

General Practitioners and Somatising Patients

Development and evaluation of a short-term training programme
for assessment and treatment of functional disorders

PhD thesis

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Preface

Outline of this thesis and the PhD project

This thesis is based on the project ‘Somatising patients in general practice – an intervention study’ conducted in Vejle County, Denmark. The project was developed and implemented in close cooperation between ‘The Committee for Quality Improvement in General Practice, Vejle County Health Insurance’, the Research Unit and Department for General Practice, Aarhus University, and ‘The Research Unit for Functional Disorders, Aarhus University Hospital’.

The concept of somatisation is introduced in **Chapter 1** and followed by a summary of prevalence, natural course, problems, treatment and aspects of changing professional behaviour. The **aim** of the PhD study is presented at the end of Chapter 1.

In order to be able to answer the study questions presented on page 14, we first developed a training programme designed for GPs addressing assessment and treatment of functional disorders in primary care. The background for this programme development in relation to the current CME in Denmark is discussed in **Chapter 2**. The contents of the educational programme and treatment model (the ‘TERM-model’) are presented in **Chapter 3**. *The introduction to Chapter 3 and Sections 4 and 5* contain my main contributions to the development of the model, and these sections *should be the focus for the assessment of Chapter 3 in this thesis*. Together with Sections 6 and 7 they describe the contents of the intervention. Chapter 3 formed part of the educational material for GPs participating in training and the first sections contain an extensive general description of somatisation targeting clinicians, which may repeat some of the issues addressed in the introduction of this thesis. The entire article has, however, been contained within this Chapter both because Sections 4 and 5 cannot stand alone and in order to provide the reader a complete picture of the educational programme and treatment model.

The training programme was evaluated in a cluster randomised clinical trial carried out in Vejle County, Denmark in 2000-2001. A brief description of the trial is given in the box below in order to provide a general view of the entire project in relation to the separate chapters of this thesis. For a more detailed description, please refer to the methods sections of Chapters 4 to 6.

Results from the randomised trial are presented in Chapters 4 to 6. The effects on GPs’ attitude towards somatising patients after twelve months follow-up are evaluated in **Chapter 4**. The effect of training on GPs’ diagnosis of somatisation at inclusion and their agreement with a patient screening questionnaire are addressed in **Chapter 5**. Aspects of patient outcome during twelve months follow-up are examined in **Chapter 6**. These three chapters have been written as independent articles for publication, which inevitably brings some repetition into sections of introduction, methods and discussion, but at the same time allows the reader to read each article on its own.

Chapters 7 to 10 offer a comprehensive and more general discussion of the methods used and the results presented in the articles, adding perspective to the research questions posed.

Finally, **English and Danish summaries** are given [page 168, 173], and references used throughout the thesis are listed alphabetically according to authors. **Appendices** provide an outline of the TERM-model and ‘The Reattribution Model’, flowcharts for the study, and questionnaires in Danish including overviews of applied measures.

Outline of the randomised trial

- All GPs registered with the Vejle County Health Insurance were invited in 1999 and accepting practices were allocated to intervention or control group [Appendix B]. GPs were described on the basis of data from Vejle County Health Insurance registers and questionnaires about previous education in communication and psychiatry.
- In April 2000 participating GPs answered a questionnaire concerning their attitudes towards somatisation.
- GPs in the intervention group subsequently accomplished the first and most intensive part of the training programme (a residential course and three follow-up meetings with video supervision).
- In May 2000 all participating practices enrolled patients consulting for a new health problem. Included patients answered questionnaires containing research instruments for assessing physical and mental health. GPs were asked to categorise the main problem presented by the patient in the consultation. For details on questionnaires and measures, see Appendix C-D.
- Because of the large sample of patients of whom many were thought not to be somatising, follow-up was only performed on the group of patients with high scores on a screening questionnaire for somatisation. Follow-up was conducted after three and twelve months using questionnaires.
- During the follow-up period GPs in the intervention group completed the training programme (booster meeting, outreach visits and postal reminder).
- All participating GPs were sent the questionnaire about attitudes towards somatisation again at the twelve-month follow-up.

This thesis is based on the following articles

- I. Rosendal M, Toft T, Fink PK, Bro F, Olesen F: Efteruddannelsesmodeller med fokus paa funktionelle lidelser i almen praksis [Models for continuing education in general practice focusing on functional disorders].
Ugeskr Laeger, 2002; 164: 5396-5399.
- II. Fink P, Rosendal M, Toft T: Assessment and treatment of functional disorders in general practice: the extended reattribution and management model - an advanced educational program for non-psychiatric doctors.
Psychosomatics, 2002; 43: 93-131.
- III. Rosendal M, Bro F, Sokolowski I, Fink P, Toft T, Olesen F: Effect of short-time training on general practitioners' attitude towards somatisation - a randomised controlled trial.
Submitted.
- IV. Rosendal M, Bro F, Fink P, Christensen KS, Olesen F: General practitioners' diagnosis of somatisation. Effect of an educational intervention in a cluster randomised controlled trial.
British Journal of General Practice, in press.
- V. Rosendal M, Olesen F, Fink P, Toft T, Sokolowski I, Bro F: Does general practitioner training targeting somatisation affect patient outcome? A cluster randomised controlled trial.
Prepared for publication.

Motivation

Soon after my graduation from Odense University in 1989, I directed my postgraduate training at general medicine. I enjoyed immensely my assignments in general practice in Kungshamn, Sweden and in Vejle, Denmark, but had to spend most of the training in hospital departments. I acquired my specialist authorisation in general medicine in 1997 and the following two years, I continued my work in general practice in Vejle. Throughout those years, I met several patients with medically unexplained physical symptoms, and I felt ill prepared for this challenge. Fortunately, my colleagues had many years of experience and they were most supportive. However, even they encountered difficulties with the somatising patients, and I think we all experienced a 'heart sink feeling' from time to time and wished for more knowledge and better skills.

During my training years I was involved in various minor research projects and my curiosity in problems arising from the clinical work in general practice led me to contact The Research Unit for General Practice at the Aarhus University. I found great inspiration in the initial meetings with professor Frede Olesen, and as we shared an interest in somatisation the present project was established.

Acknowledgements

The study would never have succeeded, had it not been for the tremendous support I have received from my GP and research colleagues, research funds and my family.

My colleagues in general practices in Vejle County showed strong interest in the project and they undertook all the hard work of implementation and patient inclusion. I am truly grateful for their participation and support and would also like to thank the practice staff and the numerous patients who spent much time filling in the questionnaires.

I am greatly indebted to my two supervisors professor Frede Olesen and professor Flemming Bro. I could not have wished for better guidance. You were always inspiring, enthusiastic and encouraging through good as well as bad times for the project, and you never compromised two important aspects of research: It needs to be of a high quality and it should be fun.

I owe my sincere thanks to the flourishing research team at the Research Unit for Functional Disorders; in particular to Per Fink, Kaj Sparle Christensen, Tomas Toft, Lisbeth Frostholt, and Mette Bech Risør who took a large share in the parallel planning and analysis of the FIP-study and my PhD project.

The Vejle County Health Service, especially the Department of Health Insurance, was exceptionally helpful, not only with financial support but also with data retrieval and assistance in all sorts of problems encountered during the study. It was excellent to meet such support and I give my special thanks to Helle Lindkvist, Bodil Munk Hansen, Frank Ingemann, Kurt Vind Petersen, and Hans Jørn Refsgaard, but also wish to thank all of the people in the departments for their assistance.

The sophisticated statistical methods that were necessary for data analysis gave me a hard time and I was most fortunate to receive help from the statisticians Ineta Sokolowski, associate professor, PhD Morten Frydenberg and Eva Ørnbøl.

The study included an intensive training programme for general practitioners. The development and the actual implementation of this programme was dependent on a group of teachers, and I am very grateful to the general practitioners Hans Kallerup, Jette Schjødt, Sven Ingerslev, Mogens Tuborgh, Annette Vibæk Lund, Marthin Holm, and associate professor

Laurits Ovesen (deceased) and the psychiatrists Emma Rehfeldt and Lene Søndergaard Nielsen for their commitment and important contributions.

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Finally, I appreciate the generosity of Vejle Hospital which provided me with a large office, and helped administer the project economy, although my project exclusively targeted primary care. Special thanks are due to the Department of Clinical Biochemistry for housing me, to the staff for their interest in my project and help with data retrieval, and to my research colleagues Charlotte Kristiansen, Kirsten Bested and Stephan Alpiger for good company and inspiring discussions on our very differing projects.

A considerable financial support was essential for the implementation of the study. The Committee for Quality Improvement in General Practice, Vejle County Health Insurance (Q2) provided the basis for the project and The Foundation for Medical Science in Vejle County ('Vejle amts lægevidenskabelig forskningsfond') (20/99, 3/2002), The Danish National Research Foundation for General Practice ('Fonden vedr. finansiering af forskning i almen praksis og sundhedsvæsenet i øvrigt') (FF-2-01-314) and The Regional Health Insurance in Vejle County awarded substantial grants. Funding from The General Practitioners' Foundation for Education and Development ('PLU-fonden') and the Foundations of Sara Kirstine Dalby Krabbe, Else Nicolajsen and dr. K. Rasmussen was crucial in the initial phases of the study.

Most of all I consider myself lucky to have a wonderful family. Thanks for your everlasting love and patience, when I spent too much time working and paid too little attention to the three of you. I thank Kelvin for reminding me how lucky I was to be allowed so much time 'playing' on the computer; and Helene for encouraging me right from the beginning, when she brought me flowers and congratulated me on my new job. In particular, I thank Janeck for his genuine interest in my work, his confidence in my capabilities as a researcher and his unconditional support.

Marianne Rosendal

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Abbreviations

CAGE	A questionnaire for alcohol dependence (Cutting down, Annoyance by criticism, Guilty feeling, Eye openers)
CI	Confidence Interval
CME	Continuing Medical Education
EUROPEP	European Patient evaluation of general Practice care
FIP	Functional Illness in Primary care (An interdisciplinary study of 'prevention of functional disorders and abnormal illness behaviour in general practice performed in Aarhus County, Denmark)
GP	General Practitioner
ICD-10	International Statistical Classification of diseases and Related Health Problems, version 10 (WHO).
SCAN	Schedules for Clinical Assessment in Neuropsychiatry
SCL-8	Symptom Check List, subscale for mental illness
SCL-12	Symptom Check List, SCL-8 and subscales for depression and anxiety
SCL-SOM	Symptom Check List, Somatisation subscale
SD	Standard Deviation
SF-36	Short Form health status questionnaire (36 items version) from the Medical Outcome Study
Whiteley-7	A rating scale for illness worry and conviction

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Chapter 1

General introduction

1.1. The concept of somatisation

In this thesis focus is on general practice, and somatisation is conceptualised according to Lipowski's definition from 1988 as

*'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'*¹

Previous research has been based on a number of diverse concepts. In order to understand the problems presented and to be able to relate the results to existing evidence, it is necessary to be acquainted with some of the other definitions of somatisation. This section will present concepts that relate to the thesis' methods and results and to current research on somatisation in primary care.

The approach of this thesis to somatisation is medical. In relation to the present study, historical and anthropological have been addressed by Fink² and Dalsgaard³ in the multidisciplinary 'FIP-study' (http://www.auh.dk/cl_psych/uk/).

1.1.1. Origin of the concept

The name 'somatisation' was first used in 1925, when Van Teslaar translated Stekel's German word 'Organsprache' into English. 'Somatisation' was originally related to the psychoanalytical concept of conversion: that is, the transduction of a psychological conflict into bodily symptoms⁴. Since then, numerous definitions and new names have been introduced and today's concept is somewhat confusing.

1.1.2. The biomedical disease model and the complexity of somatisation

The various medical concepts of somatisation all seek to deal with the fundamental problem: that a large group of patients present with physical symptoms for which a conventional pathology cannot be identified. The somatising patients do not 'fit' into the existing framework of a biomedical disease model.

In 1977 Engel wrote:

*'The dominant model of disease today is biomedical, and it leaves no room within its framework for the social, psychological, and behavioural dimensions of illness'*⁵

Words that still apply to large parts of the health care system and to some degree also to our culturally derived beliefs about diseases. Physical symptoms are often interpreted within the limits of a biomedical model, which defines disease in terms of somatic parameters only⁵. The phenomenon of somatisation lies outside these limits and calls upon a different model of illness understanding. An alternative is 'The Biopsychosocial Model', described by Engel⁵. Contrary to the reductionistic and mind-body dualistic biomedical model, the biopsychosocial model brings in the biological, social, psychological, and behavioural dimensions of illness in a multidimensional approach, moving away from a linear understanding of disorders⁵.

A multidimensional approach to somatisation and the complexity of the concept has been captured in a few definitions. One is '**Somatic fixation**', described by Van Eijk et al in 1983⁶ and later reported by McDaniel et al as:

*'A process whereby a physician and/or a patient or family focuses exclusively and inappropriately on the somatic aspects of a complex problem'*⁷

Somatic fixation focuses on the process and the patient is not seen as the only person involved [Chapter 3, page 37].

