the main results

Prevalence of somatoform disorders & comorbidity with anxiety and depression
Our first aim was to quantify the prevalence of strictly defined DSM-IV somatoform disorders and their comorbidity with anxiety and depressive disorders in general practice. In addition, the relationship between reported physical and mental symptoms was evaluated to explore the comorbidity on the level of mere symptoms.

Among attendees in Dutch general practices we established a point prevalence of 16.1% of DSM-IV somatoform disorders. Most common was the undifferentiated somatoform disorder, with a prevalence of 13.1%. These patients suffer from one or more medically unexplained physical symptoms such as fatigue, back pain, headache or gastro-intestinal symptoms, causing clinically significant distress or functional impairment for at least 6 months. Earlier, Fink et al reported an even higher prevalence of somatoform disorders of 30% in a Danish general practice consulting population.[1] In our study the prevalence of anxiety or depressive disorders was 4.0% and 5.5% respectively. When comparing our study to previous prevalence studies among attendees in primary care [2 3 4] our estimates are relatively low and more in line with rates found in community surveys.[5 6] Our lower estimates are most likely due to our strict definition of the disorders. The SCAN-interview is known as a high-threshold diagnostic interview with a comparatively strong emphasis on clinically relevant symptoms.[7 8] In addition, we took meticulous care to rate the criterion of functional impairment that was introduced in most axis 1 disorders in the update from DSM-III-R to DSM-IV. Finally, an explanation for our low estimates of anxiety and depressive disorders may be found in the use of psychotropic medication, which may vary between populations. Possibly, patients with effective pharmacological treatment may no longer qualify for a psychiatric diagnosis.

Comorbidity of somatoform disorders and anxiety or depressive disorders was 3.3 times more likely than could have been expected by chance. More than half the patients with an anxiety or a depressive disorder fulfilled the criteria of a comorbid somatoform disorder. A high co-morbidity of somatoform disorders and anxiety or depressive disorders has been a common finding in previous studies.[9 10 11 12] Functional somatic syndromes, such as irritable bowel syndrome or chronic fatigue, are also related to (but not fully dependent on) anxiety and depression.[13] We explored

this comorbidity further on symptom level using data from the questionnaires at baseline. Patients reporting mental distress more often reported all types of physical symptoms than patients without mental distress. This confirmed our hypothesis that there are no specific physical symptoms related to anxiety or depression. It makes a presumed direct etiologic pathway from anxiety or depression to particular unexplained physical symptoms less likely, assuming that such a pathway would result in an elevation of specific symptoms.

Detection of somatoform, anxiety and depressive disorders by symptom-checklists

A second aim of the study was to examine the contribution of a mental and physical symptom count to the detection of anxiety, depressive and somatoform disorders.

Several checklists with mental and physical symptoms are used to identify patients with psychiatric disorders. We found that a physical symptom count (PSC-51) and a mental symptom count (HADS total score) gave similar results in the detection of common psychiatric disorders in primary care. It seems that the number of symptoms rather than the kind of symptoms (physical or mental) determines the diagnostic value in detecting psychiatric disorders.

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/depressive disorders. Also, both PSC-51 symptom count and HADS total score preferentially detected patients with comorbid disorders.

Clinical relevance of somatoform disorders

A third aim of our study was to evaluate the clinical relevance of somatoform disorders in primary care. We assessed the burden of illness in relation to anxiety and depressive disorders in terms of symptoms, functional limitations and use of primary care. Furthermore, we established the prognosis in primary care.

At baseline we assessed symptoms and functional limitations for the subgroups of patients with and without psychiatric comorbidity. In patients with comorbid disorders physical symptoms, depressive symptoms and functional limitations increased proportionally. In the follow-up year patients with psychiatric disorders had more face-to-face contacts with the GP than patients without psychiatric 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.

The course of somatoform disorders in general practice was not favourable. We found that three-quarters of all patients with a somatoform disorder had persisting

symptoms after 6 months; representing an estimated 12% of all GP attendees aged 25-79 years. These results are in contrast with the findings of several studies in primary and secondary care, which reported improvement of medically unexplained symptoms or recovery in the majority of patients after one year.[14 15 16] We may have included comparatively more severe patients. The use of DSM-IV and the SCAN-interview resulted in a strong emphasis on clinically relevant symptoms. All patients had a current disorder, and in 90% of them symptoms had lasted for over 12 months. Since we aimed at studying a representative sample of all GP attendees, these results would imply that the patients in our primary care cohort had a worse prognosis than in other study populations. Further research on the factors that predict the prognosis would contribute to a better understanding of the mechanisms of chronicity and the course of medically unexplained physical symptoms in various populations.

At the start of the study we hypothesized that the diagnosis somatoform disorder, rather than anxiety or depression, is a specific predictor of health seeking behaviour, functional limitations and persistence of physical symptoms. Our findings suggest that this hypothesis only partly holds. We did find an independent effect of somatoform disorders on functional limitations and health seeking behaviour, since the effect was not fully explained by the presence of comorbid anxiety or depression. However, depressive disorders had an independent effect on medical consumption and were not a consequence of the comorbid somatoform disorders.

Treatment of somatoform disorders in primary care

A fourth aim was to explore if cognitive-behavioural treatment in primary care were feasible and effective. In a pilot-study we assessed the feasibility of group therapy, and in the SOUL-study the need for treatment and the effectiveness of an intervention by the GP. In a controlled study the hypothesis was tested that cognitive-behavioural treatment provided by the GP would be more effective in reducing somatic symptoms and functional impairment than usual care.

We estimated the need for treatment to be considerable as a consequence of the high prevalence of somatoform disorder. To supply adequate treatment to a large population in primary care, we were interested in two alternatives to stimulate an effective use of health care providers. A group intervention with a professional psychotherapist would offer cognitive-behavioural therapy to a fair number of patients simultaneously and the training of GPs would make cognitive-behavioural treatment available for all primary care patients.

To estimate the feasibility of group cognitive-behavioural therapy we performed a pilot study. Results from this study indicated that in spite of the high prevalence of medically unexplained symptoms, the feasibility of group treatment in primary care was limited. The majority of the patients with medically unexplained

physical symptoms did not meet the criteria for group treatment due to recovery of the symptoms or ongoing concurrent psychological treatment. In addition, some patients objected to group treatment and would prefer individual treatment by their own GP. We concluded that a group intervention by professional psychotherapists was not feasible and we went on to explore the feasibility and effectiveness of a brief individual treatment executed by the GP.

For the SOUL-study on the effectiveness of interventions carried out by the GP, our purpose was to overcome some of the limitations of the pilot-study. Firstly, we aimed at increasing the number of patients who felt a need for treatment by carefully selecting patients with current symptoms according to the DSM-IV. Secondly, to enhance the accessibility, the intervention was to be carried out by the patient's own GP. Yet, when we assessed the need for individual treatment, we found that, in general, the results replicated the unfavourable findings of our pilot study. Although we managed to include more patients with current symptoms, it appeared that we mainly included patients with severe symptoms. At least a quarter of all patients with persisting symptoms did not meet the inclusion criteria for short cognitive-behavioural treatment due to a serious somatic or psychiatric disorder, or ongoing psychological treatment. Moreover, approximately one third of the eligible patients with persisting symptoms was not interested in explicit cognitive-behavioural treatment, mostly because they had accepted the symptoms as a part of their lives.

In our controlled study on the effectiveness of cognitive-behavioural therapy by the GP for somatoform disorders, we found no additional advantage of 5 sessions of cognitive-behavioural therapy to care as usual. In the cognitive-behavioural therapy group as well as in the care as usual group about 30% of the patients showed improvement on clinically relevant outcomes. Our findings in primary care are in contrast with a similar study we conducted in secondary care, in which cognitive-behavioural therapy was superior to optimised medical care.[17] 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 this treatment model in primary care.

We considered several factors in our study that may have contributed to the lack of additional effect of cognitive-behavioural treatment to care as usual. Firstly, factors concerning treatment aspects could explain why our results differ from previous reviews that reported on the beneficial effects of cognitive-behavioural therapy. In contrast with the studies in secondary care our intervention was not carried out by a professional psychotherapist but by a trained general practitioner. Only 45% of the patients included in the intervention group completed the treatment that consisted of 5 sessions. As a result, the professional level and the intensity of our intervention are not comparable with secondary care treatment. A second important explanation relates to

differences in characteristics of the study populations. Most studies on referred participants[17 18] report that the average age was 35-40, whereas the included primary care participants were 10 years older. Compared to our secondary care study they had more severe symptoms and more functional limitations, which might have influenced the receptivity to a cognitive-behavioural treatment and thus prognosis. Apparently, with our emphasis on severity and persistence of symptoms we mainly selected patients who were already receiving treatment or had reached a chronic stage with no explicit need for treatment. Thirdly, moderate but clinically relevant effects were established in the group with care as usual as well. Recovery may have been the result of effective care as usual provided by the GPs. It may well be that the control participants also received treatment with cognitive-behavioural techniques from their GP or from a mental health professional. Furthermore, both intervention and control patients frequently used antidepressants or tranquillisers. Since a better outcome was related to prescription of this psychotropic medication, we assume that care as usual contained effective pharmacological interventions.

Strengths and limitations of the SOUL study

The main strength of the SOUL-study was the design that combined epidemiological comprehensiveness and efficient use of resources. Participants were selected using a two-stage sampling scheme. In the initial stage high-risk patients were identified by means of screening questionnaires. In the second stage all high-risk patients and a sample of the low risk patients were invited for a psychiatric diagnostic interview, which allowed reconstruction of the prevalence in the total population. This approach was chosen to make efficient use of resources: by interviewing more high-risk patients, relatively more interviewed patients had a somatoform disorder.

The 59% response rate on the screening questionnaire was rather low for a prevalence study, although not uncommon in primary care. For this study the electronic medical records of all patients were available through the central database of the family practice registration network Leiden (RNUH-LEO). This allowed a fairly detailed analysis of non-response characteristics. The response was independent of frequency of consultation and of psychological problems as seen by the general practitioner. Response was comparatively low in the younger males (46%). If we assume they were the healthier subjects, this may have resulted in some overestimation of the prevalence of disorders. On the other hand, social problems were slightly underrepresented in the responding sample, which could have affected the rates towards some underestimation.