Another concept is the '**Multi-axial classification**' suggested by Mayou et al in 1995:

*'The multi-axial classification defines somatisation on the five dimensions: somatic symptoms, mental state, cognitions, behaviour and functional impairment, and pathophysiological disturbance'*⁸

1.1.3. Classification in specialist care

In our present classification systems a dualistic approach to disorders is, however, still reflected and somatisation continues to be located in the borderland between biomedicine and psychiatry. For instance in the WHO's International Classification of Diseases (ICD-10)⁹, somatisation is classified either as biomedical or psychiatric diagnoses.

The biomedical diagnoses are listed as a number of syndrome diagnoses according to the organ specific complaints (e.g. irritable bowel syndrome, tension headache, non-cardiac chest pain). As the organ involved may vary from patient to patient and over time in the same patient, this categorisation makes it difficult to study the overall aspects of somatisation.

In the psychiatric classification the varying medically unexplained symptoms are brought together in a few diagnostic categories (somatoform disorders, dissociative disorders, neurasthenia, elaboration of physical symptoms, and factitious disorder) of which somatoform disorders is the diagnosis most widely used. The criteria for '**Somatoform disorders**', according to the ICD-10, are:

'Repeated presentation of physical symptoms, together with persistent requests for medical investigations, in spite of repeated negative findings and reassurances by doctors that the symptoms have no physical basis'

Somatoform disorders are: Somatisation disorder, Undifferentiated somatoform disorder, Hypochondriacal disorder, Somatoform autonomic dysfunction, Persistent somatoform pain disorder, other somatoform disorders, and unspecified somatoform disorder

*Diagnosis requires symptom duration of at least 6 months, affected functional level or social functioning and that symptoms are not caused by depression, anxiety, psychosis, medical side effects or abuse'*⁹

The diagnosis '**Somatisation disorder**' mentioned above is the most severe form of somatisation. This diagnosis requires multiple, variable, medically unexplained physical symptoms for at least two years, repeated health care visits, persistent refusal of non-physical explanations and a minimum of six symptoms from at least two different organ systems⁹.

Various self-administered screening questionnaires have been developed in order to make it possible to assess somatisation in large groups of patients. Some of these questionnaires have been validated against the psychiatric criteria for somatoform disorders, e.g. the SCL-SOM¹⁰ for somatisation and the Whiteley index¹¹ for hypochondriasis [Appendix D, PQ1-3].

1.1.4. Classification in primary care

The psychiatric diagnoses may be more useful than the biomedical diagnoses in the ICD-10 when the focus is on somatisation in general. They are, however, not unproblematic. Somatisation forms a spectrum of severity, and the present classification systems fail to include the milder forms. The classifications are thus less applicable to patients seen in primary care¹².

The restricted diagnostic criteria used in specialist care may have contributed to the disagreements in diagnoses between GPs and psychiatrists observed in previous studies^{13;14} [Chapter 5, Discussion, page 110]. Instead of the very narrow categories of the present diagnostic systems, primary care needs a much broader definition of the concept.

In primary care research two distinct ways of defining somatisation can be distinguished: One sees somatisation as a phenomenon that is secondary to psychological distress (presenting somatisation); the other sees somatisation as a primary phenomenon characterized by medically unexplained symptoms (functional somatisation)¹⁵.

Presenting somatisation

In 1985 Bridges and Goldberg defined ‘**Presenting somatisation**’ as:

‘A somatic manifestation of a psychiatric disturbance’, operationalised as

1. *Medical help seeking for somatic manifestations of psychiatric illness and no presentation of psychological symptoms*
2. *Attribution of symptoms to physical problems*
3. *Symptoms must justify a psychiatric diagnosis*
4. *Treatment of the psychiatric disorder will cause the somatic manifestations to disappear or revert to the level they were at before the episode of psychiatric disorder*¹⁶

Presenting somatisers may be divided into two categories: patients who accept the possibility of psychosocial origins for their physical symptoms (**partial somatisers**) and patients who persistently reject psychosocial explanations for their somatic complaints (**true somatisers**).

Despite the applicability of this definition in general practice, many patients presenting physical symptoms without organic basis do, however, not have a definite psychiatric disorder^{17;18}.

Presenting somatisation should be distinguished from the general phenomenon of experiencing and communicating distress as physical symptoms. This is a common human reaction^{19;20}, which should not be considered abnormal or a medical or psychiatric problem. Problems only arise when individuals attribute their somatic distress and symptoms to physical illness and seek medical diagnosis and treatment¹.

Functional somatisation

Functional somatisation includes various descriptive definitions, such as: definitions based on symptom count, ‘Medically Unexplained Symptoms’ and definitions containing cognitive and/or behavioural characteristics. The psychiatric criteria for somatoform disorder previously described also relate to functional somatisation¹⁵.

From the psychiatric criteria for somatoform disorders grew abridged criteria based on symptom counts. Escobar et al introduced the ‘**Somatic Symptom Index**’ in 1989^{21;22}. This index defines somatisation for men and women separately as four and six or more symptoms from a list of 37 symptoms derived from the American Diagnostic and Statistical Manual of Mental Disorders (DSM-III). In 1997 Kroenke et al suggested a concept of ‘**Multisomatoform disorder**’ defined as three or more medically unexplained, currently bothersome physical symptoms plus a long (at least two years) history of somatisation²³. The symptoms counted in these definitions are not specific to somatisation and other factors may be important for the concept of somatisation²⁴.

More comprehensive terms ‘**Medically Unexplained Symptoms**’ (MUS) or ‘**Medically Unexplained Physical Symptoms**’ (MUPS) are now being used. They were described by Mayou in 1991 as:

*‘Physical symptoms that lack an obvious organic basis’*²⁵

This term does not imply any specific attribution or behaviour and may hold the uncertainty of cause, which is often present when GPs make diagnoses. Unfortunately, the name is in

itself dualistic and implies that only physical symptoms lie within the remit of medicine. It also may indicate that no physical aetiology is present in somatisation, which disagrees with recent knowledge. Thus, alternative terms such as ‘**Functional somatic symptoms**’ or ‘**Functional disorder**’ have been suggested^{18;26}.

The definition of medically unexplained symptoms may be extensive and consequently include the major part of patients seen in general practice – unless proper restrictions are adopted, i.e. that unexplained physical symptoms must involve medical help-seeking and be the reason for encounter. Such an extensive approach may serve to improve the general awareness of non-biomedical factors in all illness processes but included patients may be rather inhomogeneous and thus have different prognoses and need different treatments.

In line with the concept of ‘medically unexplained symptoms’, Lipowski introduced a more restricted definition of somatisation in 1988 that also comprised the experiential, the cognitive, and the behavioural components. Although Lipowski assumed somatisation to be a response to psychosocial stress, his definition is purely descriptive and holds no causal relationship. He described somatisation as

‘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’¹

A comparable definition was proposed by Fink et al in relation to this study [Chapter 3, page 37]:

‘Conditions were the patient complains of physical symptoms that cause excessive worry or discomfort or lead the patient to seek treatment but for which no adequate organ pathology or patho-physiological basis can be found’²⁷

The concept of somatisation in general practice is captured well by Lipowski’s definition. It is, however, not sufficiently operational and could lead to the impression that endless diagnostic testing must be undertaken before arriving at a diagnosis of somatisation. Using Lipowski’s definition as a basis, a categorisation of somatisation into four groups has been suggested by Jorgensen et al²⁸. This classification has been slightly revised to include items ‘a’-‘d’ below²⁷, and main groups for patients presenting with physical symptoms have been added (by the author):

Patients presenting with physical symptoms may have their symptoms classified as:

1. *Physical symptoms that await further clarification*
2. *Medically explained physical symptoms = physical disease*
3. *Medically unexplained physical symptoms = **somatisation**/functional symptoms*
 - a. *Acute and subacute functional symptoms*
 - b. *Chronic somatising conditions (including somatoform disorders and syndrome diagnoses)*
 - c. *Physical symptoms in other psychiatric disorders (=presenting somatisation)*
 - d. *Illness worry, illness aggravation, and pathological illness behaviour in cases of genuine physical diseases* (Based on Jorgensen et al)²⁸

This categorisation of somatisation is identical to the classification mentioned in Chapter 3 [page 37] [Appendix D, GP-REG].

Hypochondriacs are included under chronic somatisation, but may constitute a separate group¹⁷.

1.1.5. Closing remarks

The concepts mentioned above are all being used, which contributes to the diversity and ongoing confusion of terminology. It has been difficult to agree upon an adequate definition that captures the entire concept and satisfies operational criteria in research and clinical practice, and there is, as yet, no golden standard for somatisation in general practice. Moreover, the name ‘somatisation’ may carry inappropriate implications²⁹. Sharpe stated in 2001 that:

*‘The first difficulty is confusion over what ‘somatization’ actually is. One answer is that it is a form of convenient terminological wallpaper that papers over the unsightly crack in our understanding of the relationship between mind and body’*³⁰

Summary of the concept

Many definitions of somatisation exist and the concept remains somewhat confusing.

In this thesis focus is on general practice, and somatisation is conceptualised according to Lipowski’s definition from 1988 as

‘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’.

This definition encompasses a broad spectrum of conditions that are operationalised into the four categories: acute and subacute functional symptoms, chronic somatisation, presenting somatisation, and illness worry, illness aggravation, and pathological illness behaviour in cases of genuine physical diseases.

The name ‘somatisation’ is used synonymously with ‘medically unexplained symptoms’, ‘functional disorder’ and ‘functional somatic symptoms’.

1.2. Prevalence of somatisation in general practice

According to a Danish National survey, 72% of the adult Danish population has experienced some kind of physical symptoms within two weeks^{31;32}. Having physical symptoms must hence be regarded as a normal phenomenon.

In US primary health care, Kroenke et al studied the aetiology of 14 common physical symptoms during a three-year period. The symptoms, classified as organic, psychological, or unknown, were observed in 38% of patients, and an organic aetiology could be demonstrated in only 16% of these cases. A probable psychological aetiology was established in 10% but in 74% of the cases aetiology remained unknown³³. Thus, a diagnosis of medically unexplained symptoms could be applied to three quarters of the patients with common physical symptoms seen in an outpatient clinic. In another study, Fink et al found that 60% of patients in Danish general practice had at least one medically unexplained symptom¹³.

Standard interviews done to detect psychiatric diagnoses reveal that 20-30% of primary care patients meet the criteria for somatoform disorders with somatisation disorder accounting for only 6%¹³. Defining somatisation according to Escobar’s abridged criteria yields a prevalence of 20% and worldwide surveys have shown that somatisation is a common problem in primary care across cultures³⁴.

GPs judge that somatisation is the reason for encounter in about 25% of all consultations, but they only agree with the psychiatric diagnoses elicited by questionnaires and interviews in 50-70% of cases^{13;35;36}. In these studies of GP diagnoses, the psychiatric interviewers did not evaluate whether diagnosed somatisation was relevant to the reason for encounter. This issue was raised by Weich et al examining a single clinic, who found that 25% of attenders were somatic presenters with an underlying psychiatric disorder. The physical symptoms could be related to a concomitant physical disease in half of these cases³⁷.

Similar levels of psychiatric diagnoses, GP diagnoses and agreement between the diagnoses have been found for mental disorders in general³⁵ and co-morbidity between somatisation and other psychiatric disorders is common^{13;38}.

Parallel to this study, another Danish study (the FIP-study) examined the prevalence of somatoform disorder in waiting room patients in general practice in Denmark (March 2000). The ICD-10 diagnosis of any somatoform disorder could be made in 36% of the patients. A different, concurrent mental disorder (frequently depression and anxiety) was ascertained in 39% of the patients with somatoform disorder³⁹.

Summary of prevalence

The prevalence of the comprehensive diagnosis 'medically unexplained physical symptoms' is high in general practice where it has been demonstrated in 60-75% of selected patients.

Somatoform disorders and presenting somatisation lie at the root of 15-35% of GP consultations.

Uncertainty prevails as to the prevalence according to Lipowski's definition and to the reason for encounter.

GPs indicate somatisation as the reason for encounter in about 25% of consultations.

1.3. The natural course of somatisation

In the diagnosis of somatisation disorder lies the assumption that somatisation is a chronic lifelong disorder. In general practice, however, patients often visit with acute symptoms, which may resolve quickly. We deal with different forms of somatisation and as stated by Taylor et al in 1999:

*'The relationship between the acute and chronic forms of somatisation is not clear and little is known about the natural course of somatisation'*⁴⁰

In 1993 Craig et al compared the longitudinal course of 'mood disorders with somatic presentation' with 'physical diseases with an organic explanation'. During a follow-up period of two years they found that 1) physical symptoms improved less in the group of somatisers, 2) somatisers were more likely to develop new physical symptoms, and 3) changes in physical symptoms were accompanied by synchronous changes in mood. A third of the somatisers still had physical complaints after two years and were considered chronic patients⁴¹.

Other studies with follow-up periods of one to five years have shown somatisation to persist in about 50% of cases depending on definitions and chronicity⁴²⁻⁴⁴.

A frequent and important question is, how often physical disease is missed when somatisation is diagnosed. A few follow-up studies have examined organic disease in patients with medically unexplained physical symptoms in specialised care. Only 2-5% of patients turned out to have an organic disease explaining their original symptoms over a follow-up period of 4-6 years^{45;46}.

Summary of natural course

Little is known about the natural course of somatisation diagnosed in primary health care. Somatisation is not necessarily a lifelong disorder, but a group of patients develop a chronic course (estimated to 30-50%).

Missed physical disease is rare and has only been documented in 2-5% of patients in specialised care.

1.4. Problems arising from present care-giving and viewed from different perspectives

Patients seek medical care either because they do not know what is wrong or, if they do, because they feel incapable of helping themselves⁵. In the case of somatisation, problems may arise at the moment when biomedical diagnostics and treatment are initiated without recognition of the underlying condition. This way of handling somatisation not only results in problems for the patient, but also affects professionals in the health care system and the system itself.

1.4.1. The patient perspective

Misclassification or non-recognition is frequent in primary care resulting in biomedical treatment attempts^{13;35}. This may entail endless unnecessary tests, medications, hospitalisations and surgeries exposing somatising patients to iatrogenic harm and withholding them from treatment of the underlying illness⁴⁷⁻⁴⁹. Such a course may also contribute to an iatrogenic somatic fixation and the development of chronic illness behaviour⁷.

‘...physicians tend to repeatedly pursue organic possibilities through multiple tests, procedures, medications, and operations. In patients with somatisation disorder, the dollar costs of this strategy are only exceeded by its potential for iatrogenic harm’ (Quill, 1985)⁵⁰

Chronic somatising patients have poorer physical function, poorer mental health, and poorer health perceptions compared with chronically ill patients with physical disorders and compared with the general population⁵¹. Significant health problems and disability is also found in more broadly defined groups of somatising patients^{12;34}.

Furthermore, somatising patients often feel rejected by doctors, when the biomedical solutions come to an end. They receive information running counter to their own thinking and experience and accordingly feel that the reality of their symptoms is being rejected⁵².

1.4.2. The doctor perspective

GPs may feel that they are supposed to accommodate all problems, social, psychological, as well as spiritual, although their biomedically focused training is not properly geared to tackle these domains⁵³. The feeling provoked in some doctors is elegantly captured in the frequently used term ‘Heart sink patients’.

In the absence of physical pathology, the doctor may no longer be the expert on the patients’ illness. The patients may use their authority to influence doctors and determine the outcome of the consultation. Patients may unconsciously organize complaints around a biomedical model pushing the GP to follow this model, and they may use psychosocial issues to displace responsibility and secure physical interventions^{54;55}. Such shifts in power balance influence

the doctor-patient relationship and may cause doctors to become frustrated⁵⁶ [see also Chapter 3, Sections 2 and 4].

The size of the problem has been quantified by asking GPs to rate the difficulty of patient encounters. They regarded 15% of consultations as being difficult and difficulty was highly correlated with somatisation⁵⁷.

1.4.3. The health care system perspective

The innumerable, but fruitless biomedical diagnostics and treatment attempts impose a burden upon the health care system in general. Health care charges for non-psychiatric services have repeatedly been shown to be extraordinarily high for somatising patients, especially for those with somatisation disorder^{13;51;58;59}.

Summary of problems

Somatisation poses problems at several levels.

Patients do not receive proper treatment and risk iatrogenic somatic fixation and harm.

The doctor-patient relationship is negatively affected and GPs become frustrated.

Finally, the overall health care system suffers from high expenditures on unnecessary physical investigations and treatments.

1.5. Treatment of somatisation

'Many of these problems would be avoided if physicians and patients became less concerned with cause and more with care'
(McWhinney et al, 1997)²⁹

Biomedical approaches are used intensively but they are ineffective in the treatment of somatisation⁴⁸ and other approaches are clearly required.

Not many treatments have proven effective. Specialists have pursued various psychological therapies in the treatment of somatisation and a few have demonstrated positive outcomes for up to five years⁶⁰⁻⁶². Among these therapies, psychodynamic/interpersonal psychotherapy⁶³ and cognitive behavioural therapy^{61;64;65} have performed well. However, specialist treatment of somatisation is seldom available in general practice and would only be able to serve a minority of somatising patients encountered in this setting. Furthermore, somatising patients do not readily accept referral to psychological treatments.

GPs must be capable of assessing and treating most somatising patient within primary care and also express a wish to do so^{66;67}. The extensive nature of current training programmes in cognitive behavioural therapy makes them unattractive to the majority of GPs, and there is a need for less complicated programmes in diagnosing and treating somatisation.

A recent review of treatments for somatisation in general practice described ten randomised trials performed so far. Studies were divided between psychiatric consultation letters (four), pharmacological trials (two), and cognitive behavioural therapy trials applied by non-GPs in general practice (four)⁶⁸. Psychiatric consultation letters and liaison approaches have demonstrated a positive effect on patient health and health care utilisation during one to two years of follow-up^{69;70}. However, these approaches imply involvement of specialists assisting with patient assessment and providing treatment recommendations for GPs. The pharmacological trials suffered from few participants and short follow-up periods and showed only modest effects. Cognitive behavioural therapy was effective regarding patient health and

health care utilisation, but was performed by specially trained personnel, mostly psychiatrists, working in the primary care setting.

To improve the treatment of somatising patients undertaken by GPs, 'The Reattribution Model' was developed in the UK in 1989 by Goldberg and Gask. This model took 'Problem based interviewing' as its starting point. Problem based interviewing was empirically based, patient centred, time limited and pragmatic, which facilitated implementation in general practice⁷¹. GPs were taught in small groups and were able to acquire skills important for recognition of psychological problems⁷²⁻⁷⁴. Skills were related to interviewing techniques that allowed patients to elicit emotional signs. Previous studies had shown these techniques to be important for recognition of psychological distress^{72:75:76}, and a later randomised controlled study by Roter et al demonstrated a reduction in patients' emotional distress when doctors were trained in problem-defining or emotion-handling skills⁷⁷.

An important feature of the Reattribution Model was the incorporation of group training with video feedback and micro skills training to facilitate learning of new techniques. This kind of training had previously been shown to be effective in learning processes^{74:78}. It was also important that the programme was brief (8 hours in total) as GPs' time resources are limited. The programme adopted a cognitively oriented approach but refrained from true cognitive behavioural therapy, which is difficult to teach effectively in brief interventions^{79:80}. The resulting model⁸¹ was tested in two to three month prospective before-and-after studies demonstrating that GPs acquired the necessary interviewing skills⁸², overall health care cost were reduced for somatising patients⁸³, and patients' health beliefs changed⁸⁴. Patients' mental and physical health improved, but merely for somatisers who believed that their symptoms were only partly physically caused⁸⁵. There was no effect on the overall patient satisfaction⁸⁵, but increased satisfaction was measured on 'receiving the help they wanted'⁸⁴ [Chapter 8, Table B, page 155].

In continuation of the British studies, a randomised controlled study was performed in the Netherlands testing the implementation and effect of a modified reattribution model. This study confirmed that the model could be implemented in general practice⁸⁶. It also demonstrated a marked increase in patients' health and a decrease in health care visits during a two-year follow-up for somatising frequent attenders whose GPs were given their diagnosis beforehand⁶⁸ [Chapter 8, Table B, page 155].

The Reattribution Model was developed to treat somatisation according to the definition of 'presenting somatisation', i.e. patients with underlying psychological distress. Furthermore, it did not pay special attention to the chronic forms of somatisation. Considering the definitions for somatisation applied in this study and in order to optimise the chances of successful treatment, changes were introduced to the model as described in the introduction of Chapter 3 [page 30].

Summary of treatment

Somatisation may be treated effectively in specialist care.

Little is known about effective treatment in primary care, but the Reattribution Model has shown promising results.

Previous studies afford us reasonable grounds to assume that a similar model could be implemented in Denmark and that it would be instrumental in improving GPs' skills concerning recognition and treatment of somatising patients.

1.6. Changing professional behaviour

Traditional professional behaviour only needs to be changed if there is a logical, evidence-based argument that alternative behaviour is preferable, and if physicians are not choosing the preferred approach when they should⁸⁷. In the case of somatisation, effective treatment in the form of cognitively oriented therapy is available, but somatising patients are rarely diagnosed and treated appropriately. Hence, there seems to be a potential for a favourable change through improved professional handling of patients in general practice, even though other factors associated with the patients and their families also may contribute to the present state. To develop this potential, we need to know how to influence the GPs' behaviour.

A change in behaviour is a complex process involving many different factors⁸⁷. Multiple strategies based on varying theories have been proposed in order to take these factors into account. A number of these approaches have been considered in an overview by Grol and are listed in Table A⁸⁸. When planning an intervention, it may be impossible to incorporate all of the listed alternatives, but it is important to consider them all to improve the chance that behavioural change will happen.

When focus is on the internal processes, previous studies have demonstrated the most effective formats to be combined interventions with interactive sessions⁸⁹⁻⁹¹. This also applies to general practice where multifaceted approaches have been superior to single strategies⁹². In learning situations GPs will often have advance experience and adult-learning principles should be considered within these formats. New knowledge communicated to general practice must be relevant to GPs and must be scientifically grounded in primary care. Passive transmission of such knowledge seldom brings about a change in professional behaviour, however; also attitude and skills must be addressed. The learners' needs and barriers must be identified and met during mutual collaboration between GPs and teachers, and new models should be tailored to the clinical context to enable implementation and integration in routine practice. Finally, the time perspective must not be underestimated. Learning and changing behaviour is complex and is a process that takes time⁹³.

Little is known about the long-term effect of education and training in interviewing skills and treatments. A lasting effect has been demonstrated in young doctors over a period of five years⁹⁴. In one study skills even improved over time⁹⁵, but another study showed a decline in patient outcomes over three years⁹⁶.

Summary of changing professional behaviour

It is necessary to induce a change in professional behaviour when a new treatment model is to be implemented in general practice.

Changing behaviour is a complex process involving numerous factors, and many different strategies may be applied when attempting to induce change. Multidimensional approaches seem to be more effective than single strategies.

Concerning the adult learning process, knowledge, attitudes and skills must be addressed in an interactive process and the learner's needs and barriers, the clinical context, and the time perspective must be taken into account.

Table A. *Approaches to changing clinical practice (Grol 1997)⁸⁸*

Approach	Theories	Focus	Interventions, strategy
Focus on internal processes			
Educational	Adult learning theories	Intrinsic motivation of professionals	<ul style="list-style-type: none"> • Bottom up, local consensus development • Small group interactive learning • Problem based learning
Epidemiological	Cognitive theories	Rational information seeking and decision making	<ul style="list-style-type: none"> • Evidence based guideline development • Disseminating research findings through courses, mailing, journals
Marketing	Health promotion, innovation and social marketing theories	Attractive product adapted to needs of target audience	<ul style="list-style-type: none"> • Needs assessment, adapting change proposals to local needs • Stepwise approach • Various channels for dissemination (mass media and personal)
Focus on external processes			
Behavioural	Learning theory	Controlling performance by external stimuli	<ul style="list-style-type: none"> • Audit and feedback • Reminder systems, monitoring • Economic incentives, sanctions
Social interaction	Social learning and innovation theories, social influence/power theories	Social influence of significant peers/role models	<ul style="list-style-type: none"> • Peer review in local networks • Outreach visits, individual instruction • Opinion leaders • Influencing key people in social networks • Patient mediated interventions
Organisational	Management theories, system theories	Creating structural and organisational conditions to improve care	<ul style="list-style-type: none"> • Re-engineering care process • Total quality management/continuous quality improvement approaches • Team building • Enhancing leadership • Changing structures, tasks
Coercive	Economic, power, and learning theories	Control and pressure, external motivation	<ul style="list-style-type: none"> • Regulations, laws • Budgeting, contracting • Licensing, accreditation • Complaints/legal procedures

1.7. Background at a glance

Many definitions of somatisation exist and the concept is somewhat confusing. In this thesis focus is on general practice, and somatisation is conceptualised according to Lipowski's definition from 1988 as '*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.*' This definition encompasses a broad spectrum of conditions, which have been operationalised into:

1. Acute and subacute functional symptoms
2. Chronic somatising conditions
3. Physical symptoms in other psychiatric disorders / presenting somatisation
4. Illness worry, illness aggravation, and pathological illness behaviour in cases of genuine physical diseases

The name 'somatisation' is used synonymously with 'medically unexplained symptoms', 'functional disorder' and 'functional somatic symptoms'.

The prevalence of the comprehensive diagnosis 'medically unexplained physical symptoms' is high in general practice where it has been demonstrated in 60-75% of selected patients. Somatoform disorders and presenting somatisation lie at the root of 15-35% of GP consultations. Uncertainty prevails as to the prevalence according to Lipowski's definition and to the reason for encounter. GPs indicate somatisation as the reason for encounter in about 25% of consultations.

Little is known about the natural course of somatisation diagnosed in primary health care. Somatisation is not necessarily a lifelong disorder, but a group of patients develop a chronic course (estimated to 30-50%). Missed physical disease is rare and has only been documented in 2-5% of patients in specialised care.

Somatisation poses problems at several levels. Patients do not receive proper treatment and risk iatrogenic somatic fixation and harm. The doctor-patient relationship is negatively affected and GPs become frustrated. Finally, the overall health care system suffers from high expenditures on unnecessary physical investigations and treatments.