In the introduction we gave an overview of the terminology and classification of medically unexplained physical symptoms. We diagnosed somatoform disorders according to the DSM-IV classification. This is all the more relevant since medically unexplained physical symptoms can include a broad and ill-defined range of symptoms, which can induce diagnostic uncertainty. In addition, we took meticulous care to rate the criterion of functional impairment that was introduced in most Axis I disorders in the update from DSM-III-R to DSM-IV. Despite the scale of the SOUL study, the power to study the more specific somatoform disorders such as somatisation disorder or hypochondriasis was limited. Also, the number of patients per category of specific comorbid disorders was low. Disorders related to substance abuse, psychotic disorders or personality disorders were not taken into account.

The treatment study was nested in a population-based cohort, allowing us to evaluate the generalisability towards the entire primary care population. Attendees as well as listed patients were sampled and assessed using a similar procedure, independent from the GP. Despite an elongation of the study period we were not able to include the preset number of patients. Still, the power to detect a 30% difference in VAS during the follow-up period was 70%. Several safeguards ensured the quality of the treatment. A protocol for cognitive-behavioural therapy that had proven to be successful in secondary care was tailored to use for primary care. A detailed manual for the GP and self-help materials for the participants supported the integrity of the treatment, whereas the same experienced cognitive behaviour therapist as in the secondary care study supervised the training and treatment.

Implications and recommendations for research

The ongoing debate on the validity of the diagnosis of somatoform disorders [19 20] and the practical implications of their recognition [21] highlight the need for further research. Although there is substantial criticism on the classification of the subcategories of somatoform disorders, all involved agree that the number of somatic symptoms is an important dimension since it is associated with impairment and healthcare use.[22 19] Such a dimensional approach in research might be more fruitful than focussing on DSM-axis I-categories.

A classification also has a pragmatic goal: it is essential in the communication among physicians and researchers. Some argue that DSM-IV has not succeeded in this goal for somatoform disorders [23] but alternatives have long been overdue. There is evidence for a common ground of functional syndromes.[24] Further research might

clarify if this ‘common ground’ can contribute to a better communication, and if it has clinical implications for the general physicians.

Although we could not confirm that cognitive-behavioural treatment supplied by the GP is more effective than care as usual, our findings provide directions for further research in this field. Somatoform disorders in primary care are highly prevalent and tend to have a worse prognosis than in secondary care. Future research should therefore focus on aspects of prognosis and treatment. Firstly, factors that predict the prognosis of a somatoform disorder in primary care should be assessed. This might clarify the mechanisms that determine the course of medically unexplained symptoms. Secondly, suitable treatment options should be developed and tested for the whole spectrum of somatoform disorders seen in GP attendees. On the one hand, many patients recover within due time or are not motivated for an intensive treatment. They might benefit from more implicit interventions by the GP during regular consultations.[25] On the other hand, a large number of patients have chronic and disabling symptoms, complicated by comorbid psychiatric and somatic disorders. For these patients more intensive interventions in secondary care could bring about substantial improvements.[18 26 27] Pharmacological interventions may add to treatment success since psychotropic medication was associated with better treatment outcomes in our treatment study as well as in the literature.[28] To evaluate the (cost-) effectiveness of medication in somatoform disorders in primary care, randomised trials should be carried out. These trials should also provide answers on duration of treatment and choice of medication (e.g. tricyclic antidepressant or SSRI, appropriateness of benzodiazepines).

Considering the differences among primary care patients, we suggest the development of a stepped-care model.[27 29] A treatment model with a stepwise increasing intensity would allow better for the variation in severity and patient characteristics as encountered in primary care.

Implications and recommendations for general practice

The implications of this study focus on the main aspects of somatoform disorders in primary care. The magnitude of the problem is evident: 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 amplified the burden of disease. Patients with somatoform disorders show an increase in GP-contacts independent of the presence of anxiety and depressive disorders. These findings underline the importance of a comprehensive diagnostic approach to

psychiatric disorders in general practice: the diagnosis of a somatoform disorder provides extra information on the severity of the functional limitations and the need for health care. The number of symptoms, whether physical or mental, may be a helpful tool to recognise the most severe patients.

The implications for treatment ensue from the finding that three-quarter of all patients with a somatoform disorder has persisting symptoms. The GP should be aware of the fact that the spectrum of severity ranges from patients with mild self-limiting symptoms to chronically disabled patients. To improve the care for all patients we propose a stepped-care treatment approach. The first step would provide adequate care as usual for patients with recent and self-limiting symptoms. To improve care as usual, GPs should receive supplementary training in the diagnosis and treatment of somatoform disorders with a special focus on cognitive-behavioural techniques. Subsequent steps should include cognitive-behavioural interventions by specialised professionals. For severe or chronic patients more intensive interventions should be tailored to the needs of the patients. Since somatoform disorders show a considerable overlap with depression, anxiety and somatic conditions, patients as well as doctors may benefit from an integrative approach to all these disorders.

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