Somatisation may be treated effectively in specialist care. Little is known about effective treatment in primary care, but the Reattribution Model has shown promising results. Previous studies afford us reasonable grounds to assume that a similar model could be implemented in Denmark and that it would be instrumental in improving GPs' skills concerning recognition and treatment of somatising patients.

It is necessary to induce a change in professional behaviour when a new treatment model is to be implemented in general practice. Changing behaviour is a complex process involving numerous factors, and many different strategies may be applied when attempting to induce change. Multidimensional approaches seem to be more effective than single strategies. Concerning the adult learning process, knowledge, attitudes and skills must be addressed in an interactive process and the learner's needs and barriers, the clinical context, and the time perspective must be taken into account.

1.8. Aim

This PhD study had two main objectives. One was to develop and implement an educational programme for GPs about assessment and treatment of functional disorders, the other was to evaluate the effect of this programme during routine care in general practice.

The educational programme was targeting general practice and was developed in cooperation between GPs and psychiatrists. Its aim was to improve assessment and treatment of somatising patients in a form acceptable and practicable to a broad section of GPs. Adopting a cognitively oriented approach, we based the theoretical part of the programme and the treatment model on current scientific knowledge about somatisation. Training was based on adult learning principles. The programme aimed at mediation of knowledge about somatisation, training of skills in interviewing techniques and treatment principles, and finally changing attitudes towards somatising patients. The model was designed to allow its implementation in everyday clinical practice without exceeding prevailing time and financial constraints (**Chapter 2 and 3**).

The effects of the training programme on GPs were assessed at various levels. Firstly the effects regarding different aspects of GPs' attitude towards somatisation were evaluated (**Chapter 4**). Subsequently, we evaluated the effect of training on GPs' diagnostic abilities in routine clinical practice. Diagnoses were evaluated both regarding diagnostic rates and agreement with psychometric rating scales for somatisation (**Chapter 5**). Finally, effects were assessed at patient level by the measurements of self-rated physical health, mental health and satisfaction with care (**Chapter 6**).

The primary outcomes were supplemented by measures of health care utilization, which, however, have to await further data processing and analyses before publication.

The research questions addressed in this study were:

- Can a theoretically sound educational programme on assessment and treatment of somatisation be developed for and be accepted in general practice?
- Does this training programme produce a change in GPs' attitude towards somatising patients?
- Do trained and untrained GPs differ in their patterns of diagnosis and in their diagnostic agreement with rating scales for somatisation?
- Is patient health and satisfaction with care affected by GP training?

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Chapter 2

[Models for continuing education in general practice focusing on functional disorders]

Efteruddannelsesmodeller med fokus på funktionelle lidelser i almen praksis

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Abstract

Background

The article gives an overview of programmes for continuing medical education (CME) addressing functional disorders and targeting GPs. Functional disorders are highly prevalent in general practice, but are seldom addressed specifically in professional training programmes. A number of CME activities do, however, touch on the subject and are described according to target group and theme.

Models in Denmark

Supervision groups, such as Balint and Bendix groups, are widespread. These groups often focus on psychological disorders in general, doctor-patient relationships and skills training. Supervision groups provide long-term training for general practitioners, but it has been difficult to evaluate the effect. A variety of short courses have also been offered in Denmark. General practitioners show great interest in CME activities dealing with psychiatry and communication.

International models

Especially ‘the Reattribution Model’ has shown promising effects in recent years. The model has been implemented in the UK, the Netherlands and Australia and has demonstrated effect in evaluation studies. Several other treatment models and detailed guidelines exist but only few have been evaluated. Liaison psychiatry is an alternative approach to education in primary care and has proven effective in a few studies.

A new treatment model

The development of a new Danish treatment model for functional disorders (The Extended Reattribution and Management Model) is described briefly. The model is cognitively oriented, is based on current evidence about functional disorders, on the English ‘Reattribution Model’, and on evidence about implementation strategies.

Conclusion and perspective

CME in the treatment of functional disorders has mainly been based on general knowledge about psychiatric disorders or on general communication and treatment skills. Many programmes lack scientific and theoretical knowledge about functional disorders and do not link evidence about these disorders to skills training. A new treatment model for functional disorders seeks to link theory, skills and acknowledged implementation strategies.

In general, considerable resources are spent on professional training with the intention of improving clinical practice, but the actual outcome is seldom evaluated. Improvement of clinical practice is a continuing process that requires more than dissemination of new knowledge. CME may improve by incorporating a theoretical framework and evidence for disorders, knowledge about implementation, and evaluation.

2.1. Perspektivartikel

Funktionelle lidelser kendes i alle dele af sundhedsvæsenet, men der undervises kun lidt i emnet prægraduat. Der er derfor et væsentligt behov for efteruddannelse på området. I denne artikel gives der en oversigt over efteruddannelsesmodeller anvendt i Danmark, udenlandske modeller beskrives, og en nyudviklet dansk model præsenteres.

Funktionelle lidelser benævnes også somatisering, 'de nye sygdomme' mv. Betegnelsen funktionel lidelse refererer til en rent deskriptiv definition, som er: "tilstande, hvor patienten er plaget af eller bekymret over fysiske symptomer og tilskriver disse en somatisk lidelse, men for hvilken der ikke kan påvises et adækvat organisk eller patofysiologisk grundlag". Definitionen er bred og omfatter såvel forbigående tilfælde (fx reaktion på psykosocial belastning) som langvarige lidelser (somatoform disorder if. ICD-10)¹. Lidelsen er hyppig med en prævalens alene af somatoform disorder på 20-30 % blandt 18-50-årige i almen praksis.

Trods den høje forekomst af funktionel lidelse og et stort udbud af efteruddannelsesprogrammer indgår sygdommen sjældent som selvstændigt emne i efteruddannelsen. Dette skal ses i lyset af, at lidelsen befinder sig i grænselandet mellem somatik og psykiatri. Placeringen har bevirket, at der ikke er den samme tradition for efteruddannelse i emnet, som når det gælder de 'rent' somatiske eller psykiske sygdomme. Desuden ligger ansvaret for behandling primært i almen praksis - et ungt fag, når det gælder forskning og uddannelse.

En række efteruddannelsesprogrammer berører dog emnet "funktionelle lidelser" og kan inddeles efter målgruppe og overordnet tema. Her fokuseres på programmer rettet mod almen praksis. Temaer har i denne sammenhæng været psykiske lidelser generelt og/eller læge-patient-forholdet, eller fokus har været på specifikke metoder som kommunikation, problemløsende teknik, kognitiv behandling m.fl. Fælles for programmerne er, at efteruddannelsen kun i ringe grad har bygget på videnskabelig og teoretisk viden om funktionelle lidelser. Kun få har taget højde for, at implementeringsstrategi er afgørende for ændring af klinisk praksis, og en videnskabelig evaluering er sjældent blevet gennemført.

2.2. Modeller anvendt i Danmark

Forskellige supervisionsgrupper har arbejdet med problemstillinger, der berører emnet funktionelle lidelser. *Balint* beskrev i 1950 en model, der primært arbejder ud fra psykodynamiske metoder. *Bendix* introducerede i 1977 en lignende model, der i højere grad anvender færdighedstræning. Arbejdet i supervisionsgrupperne har overvejende været metodeorienteret og med fokus på psykisk lidelse og læge-patient-forholdet. Grupperne eksisterer typisk i en årrække, hvorved deltagerne bliver aktive i en længerevarende efteruddannelsesproces. Effekten af deltagelse har været vanskelig at måle.

Som alternativ og supplement til supervisionsgrupper har Lægeforeningen udbudt korte kurser, der omhandler terapeutiske metoder i relation til funktionelle lidelser, psykiske lidelser generelt og beslægtede emner.

Modellerne har forskellige indfaldsvinkler, men inddrager ikke et teoretisk grundlag for funktionelle lidelser. Fokus er ofte sat på kommunikation, som uomtvisteligt er et vigtigt element. Hvad man imidlertid har været mindre opmærksom på er at koble viden om kommunikation til viden om den lidelse, man beskæftiger sig med.

Praktiserende læger efteruddanner sig i stort omfang i kommunikation og psykiatri, og mange har deltaget i en supervisionsgruppe². Det er altså ikke interesse og engagement, der mangler. Med kvantitative evalueringsmetoder har det imidlertid ikke været muligt at vise nogen afgørende effekt af aktiviteten. Det betyder ikke, at efteruddannelse ikke har nogen effekt, men vores viden på området og vores evalueringsmetoder er mangelfulde.

Efteruddannelsesmodeller i Danmark med relation til emnet funktionelle lidelser i almen praksis

Modeller med fokus på funktionel lidelse

- TERM-modellen
- Lægeforeningens korte kurser om psykosomatik

Modeller med fokus på psykisk lidelse generelt og læge-patient-forholdet

- Bendix-grupper
- Balint-grupper
- Korte terapikurser vedrørende psykiske lidelser - herunder kognitiv terapi

Modeller med fokus på læge-patient-forholdet og metodefærdigheder

- Den motiverende samtale
- Konsultationsprocessen
- Kommunikationskurser

2.3. Udenlandske modeller

I udlandet markerer især *Gask & Goldberg* sig med The Reattribution Model (*reattribute* betyder "at tillægge en ny egenskab"). Modellen anvendes i England, Holland og Australien og bygger på mange års forskning og samarbejde mellem psykiatere og almenmedicinere. Udgangspunktet har været analyser af psykiske lidelser i almen praksis, betydningen af lægens kommunikation og implementeringsstrategier (fx effekt af videosupervision). Også samarbejdet med en canadisk psykiater (*Lesser*) om smågruppebaseret træning af praktiserende læger i problemløsende teknikker har inspireret til udformning af modellen. Modellen har udviklet sig trin for trin til en egentlig behandlingsmodel for somatisering. I udviklingsforløbet er programmet blevet videnskabeligt evalueret, og man har i followupstudier fundet effekt på flere niveauer (**Tabel 1**)³. Der har også kunnet vises effekt i et randomiseret studie af en modificeret udgave af modellen i Holland⁴. En ny model med flere lighedspunkter er blevet udviklet i Tyskland og testes i øjeblikket.

I litteraturen er det vanskeligt at finde andre efteruddannelsesmodeller med fokus på funktionelle lidelser i almen praksis. Der findes enkelte detaljerede og velbeskrevne

anbefalinger. De er ikke evaluerede^{5;6}, men bygger delvist på den viden, der foreligger fra videnskabelige studier. Det samme gælder en række nationale retningslinjer for behandling af funktionelle lidelser og efteruddannelse heri.

En anden form for efteruddannelse finder sted inden for liaisonpsykiatrien. Her forestår specialister (ofte psykiatere) i samarbejde med praktiserende læger behandling af funktionelle lidelser, hvilket kan have en uddannelseseffekt på lægerne. Forskellige modeller er beskrevet, men kun få er videnskabeligt testede⁷.

Endelig findes ligesom i Danmark en række programmer, der er rettet mod almen praksis, og som fokuserer bredt på psykiske lidelser.

2.4. Implementering af ny viden

Forskellige strategier kan anvendes ved efteruddannelse af læger, men ikke alle er lige effektive, når det gælder ændring af klinisk praksis. Studier fra almen praksis og fra lægers efteruddannelse generelt har vist, at en flerdimensional tilgang virker bedre end anvendelse af en enkelt strategi, og at passiv modtagelse af information ikke giver anledning til adfærdsændring⁸.

En oversigtsartikel om efteruddannelse af praktiserende læger i psykiatri viser samstemmende med den øvrige litteratur, at man skal være opmærksom på flere forhold ved udvikling af efteruddannelsesprogrammer: Individets (her den praktiserende læges) barrierer og behov må identificeres og imødekommes, modeller skal tilpasses den kliniske kontekst, og tidsperspektivet bør ikke undervurderes⁹.

Læring er en kompleks proces, som sker gennem en serie af påvirkninger, der indvirker på viden, holdninger og færdigheder. En proces, som bør vægtes lige så højt som det faglige indhold af et program.

2.5. Et nyt dansk initiativ - TERM-modellen

På basis af foreliggende viden og evidens er en ny behandlingsmodel for patienter med funktionel lidelse blevet udviklet. Modellen hedder The Extended Reattribution and Management Model (TERM-modellen) og er lavet i et tæt samarbejde mellem psykiatere og almenmedicinere¹⁰. Eksisterende viden om funktionelle lidelser udgør det teoretiske fundament for modellen. Den er udviklet på baggrund af videnskabelige resultater af forskellige behandlingsforsøg, hvor The Reattribution Model og anbefalinger for håndtering af kroniske tilfælde har været centrale^{3;6;7}. Endelig er generel viden om kommunikationsfærdigheder inddraget og integreret i modellen. Modellen er kognitivt orienteret og indeholder elementerne viden, holdningsbearbejdelse og færdigheder i diagnostik, behandling og håndtering af funktionelle lidelser. I løbet af udviklingsprocessen er modellen blevet indbygget i et efteruddannelsesprogram, der bygger på viden om implementeringsstrategier. I programmet indgår bl.a. færdighedstræning, videosupervision, diskussionsmøder og personlige efteruddannelsesbesøg. Med denne programudvikling har vi forsøgt at skabe et efteruddannelses tilbud, som indeholder et underbygget behandlingsprogram for funktionelle lidelser og samtidig optimerer mulighederne for, at deltagerne udmønter det lærte i adfærdsændringer. For at undersøge det endelige udbytte af efteruddannelsen med hensyn til effekt på patienter, sundhedsøkonomi og læger, har 80 praktiserende læger i Århus og Vejle Amter deltaget i en randomiseret afprøvning, hvis første resultater vil foreligge i år.

Tabel 1. *Udenlandske efteruddannelsesmodeller for almen praksis med fokus på funktionelle lidelser*

Model	Studie	Effekt	
<i>Model indbygget i et formaliseret efteruddannelsesprogram</i>			
Goldberg & Gask ³ : The Reattribution Model (England, 1985 - 2000)	Followupstudie med anvendelse af: Patientspørgeskema, patientinterview og lægejournaler	Patient: Læge: Sundhedsøkonomi:	bedre almen funktion og psykisk helbred i subgruppe bedre interviewfærdigheder lavere omkostninger
Blankenstein ⁴ : The Reattribution Model - modifieret (Holland, 2000)	Randomiseret, kontrolleret studie med anvendelse af patientspørgeskema	Patient: Sundhedsøkonomi:	bedre subjektivt helbred lavere forbrug af sundhedsydelser færre sygedage Uændret medicinforbrug
Fritzche: 3-trins behandlingsmodel (Tyskland, 2000)	Randomiseret, kontrolleret studie	Under afprøvning med evaluering på læger og patienter	
<i>Udførligt beskrevne anbefalinger</i>			
Servan-Schreiber ⁵ : Diagnostik og principper for management (USA, 2000)		Der foreligger ingen evaluering	
Bass ⁶ : Management af kronisk somatisering (England, 1993)		Der foreligger ingen evaluering	
Smith: Diagnostik, behandling og management (USA, 1985)		Der foreligger ingen evaluering	
<i>Liaisonmodeller - behandling udført i samarbejde med specialister</i>			
Smith ⁷ : Psykiaters anbefalinger tilsendt 'egen læge' (USA, 1986 - 1995)	Randomiseret kontrolleret studie med anvendelse af patientspørgeskema og registerdata	Patient: Sundhedsøkonomi:	forbedret fysisk funktion øvrige helbred uændret lavere omkostninger
Katon: Én fælles konsultation (praktiserende læge, psykiater og patient) (USA, 1992)	Followupstudie og randomiseret, kontrolleret studie med anvendelse af patientinterview, lægespørgeskema og registerdata	Patient: Læge: Sundhedsøkonomi:	bedre medicinkomplians Ingen ændring i helbred stigning i ordination af antidepressiv medicin uændret forbrug af sundhedsydelser i øvrigt

2.6. Perspektiv

Efteruddannelse vedrørende funktionelle lidelser har hovedsageligt baseret sig på generel viden om psykiske lidelser eller på kommunikations- og terapimetoder. Men vi bør vide mere om det, vi bruger metoderne til: at diagnosticere og behandle teoretisk og empirisk velbeskrevne sygdomme. Ofte overlades det til den enkelte læge selv at sammenstykke en behandlingsmodel, fordi forbindelsen fra de generelle færdigheder til det teoretiske grundlag for lidelsen mangler. Det er nu gennem årtiers forskning lykkedes at forbinde teori, metoder og implementering i en specifik behandlingsmodel for funktionelle lidelser. En tilgang, der med fordel kan anvendes i den videre udvikling af modeller for diagnostik og behandling af disse og evt. andre lidelser.

Generelt må man sige, at der er meget fokus på lægers efteruddannelse, og ressourcerne, der anvendes herpå, er store. Målet er at forbedre klinisk praksis, men en undersøgelse af effekt gennemføres sjældent. At forbedre klinisk praksis er en vedvarende proces, der stiller krav til efteruddannelsesstilbud om ikke blot at formidle ny konkret viden, men også at inddrage teoretiske referencerammer, viden om implementering og videnskabelig evaluering. Kun derved sikres et reelt udbytte af efteruddannelsen for både patient og læge.

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Kvalitetsudviklingsudvalget for almen praksis i Århus Amt, Vejle Amts Lægevidenskabelige Forskningsfond (20-99), Fonden vedr. finansiering af forskning i almen praksis og sundhedsvæsenet i øvrigt (FF-2-01-314), PLU-fonden, Sygesikringen i Vejle Amt, Sara Krabbes legat og Else Nicolajsens legat.

Litteratur

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Chapter 3

Assessment and Treatment of Functional Disorders in General Practice: The Extended Reattribution and Management Model

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Translation: M.L. Pold

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3.1. Introduction

Physical symptoms with no organic basis should generally be regarded as a mechanism that allows humans to respond to stressors in the same way that anxiety and depression may reflect distress. Treatment of patients who present with such symptoms is often difficult, and some patients have even been conceived to be “troublesome.” As a physician, one evidently wants this group of patients to share the treatment options and quality of care offered to patients without such symptoms. The objective of The Extended Reattribution and Management (TERM) model presented here is to assist the process of improving our treatment options for this group of patients and prevent inappropriate illness behavior.

The Research Unit for Functional Disorders, Psychosomatics and C-L Psychiatry, Aarhus University Hospital, Denmark, has developed an advanced educational program for assessment and treatment of functional disorders in general practice in cooperation with the Research Unit for General Practice, Aarhus University, Denmark. Associate Professor L. Gask, of Manchester University, United Kingdom, has provided important advice in the process of developing the program.

The program consists of this manual and an intensive course that joins the various elements in hands-on training. Course participants also receive separate training materials (see below).

The primary target group is physicians in primary care or general practice, but the program could probably also find good use in other areas. Hence, it has been recently used for physicians in social medicine. Furthermore, the training techniques can be used both in the everyday clinical practice and in the treatment of psychiatric disorders other than somatization.

The project is developed in connection with the Prevention of Functional Disorders and Abnormal Illness Behavior in General Practice study^a, which is an interdisciplinary cooperative effort that includes the participation of The Research Unit for Functional Disorders, Psychosomatics and C-L Psychiatry, Aarhus University Hospital; and The Research Unit for General Practice, The Department of Ethnography and Social Anthropology, and The Department of Psychology, University of Aarhus, Denmark. The program was developed in close cooperation with a second study, Somatising Patients in General Practice^b, which originates from the Committee for Quality Improvement in General Practice in Vejle County and The Research Unit and Department for General Practice, University of Aarhus, Denmark.

We wish to express our gratitude to the professor in primary care, Frede Olesen; primary care physicians, Hans Kallerup, Jette Schjødt, Sven Ingerslev, Mogens Tuborgh, Annette Vibæk Lund, Marthin Holm, Kaj Sparle Christensen, and Jette Møller Nielsen; associate professor Laurits Ovesen (deceased); psychiatrists Emma Rehfeldt and Lene Søndergaard Nielsen; and psychologist Lisbeth Frostholt for reading, commenting, and actively participating in TERM model development, as well as Ph.D. of psychology Lisbeth Bindslev and senior lecturer Morten Pilegård for linguistic revision of the text.

The educational program is based on the Reattribution Model, developed by David Goldberg and L. Gask in Manchester during the early 1980s and later extended by L. Gask. The model has been tested in different studies¹⁻¹¹, which have indicated that it may be instrumental in improving physicians’ communication skills and reducing the use of health

^aThe FIP study is financed through a governmental research council program set up to enhance interdisciplinary research: Sundhedsfremme og forebyggelsesforskning, which is a program under Tværrådsligt program for Sundhedsforskning (grant number 9801278) and the Quality Improvement Committee for General Practice in Aarhus County.

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care services. We have changed and modified the Reattribution Model somewhat, and we have also added new elements. The name has therefore been changed to TERM model. The most significant modifications are as follows:

1. A general interview technique has been incorporated into the model.
2. A clearer discrimination is made between the different principles. For example, we emphasize only the use of active listening and assessment during the first phase. Many physicians tend to be overly “efficient,” to give advice and offer explanations too quickly, which is very inappropriate when dealing with somatizing patients.
3. Questions about mental illness, functional level, and expectations of treatment, etc., have been added as independent items.
4. The biological basis of somatoform disorders is now central to the explanatory model.
5. We have added a guide for follow-up treatment.
6. We have added a guide for treatment or management of subacute and chronic somatizing patients.
7. The project and the educational program are described in detail for documentation purposes.

This educational program focuses on diagnosing and treating patients with functional disorders. However, quite a few of the methods taught are general and may be used to good effect in other mental disorders and in everyday clinical practice. Several comprehensive programs have been developed for the treatment of depression in primary care¹² and of alcohol and substance abuse¹³. The section below describes the aim and structure of the course. If you read the material as part of course participation, you may omit these sections and continue reading from Section 1.

3.1.1. Aim

The project’s main aim is to offer physicians in general practice an advanced course in the diagnosis and treatment of somatizing patients in a form acceptable and practicable to a broad section of primary care physicians. The course will cater for the training needs of those physicians who are least experienced in these fields in particular, but all participants will be able to profit from the training, irrespective of their qualifications.

The practical limits were discussed and defined when developing the course. First, most physicians were assumed not to be able to spend more than 2 days for a residential course and three–four evening sessions during a month. Second, we presumed that the physicians would be compensated for the loss of earnings due to course participation. Finally, the model was designed to allow its implementation in everyday clinical practice without exceeding prevailing time and financial constraints.

However, it is hardly realistic within this framework to train physicians who are not psychiatrists to master the diagnosis and treatment of all aspects of functional disorders; therefore, we decided to focus the training on special themes and not to use techniques that involve the use of schedules, diaries, etc. Diagnosis and treatment of depression and anxiety disorders are briefly described. In other words, we decided to develop what we believe is a complete program for the treatment of somatizing patients in general practice. It is not the intention that all participants master all the elements of the model; it will be satisfactory if they learn to master parts of the program. We hope that this will inspire the participating physicians to keep working with the program and that some of them will become interested in continuing the process in other postgraduate courses. We also hope that the participants will appreciate the broader purpose the techniques may serve, including their potential use in the treatment of other than functional disorders, be they well-defined physical diseases or other psychiatric disorders.

The educational program has three main aims:

1. Mediation of knowledge about functional disorders—etiology, epidemiology, diagnosis, and treatment.
2. Giving physicians proficiency in (1) general interview technique and (2) specific principles for treatment of functional disorders. The main focus is on quite simple techniques, which all physicians, in principle, should be able to learn, and which most can master. Our focus is on cognitive, behavioral, and “administrative” techniques—we do not directly teach the use of traditional psychoanalytical techniques such as transference and countertransference. The techniques are mainly trained through specific microskills training.
3. Change of attitude, because psychiatric disorders and especially functional disorders are still stigmatizing conditions. Some patients with functional disorders are severely disabled and in great emotional pain because of their illness. This involves great costs for society, not only due to increased health care costs but also through lost working years, early retirement pension, and other social expenses. Failure to diagnose and treat these conditions may have severe consequences for patients. This program seeks to initiate a change of attitude toward patients with functional disorders, to ensure that functional disorders are treated as seriously as other disorders and that the patients receive the same comprehensive treatment as other patients.

The time constraints on the course made it necessary to strike a balance between, on one hand, reducing theory to a basic but sufficient level to allow physicians to feel confident and articulate about the nature of the psychiatric conditions while treating the patients and, on the other hand, focusing on practical case-driven exercises.

3.1.2. Overall structure

The program consists of a 2-day residential course (16 hours) followed by three–four evening courses (2 hours’ duration) with an interval of about one week, one booster meeting (2 hours) after three months, and, finally, a facilitator visit to the physician’s practice (a half-hour) after six months. Instructional materials:

- The present manual describes in detail the latest research about functional disorders and the treatment model in theory and practice.
- A work folder for the participants with detailed instructions for each exercise, including concrete suggestions for the wording of questions, case notes, copies of overheads from all presentations, TERM model memory cards, advice on how to manage chronic conditions, and diagnostic guidance.
- A teacher folder with the same contents as the participant folder, overheads for each theoretical presentation, and the matching speaker’s notes as well as a guide to group supervision.
- Instruction for actors (four case stories).
- A video with examples of the different techniques produced by L. Gask.

The materials can be ordered or downloaded from homepage:
www.auh.dk/clppsyh/dk/index.htm.

Structure of the Residential Course

The residential course lasts 2 whole days. It consists of four 3-hour modules. The sequence of the modules can be seen in Figure 1. The first day starts with a general introduction and a 30-minute workshop about the participants’ own experiences and expectations.

Round of Introduction and Workshop about Personal Experience

After the general introduction, the participants gather in training groups, which are organized in advance. The groups consist of 6–10 physicians, 8 being the ideal number. Each group has two supervisors (a physician and a psychiatrist). Group participants introduce themselves, and the participants are encouraged to formulate their own needs and expectations from the course. The supervisor's main focus is to create a relaxed environment to encourage confidence and good learning skills.

Figure 1. *Educational Modules*

Introduction (20 min)	<u>Plenary:</u>	Introduction to the exercise including a short video demonstration.
Exercise 1 15 + 15 min. Video supervision 30 min.	<u>Group exercise:</u>	Training of specific skills in groups of 2 physicians. Two physicians train in a separate room by interviewing an actor. The first physician is recorded on video. Supervision of the video recording with actors in groups of 8 persons.
Break		
Exercise 2 15 + 15 min. Video supervision 30 min.	<u>Group exercise:</u>	As the above. There is a continuous rotation so that all physicians will record at least one video with an actor. Video supervision as the above.
Theory (20 min.)	<u>Plenary:</u>	Theoretical presentation about functional disorders.

Introduction to Exercises and Theoretical Presentation

The participants meet for plenary sessions in which they are introduced to the exercises and theoretical presentations. The preliminary introduction is followed by a 5- to 10-minute introduction video designed to make participants feel more relaxed and comfortable. After each exercise has been introduced, participants watch a short instructive sequence from the video “The Reattribution Model” by L. Gask.

The theoretical presentations cover the following subjects:

1. The somatization concept (definitions and clinic)
2. The patient's illness beliefs
3. Iatrogenic factors
4. Etiology and epidemiology

Each presentation comes with a set of overheads with matching speaker's notes and precise instructions about what information goes with each overhead and notes referring to relevant

pages in the TERM folder as well as relevant articles. The teachers are encouraged to use their own words, to facilitate discussions, and to welcome comments from the audience.

Hands-on Exercise

Prior to the first exercise, the participants receive careful instruction, both verbally and in writing, about the principles of the exercises and rules for feedback. Seven minutes are allotted for the interview and 5 minutes for feedback for each of the four exercises in each module. Two participants are selected to take turns in interviewing an actor in a separate video room. The physician who is not conducting the interview will act as an observer. Only the first interview is recorded on video. The actor is instructed in advance and has received the patient presentation with which the other participants are working. If the participants are divided into more than one group, the actors will alternate between the groups for each exercise.

The other participants work in pairs, taking turns in being “doctor” and “patient.” After each module, the participants pair up with new partners.

A written exercise instruction is handed out. The “doctor’s” instructions contain an outline of the items to be given special attention and some suggestions for the wording of questions and answers. The “patient” receives a case story and instruction on how he or she should react in specific situations. The roles are reversed after 15 minutes and a new case story is handed out, although the “doctor’s” instructions remain the same. Four case stories are used and extended as the exercises progress.

The supervisor is available during the exercises, and he or she may intervene to give advice. The groups are encouraged also to take time out when something is difficult. The time out may allow the “doctor” to discuss alternative approaches and wordings with the “patient” and the supervisor and to test these at once.

Group Supervision

A period of 30 minutes is allotted for supervision of each video in groups of eight participants. Group supervision is performed according to a set of rules designed to guide supervisors through the process. The exercise is based on the training of micro skills or training of special skills and adopts a mainly cognitive approach that focuses on concrete wording.

Evening Meetings

The supervision groups formed during the residential course meet again for weekly evening meetings three–four times. For each meeting, the participants will bring a video recording of a consultation with one of their own patients. It is possible to supervise two recordings at each meeting, which allows each physician to have at least one recording/consultation subjected to joint supervision. The physicians are encouraged to focus on a specific TERM model theme.

Booster Meeting

The booster meeting, held 6 weeks after the last evening meeting, allows the group and the supervisors to discuss their clinical experience with the TERM-model use.

Facilitation

After 6 months the participating physicians receive a visit in their practice. The person who visits them is a colleague (facilitator), who has been introduced to the educational program but has not necessarily been a teacher. The visit takes about a half-hour and is designed in particular to assess with the physician the incentives, barriers, strengths, weaknesses, opportunities, and threats in connection with daily clinical TERM model use. Three months

later, the physicians receive a letter describing the collective experience gained from the facilitator's practice visits.

3.1.3. Training of supervisors

The project saw the formation of a team of teachers that consisted of six physicians and four psychiatrists. The physicians all had previous experience from teaching and supervision of colleagues. It was found inexpedient to use psychologists as teachers, because the target group was physicians and the subject demanded both general medical knowledge and knowledge of everyday clinical practice.

Three of four psychiatrists had received formalized psychoanalytic psychotherapeutic training, and all had extensive experience or had received formalized training in group therapy. Two of the psychiatrists had received cognitive therapeutic training.

The supervisors were trained at a 3-day workshop, during which all elements of the program were presented and trained. This allowed us to change some of the elements and to add or leave out minor themes during the practical testing. On the first day, L. Gask conducted training in the supervision of groups based on experience derived from training English physicians in the Reattribution Model.

The teacher group had primarily received analytically oriented psychotherapeutic training, and the focus was therefore primarily on the cognitive elements and practical aspects of the training on the basis of the rehearsal of microskills. In the supervision of the physicians, emphasis was given to avoiding some of the central themes in psychoanalytic theory, namely transference and countertransference, and to showing utmost caution when addressing the physician's own emotions toward patients. Furthermore, it was emphasized that the program primarily focuses on the cognitions of the patient and only secondarily on the patient's emotionality. Emphasis was given to this particular aspect to facilitate physician learning by relying on the classical skills training paradigm, avoiding the reluctance and anxiety that could otherwise result among participants who were not inclined or motivated toward analytical approaches.

3.1.4. The Danish Health Care System

The Danish Health Care System is almost entirely financed via taxes, and all medical treatment, including psychiatric treatment, is free of charge. All Danish inhabitants are covered by public health care and can choose to belong either to Group I or II. Everybody who belongs to Group I is part of a general practitioner listing system. People who belong to this group are registered with one general practitioner and cannot freely seek another. If it becomes necessary to receive specialized treatment, including admission to a hospital, the patient must usually obtain a referral from the general practitioner or the on-call physician. However, this rule does not apply to emergency situations and when patients wish to seek treatment by a general eye or ear, nose, and throat specialist. Physicians on an alternating schedule (on-call doctors) handle off-hours visitation and treatment. All medical treatment is free for persons who belong to Group I. People who belong to Group II are not registered with one physician and can freely choose among physicians. They can also receive treatment from specialists without a referral. However, they have to pay part of the costs of the consultation themselves; 98% of the population belongs to Group I. All patients must pay some of the costs of the medicine they may need, and they must also pay part of the costs for examination and treatment by dentists, chiropractors, physiotherapists, psychologists, etc.

Physicians are paid by the public health care service. They receive a fixed yearly amount for every person listed with their practice and an amount for every consultation and the associated services.

3.1.5. Testing the Program

The effect of TERM model training of physicians is being tested in two randomized controlled studies that include 80 physicians and approximately 4,000 patients from Aarhus and Vejle County. The patients and physicians will be followed for 1–2 years to evaluate the effect of the intervention on the patients' health and use of health care. The results are not yet available, but the participating physicians were very positive when evaluating the course both immediately after the course and during the practice visits 6 months later.

3.2. Section 1: Background and Etiology

3.2.1. Background

Epidemiology and Presentation of the Problem

Studies that have used standardized psychiatric interviews have shown that at least 20%-30% of consecutive patients who consult their family physician suffer from a psychiatric disorder¹⁴⁻¹⁶. Furthermore, psychosocial factors are often more important for the course of a given physical disease and the use of health care than the severity of the disease itself when judged by biomedical data¹⁷⁻²⁴, and the physician only diagnosed a psychiatric disorder in about half the cases^{24;25}.

The most frequent mental disturbances in general practice are somatoform disorders, depression and anxiety^{14-16;19;24-27}. These disorders have a significant comorbidity. Thus, approximately 50% of all patients who have a somatoform disorder (according to ICD-10 criteria) also have another mental disorder, usually depression and/or anxiety²⁸.

The essential characteristics presented in somatizing conditions are functional symptoms, that is physical symptoms that may indicate a physical disease but for which there are no adequate organ-pathology or pathophysiological explanation²⁸.

Objectives of the TERM-Model

The overall objectives of this postgraduate training program are:

1. To give physicians a better understanding of the characteristics of somatoform and functional disorders
2. To improve physicians' capability of diagnosing somatoform and functional disorders
3. To improve through practical training physicians' capability of:
 - treating less severe cases of somatoform disorders and functional symptoms
 - managing chronic cases of somatoform and functional disorders
4. To improve physicians' coping strategies and reduce the burden associated with caring for this group of patients

About one-fourth of all patients seeking treatment in primary care are reported to suffer from a somatoform disorder according to the ICD-10 criteria, and many more seek treatment for medically unexplained physical symptoms¹⁹. In a United States study of the 25 most prevalent physical symptoms among patients who sought treatment in an internal medical outpatient clinic, less than 10%-15% of the cases presented with symptoms that could be attributed to a genuine physical disorder²⁹. It would hence seem to be the exception rather than the rule in primary care for physical symptoms to be caused by organ pathology or pathophysiological disturbances.

According to general population studies, most people experience physical sensations and symptoms every day. Physical sensations are therefore to be regarded as normal phenomena³⁰.

Patients with somatoform disorders have an excessive use of health care services both in primary care and in the specialized health care sector³¹. Chronically somatizing patients will, over time, often have gone through numerous hospitalizations, operations, and futile treatments with the impending risk of being exposed to iatrogenic harm. Somatoform disorders are thus very costly not only to society, but also to the patients because of the suffering inflicted on them.

Classification of Patients Who Present with Functional Symptoms

Below, physical symptoms without organic basis will be referred to as *medically unexplained or functional symptoms*. These terms are used synonymously with somatization.

Definition of somatizing conditions and functional disorders

Conditions where the patient complains of physical symptoms that cause excessive worry or discomfort or lead the patient to seek treatment but for which no adequate organ pathology or pathophysiological basis can be found.

The term is thus only used descriptively without inferring a causal relationship. Somatization is to be regarded as a continuum that ranges from mild conditions that are difficult to discern to serious conditions that cause the patient to suffer and make him or her seriously ill.

The Canadian psychiatrist McDaniel has suggested a broader and more apt definition of the overall somatization concept, "[a] process whereby a physician and/or a patient or family focuses exclusively and inappropriately on the somatic aspects of a complex problem"³².

Somatoform disorders form the main class of psychiatric disorders of the ICD-10 and DSM-IV and they include most somatizing conditions. Somatoform disorders are usually subdivided into somatization disorder, hypochondriasis, somatoform autonomic dysfunction, and somatoform pain disorder, etc. Other somatizing conditions are found among the group of dissociative disorders, neurasthenia, elaboration of physical symptoms, and factitious disorder including Münchhausens' syndrome. According to the ICD-10 criteria, a somatoform diagnosis requires an illness period of at least 6 months, which makes the classification less useful in primary care.

A more simple classification more suitable for primary care is found in Table 1.

Table 1. Classification of patients presenting with functional symptoms

1. Acute and sub-acute functional symptoms
2. Chronic somatizing conditions
 - a. Chronic somatizing (multisymptomatic / oligosymptomatic) conditions.
 - b. Syndrome diagnosis (fibromyalgia, chronic fatigue syndrome, etc.)
3. Physical symptoms in other psychiatric disorders (facultative somatizing as, e.g., in anxiety and depressions)
4. Illness worry, illness aggravation, and pathological illness behavior in cases of genuine physical diseases

Acute functional symptoms are medically unexplained transient symptoms, and the patients are easy to reassure. Such reactions are frequent in strain and stress.

Sub-acute functional symptoms include conditions where symptoms have been present for less than 6 months but where it is difficult to reassure the patients or they can only be temporarily reassured. This program is designed such that patients who seek treatment more

than once because of functional symptoms (lasting less than 6 months duration) will be classified as having subacute symptoms.

For a *somatizing condition* to be classified as chronic, the patients must have complained of medically unexplained symptoms for at least 6 months. The condition may be further subdivided according to whether the patient presents with multiple symptoms – most often from numerous bodily systems (*multisymptomatic*) – and patients with only few symptoms or with a symptom picture focused on a single organ system or symptom pattern (*oligosymptomatic*). A multisymptomatic illness picture should, however, be observed over a certain period of time, because the patient may focus his or her complaints first on one symptom pattern (e.g., “gastrointestinal disorder”) and then later shift his or her focus to another pattern of symptoms (e.g., “cardiopulmonary disorder”), which at the time of the examination may present as oligosymptomatic.

The group of chronic somatizing conditions also includes the diagnoses of complex syndromes such as fibromyalgia and chronic fatigue syndrome. The nosologic status of these syndromes has not been settled yet, because some physicians hold the opinion that a specific organic basis of the symptoms has still to be found. However, existing scientific evidence strongly suggests that these syndromes are artificially created and the majority of the patients have to be regarded as chronically somatizing.

Table 2. Symptoms of a depression³³⁻³⁵

Physical symptoms	Emotional symptoms
Fatigue	Melancholic/depressed mood
Pain	Loss of interest and the capacity to be pleased
Insomnia and early awakening	Reduced self-esteem, feelings of guilt
Dryness of the mouth plus other autonomous symptoms	Irritability, feelings of inner uneasiness
Changing appetite and weight	Concentration problems
Motoric restlessness	Thoughts of death and suicide
Slowed movements and stiffness	Pessimism, tendency of isolation
	Latency period, slowed reaction
	Reduced libido

Physical symptoms related to other mental disorders (also called facultative or presenting somatization): In most mental disorders the patients primarily present with physical rather than emotional symptoms³⁶ as seen in 50%-90% of the cases of depression. Please refer to Tables 2 and 3 for the most common physical symptoms in depression and anxiety.

The prominent physical symptoms in mental disorders make it only natural for patients to fear that they suffer from a physical disease. However, contrary to “true somatizers”, facultative or presenting somatizing patients will accept the correct diagnosis of a mental disorder as opposed to a physical disease.

Illness worry, illness aggravation, and pathological illness behavior in physical disease: This group of symptoms is poorly defined, because we still lack thorough knowledge about the interaction between illness behavior and the emotional reactions to illness. Patients in this group suffer from a verifiable physical disease. However, there is a discrepancy among the subjective difficulty, the patient’s worry, functional level, and treatment results and the severity of the disease – on the basis of biomedical data. It is often difficult to determine whether these patients are better classified as belonging to the group of somatoform disorder,

because they may have incorporated their genuine physical disease into their somatization. In this case it is not appropriate to use a rigid psychic versus nonpsychic dictum, because the problem is most often a combination of both, especially in more chronic cases of somatization.

This rough classification includes three diagnoses that do not form an independent target in this treatment program.

Hypochondriasis is frequent and is characterized by excessive and inappropriate worry and with preoccupation with the fear of having or developing a serious physical disease. Patients are usually excessively preoccupied with bodily sensations and functions. They are often influenced by information about diseases reported in, for example television or radio. The disorder has much in common with obsessive-compulsive disorder. Patients feel distressed by constant worrying but are unable to control it.

Factitious disorder: The patients feign illness or deliberately inflict a disease on themselves. In contrast to malingering, there is no apparent external incentive for producing the symptom(s) and the motive is unconscious and understandable only in a psychopathological context. Patients who have factitious disorder often have a severe personality disorder where the patient borders on psychotic breakdown.

Dissociative disorder: Patients usually present with pseudo neurological/physical symptoms, such as paralysis, blindness and confusion. The onset is sudden and closely associated in time with emotionally traumatic events, insoluble and intolerable problems or disturbed relationships. Less severe cases are probably quite common, and even mentally stable and previously healthy individuals may react with dissociative symptoms when exposed to disaster. The condition is usually transient and with sudden spontaneous remission. A precondition for making a diagnosis of dissociative disorder is the identification of a provoking psychological trauma.

Table 3. Symptoms of anxiety^{33;34;37}

Physical symptoms	Emotional symptoms
Heart pounding or accelerated pulse rate	Anxiety
Hot or cold sweats	Feeling of inner uneasiness
Trembling or shaking	Fear of dying
Dryness of the mouth	Feeling tense or on edge
Difficulty in breathing	Fear of losing control/of insanity
Feeling of choking	Excessive worry
Flushing or blushing	Concentration difficulties
Churning in stomach, "butterflies"	Feelings of unreality or depersonalization
Dizzy, light-headed, faint, unsteady	Being easily fatigued
Tingling, numbness in face or fingers	Irritability
Tightness, discomfort, or pain in chest	
Muscle tension	
Other, e.g., urinary frequency	

The Differential Diagnosis Between a Genuine Physical Disease and a Functional Disorder

Today functional disorders are, by definition, exclusion diagnoses, because the diagnostic criteria demand the symptoms to be medically unexplained. This does not imply, however, that the diagnoses rest on the exclusion of organic disease alone. Today's plethora of

diagnostic options would also simply make it less than reasonable not to give due consideration to the diagnosis of functional disorders. Different characteristics, symptoms, and features are available for diagnosing somatization, and these should be used in differential diagnosis. Please refer to Section 5.

The somatizing patient often (but not always!) presents with vague, *atypical* symptoms; that is, symptoms lying outside what is usually expected in authentic physical diseases, and they are *unspecific*, which gives the symptoms a low differential diagnostic value, because they can be encountered in many different mental and physical diseases (such as fatigue and headache). The patients therefore find it difficult to give further details about their symptoms; that is, describe their intensity, quality, chronology, etc. Patients who have a genuine physical disease do not have this problem. They are usually very precise in their description of the symptoms; for example, the pains are shooting, burning, or are like a toothache. Instead, the attention of a patient with functional disorders is directed toward the subjective suffering caused by the symptoms and the negative consequences the symptoms have on his or her life and quality of life³⁸.

3.2.2. Etiology

The etiology of functional disorders is unknown, but it is probably multifactorial. Medically unexplained physical symptoms can generally be regarded as a basic mechanism that allows some people to respond to stressors in the same way that others may respond with anxiety or depression. It appears that different unspecific predisposing factors commonly seen in different mental disorders assume importance depending on the person's general vulnerability. Examples of unspecific factors could be the loss of a close relative, loss of job or moving to a new area. Specific predisposing factors for somatoform disorders may include childhood physical or sexual abuse and parental somatization. However, neither parental nor childhood well-defined physical disease lead to somatization. The reported familiar transmission in somatization may be rooted in socio-cultural variables, but there is also some support for a genetic transmission²⁸.

Predisposing factors may include, besides patient and illness-related factors, iatrogenic factors embedded in the way physicians and the health care system manages and cares for the patients. This appears to be of great importance for the course of the disorder. Likewise, social factors, especially the family, may maintain the patient in the sick role. Finally, these are strong indications of the involvement of biological factors.

The next Section will discuss the factors that precipitate, initiate, and maintain functional disorder. These factors must be known for proper treatment to be given.

Background and etiology of functional disorder

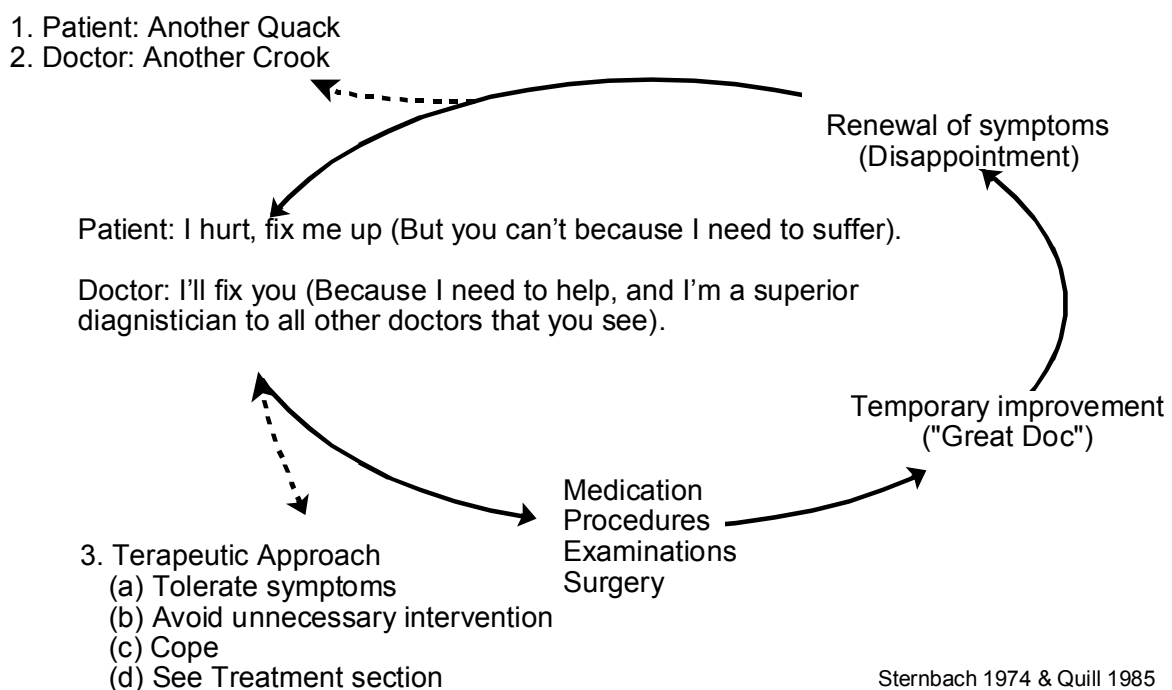
- At least 20%-30% of patients who seek treatment from their physician have a mental disorder, of which anxiety, depression and somatoform disorders are the most frequent.
- In primary care about one-fourth of the patients have a somatoform disorder. More than 50% of patients below 50 years of age present with physically unexplained symptoms, but they are often transient, such as, for example, reactions to stress.
- In primary care, persons with mental disorders usually present with physical symptoms.
- In most cases where patients present with common physical symptoms in primary care, it is not possible to find an adequate organic basis.
- There is a high level of comorbidity among somatizing, depression and anxiety disorders.
- A clear differentiation between mental and physical disorders is inappropriate, especially in chronic cases, where mental and physical symptoms often combine.
- The somatization diagnosis is based on clinical assessment, which presumes the exclusion of genuine physical disease. Important factors in the differential diagnosis are, among other things, the physician's familiarity with the patient, the course of the illness, and the presenting symptom pattern; that is, whether symptoms are vague, atypical, or unspecific. Furthermore, the somatizing patient is typically more preoccupied with the psychosocial consequences of his or her illness than with the actual symptoms.
- With repeated examinations, there is a risk of iatrogenic introduced chronicity.
- The etiology of functional disorders is not sufficiently clear. Socio-cultural, learning and biological factors seem to be important.

3.3. Section 2: The Interaction Between the Physician and the Somatizing Patient

3.3.1. The Contribution of the Health Care System (Iatrogenic Factors)

The way the physician and the health care system react, handle, and manage the patient may increase both the number and severity of the symptoms. The patient may be kept in the role of the sick and the illness may become chronic. In Figure 2 Sternbach³⁹ and Quill⁴⁰ illustrate very well this pathological cycle of examinations and interventions frequently found in somatizing patients. Figure 2 also illustrates the close, almost symbiotic interaction that may emerge between the physician and the somatizing patient.

Figure 2. Pathological intervention cycle



It is often puzzling how chronically somatizing patients can go through numerous futile hospitalizations, examinations, interventions and attempts at treatment without relief. What makes physicians continue to examine and "treat" the patient despite no evidence of an organ pathology? What makes physicians unable to stop it? Some of the reasons for this irrational pattern of reactions are stated in Table 4.

The Fear of Overlooking a Genuine Physical Disease

When physicians are asked why they continue examinations and tests for which there are no objective indications, the most frequent answer is the fear of overlooking a genuine physical disease. However, this is hardly a reasonable fear, because genuine physical disease is reported to be overlooked in less than 3%-4% of the cases^{31;41;42}. On the contrary, a physical disease is, it would seem, less often overlooked in patients who somatize, because their threshold for registering physical symptoms is lower than that of nonsomatizing patients and because they seek family physician care at an earlier stage than non-somatizing patients⁴³. If

the patients are not satisfied with their physician, they will consult the doctor on night duty or in the emergency room.

However, most physicians will probably agree that they cannot totally avoid overlooking physical diseases or making an erroneous diagnosis no matter how careful they are. Serious consequences for the patient are believed to be rare, indeed, and in most cases they amount to little more than a delay in diagnosis and, by implication, treatment.

The argument for making unnecessary examinations on a doubtful indication is often that “you can never be absolutely sure”. This is true, but it may also be the best argument for drawing the line and stopping the examinations. The wish for complete certainty is often rooted more in the physician’s need or wish not to be blamed than in consideration for the patient.

The large group of somatizing patients is paying the price for this approach in terms of undue discomfort during unnecessary examinations and an increased risk of being exposed to iatrogenic harm. Furthermore, an exaggerated examination program may keep the patient in the sick role, and he or she may develop a chronic condition if sufficient treatment is not initiated or is delayed unnecessarily. Mental disorders should be regarded with the same seriousness as physical diseases because of the associated high mortality rates and the very significant consequences for patient functioning.

It may seem paradoxical that the fear of overlooking a physical disease is much stronger in the case of functional disorders than in physical disease. The etiology of many physical diseases, for example, essential hypertension, remains unknown. Yet, even if hypertension may be multifactorial, we do not relentlessly pursue its etiology, but are satisfied that it is “essential”, provided a *reasonable* examination program has been carried out.

The Fear of Complaints and Prosecution

The fear of being scorned by colleagues or the media or of being sued by the patient for having overlooked something may also be of importance⁴⁴. In order to avoid subsequent criticism, the physician may feel compelled to perform tests and examinations that may appear superfluous from a medical point of view. In the United States defensive tests and examinations seem to be part of clinical practice, and we may fear that this approach will also gain ground in Europe. However, complaints associated with somatizing conditions remain rare in Denmark³¹.

No Other Treatment Option and Lack of Confidence in Psychiatric Treatment

Nonpsychiatric physicians may have a limited knowledge of state-of-the-art psychiatric principles and methods of treatment. They may still hold the belief that referrals to psychiatric care may imply long-term treatment during which patients do not improve significantly.

A physician with no confidence in psychiatric treatment may choose to “treat” the patients despite the lack of indication of a medical disease and to give a biomedical treatment the benefit of doubt, “because you can never be absolutely sure” that the treatment does not work. This attitude may have the effect that patients are not properly diagnosed and, hence they may be denied effective psychiatric treatment.

Unfortunately, the attitudes of the nonpsychiatric physicians are not completely unfounded. Psychiatrists may have only limited knowledge of functional disorders and their treatment. Psychiatrists tend to regard somatoform disorders as less-severe mental illnesses that demand more time and capacity than are available in psychiatric care. This view may be rooted in psychiatrists’ rather poor experience with such patients, who are primarily consulting nonpsychiatric physicians because they believe that they have a physical disease, not a mental disorder.

As a consequence of this attitude, a group of severely ill patients are denied appropriate treatment. The health care providers thus continue to leave these patients to their own devices.

Table 4. Iatrogenic factors in somatizing

- The fear of missing a physical disease is the most frequently stated reason physicians give for excessive examination of somatizing patients. An overlooked somatoform disorder may give rise to somatic overtreatment and cause the patient to suffer unduly and patient and society health care expenses to rise unnecessarily.
- The fear of complaints and prosecution may result in defensive tests and referrals.
- The lack of accessible psychiatric treatment may cause the patient to continue seeking medical treatment to no avail.
- A lack of understanding of the nature and character of mental disorders and lack of knowledge about how to manage these disorders may lead to the prompt acceptance of the patient's insistence on examinations.
- Insufficient knowledge and skills: pre- and postgraduate physicians receive very little training in how to handle somatizing patients.
- Some physicians define the physician's role exclusively in terms of catering for the patient's "biomedical problems". They do not feel prepared to deal with psychic problems.
- Physician modesty and fear of violating the patient's personal boundaries may be the reason why he or she is not asked about his or her private life and mental state.
- Time pressure and the fear of "opening Pandora's box" may be a concern among many physicians when raising the "problematic" questions. Physicians may also fear that patients will get hooked and become dependent on them.
- Physicians may feel a need to take time out from the treatment of these, at times, rather troublesome patients and therefore refer the patients to hospitals or other specialists.

Lack of Understanding of the Nature and Character of Mental Disorders

The somatizing patient often insists on further tests to rule out organ pathology. Some physicians may think that the patient is just being tested and treated at his or her own request and therefore, in other words, is assuming responsibility for the process himself or herself^{40;44}. However, this attitude expresses a lack of understanding of the nature of mental disorders. It is assumed that patients always act in their own best interest, and the existence of unconscious motives is rejected. The physician is thus reduced to an "organ mechanic" with no general concern for the well-being and interest of the patients.

Some physicians believe that humans in general act rationally, and they will examine patients with the sole purpose of convincing them that they are wrong to think that they are having a physical disease. In most cases, this will comfort psychologically healthy people, but not mentally unstable patients. On the contrary, mentally unstable patients may interpret testing and examination as indicating that there is some truth in their illness after all. The patient may even believe that the physician is hiding the truth to prevent the patient from feeling hurt⁴⁵.

Insufficient Knowledge about Handling Behavioral Dysfunctions and Mental Disorders

Physicians are primarily trained in a biomedical illness model and are often at a loss when this model turns out to be insufficient. The patient may put heavy pressure on the physician by saying things like, “I know my illness is for real and not a figment of my imagination”. The physician may be frustrated when he or she cannot cure the patient and may therefore resort to the well-known practice of testing and repeated, but futile, attempts at treatment.

The physician may fall back on attributing the patient’s complaints to random findings; for instance, back pains may be attributed to minor changes found on X rays. Such abnormal findings are frequent in symptom-free individuals, so the correlation may be highly speculative. Both physician and patient may be quite content to have found “the explanation” for the symptoms. Nevertheless, the symptoms almost always return after a short while.

Some physicians accede to the patient’s request for examinations and tests, arguing that that the patient would otherwise go to another physician. This would lead to further examinations, tests, admissions and treatment attempts before the new physician get to know the patient (see Figure 2). This pattern may repeat itself. To protect the patient from unnecessary suffering, the physician may comply with the patient’s desire for more tests. A strategy in which such tests are performed on an psychological indication may be appropriate in some cases, provided that the tests are conducted in a sober and carefully considered way and on safe indications.

The Physician’s Personality and Understanding of the Medical Profession

The universal nature of most emotional problems makes it difficult for the physician to entirely avoid personal involvement when faced with the patient’s emotional problems. Physicians may deal with their own problems in a less appropriate way and the discussion of mental issues may therefore become an unpleasant experience to the physician⁴⁶. Some physicians try to solve this problem by avoiding “subjective” patient contact and maintaining an “objective” view of the presented symptoms.

Some physicians believe that they should only examine and treat physical problems and that an organic cause of the problem should always be excluded first. They do not feel qualified to explore psychosocial problems and may believe that this type of problem has nothing to do with physical disease^{40;44}.

Physicians often join the profession with the idealistic belief that physicians should be nice, kind, knowing, selfsacrificing and caring. Physicians have an inherent urge to prove to themselves and others that they are skilled and fulfill these ideals⁴⁶. Patients may put heavy pressure on physicians by appealing to the emotional part of his or her self-conception with statements such as, “I would do anything to get well, but I can’t”, “I can’t take it anymore (so you must take over)”, “you’re the doctor”. When cornered in this way, the physician will be inclined to use the more familiar model, the biomedical one, which seems to be what the patients want.

Modesty

Some physicians may feel uncomfortable when asking about the patients’ emotional well-being, in the same way that a gynecological examination or rectoscopy may be seen as an infringement of privacy^{44;46}. In some cases, the impression is that physicians find it easier to perform the above-mentioned examinations than to ask patients about their psychosocial well-being.

To avoid offending the patients, it is important to ensure that they understand why a question is asked or an examination is performed.

Pandora's Box or the Fear of Loss of Control

Many physicians have experienced that patients, when asked about personal problems, reveal a pent-up need to discuss these problems. It may be overwhelming to physicians, who do not know how to stop or help patients cope with their apparently huge problems⁴⁷. Furthermore, physicians may fear the patient's reaction (walking out, anger, crying, etc.), and to avoid this confrontation, they may order a test "just to be certain".

The Fear of Dependency

Physicians may avoid psychosocial subjects because they fear that patients may become dependent on them and will not be able to end the relationship⁴⁴⁻⁴⁶. This should not usually be a problem if due attention is paid to the physician's as well as the patient's limits and if such limits are discussed with the patient. Raising this issue in an empathetic manner will only rarely cause the patient to feel offended. On the contrary, most patients will find it reassuring. Nevertheless, if this turns out to be a problem, it may be a good idea to discuss the case with a colleague or a psychiatrist.

Lack of Time

The physician may find that there is insufficient time to conduct a psychosocial interview and to deal with mental disturbances. This argument is based on the erroneous idea that it is more time-consuming to assess mental illness than to assess physical disease. Much may, however, be achieved in a short time if the efficiency and approach used for taking a medical history is also used in case of a mental disorder. Thus, in the long run, time can be saved if the physician conducts a careful assessment and thorough examination at the first contact, because the patient will not return with uncertainty and unanswered questions. Furthermore, studies have shown that it saves time to ask directly about mental problems and social conditions. Physicians may thereby avoid the so-called doorknob questions; for example, when the patient on the way out and with the hand on the doorknob says, as if an afterthought "by the way ..."⁴⁸.

3.3.2 The Patient's Symptom Perception and Illness Understanding

From Sensation to Symptom

People react in different ways to symptoms of illness, and they have different thresholds for seeking treatment. In other words, they differ in illness behavior. *Illness behavior determines the use of health care services, whereas the severity and character of a physical disease often is of lesser importance*¹⁸.

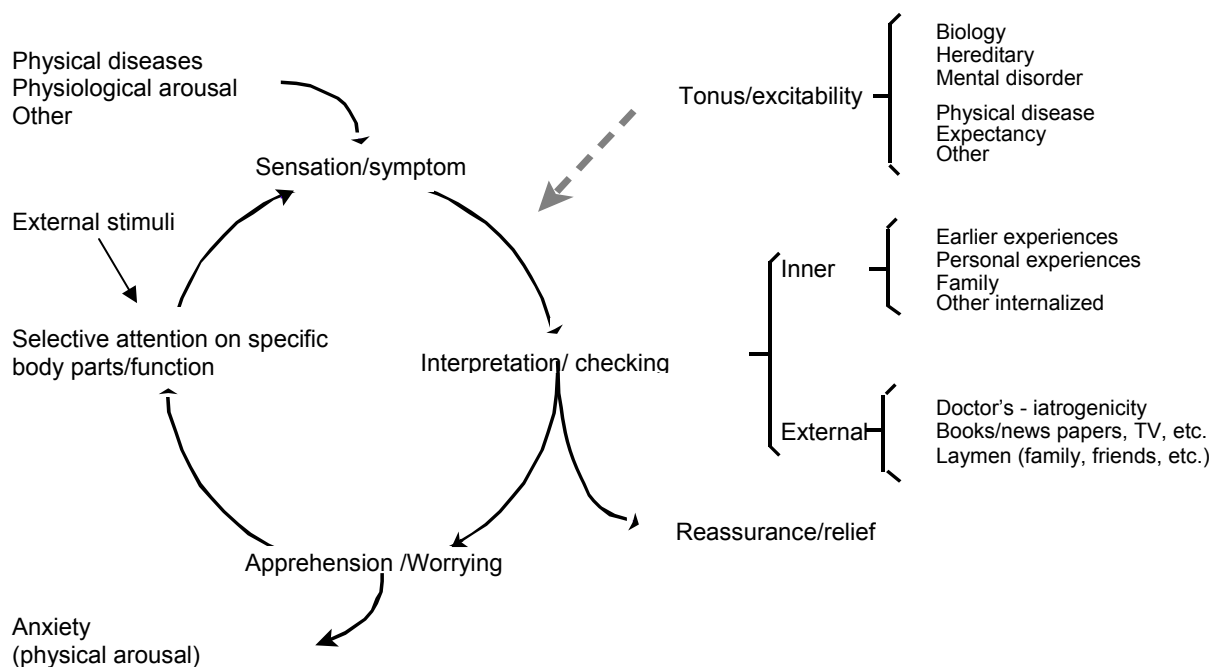
Illness behavior can be subdivided into treatmentseeking behavior and social illness behavior. Illness behavior is determined by our interpretation, evaluation, and perception of symptoms⁴⁹. Cognitive and emotional factors thus activate a given behavior, and the illness behavior in turn is influenced by individual upbringing, culture, social factors, etc.

A model of symptom and illness perception (Figure 3) shows how people perceive and evaluate physical sensations and symptoms^{31;49-52}. The outlined processes are universal (i.e., not pathological) and are continuous processes. The process ranges from the totally unconscious level to a level where all attention is focused on the symptoms and sensations. The latter is seen in hypochondriacs, who can think only of their prospective disease and in patients who have just been given the diagnosis of a severe physical disease. The process may have different tonus or excitability from person to person, according to person-specific biological factors and acquired experiences. Furthermore, the general tonus or level of arousal is influenced by moods or mental stress. A person who is depressed or anxious will, for instance, be more sensitive and worried, which will lower the symptom perception threshold. Also expectations influence the tonus of the process⁵³.

The model presupposes that all people experience nonpathological physical sensations or symptoms daily, which both the patient and the physician may misinterpret as being symptoms of a physical disease⁵⁴. The process of somatization can hence be seen as a tendency to misinterpret and/or intensify normal bodily sensations or even common diseases or minor injuries.

The process may be initiated by a number of different factors, internal as well as external. A good example of the *suggestive element* is the epidemic of allergic reactions to copy paper^{55;56}, which was given much attention in the Swedish media during 1979. When the phenomenon was investigated it turned out that only a certain type of copy paper caused an allergic reaction. The majority of those who complained about allergic reactions had never touched this particular type of copy paper. After the publication of the results and the removal of the concerned copy paper from the market, the number of cases quickly dropped to zero.

Figure 3. Symptom perception and illness perception



Previous Experience and Inner Evaluation

Everybody has a personal sensation/symptom panorama with which he or she is familiar. This knowledge accumulates throughout life in a continuous process. When girls reach puberty they become familiar with new symptoms in connection with menstruation, which they add to their personal symptom picture. Also, in chronic diseases patients add the new symptoms to their picture, and only when the intensity, the type, or composition of the symptoms change, will patients start considering whether there could be some other cause or the disease has deteriorated. Experiences with symptoms from various diseases will also form part of the individual's inner frame of reference.

Thus, each person primarily judges his or her condition through inner evaluation, that is, from subjective symptoms, experiences, and emotions that are tied to these. The type of sensation is affected by cultural and social factors, whereas its severity seems to be of minor importance. Even the most severe physical sensations can be quite normal, for example,

severe dyspnea and palpitations after a run, and would therefore not be interpreted as signs of illness.

This can be illustrated by the illness behavior of a family with an unusually severe form of migraine in which the fits led to hemiplegia⁵⁷. The members of the family did not consult their physician to any major extent, because the symptoms were well known. They knew from the experience of other family members that the fits would cease by themselves and, so far, the physician and neurologists had been unable to help.

External Sources and External Evaluation

When the personal evaluation of the sensations/symptoms is no longer sufficient, individuals may seek information or help from *external sources*: family members, colleagues, books, medical encyclopedia, weekly magazines, etc. As a last resort, individuals may consult physicians to be reassured or to receive treatment. The physicians' information and reaction will be crucial, so he or she must be acquainted with the patient's own perception of the problem. The physician's questions and responses can reinforce or reduce the patient's focus on special symptoms or organs. The patient will internalize this experience, which becomes part of the personal symptom panorama.

External information may make an individual change the interpretation of personally well-known sensations; that is, they are suddenly misinterpreted as signs of illness. Most physicians have experienced this themselves during their medical training. External information can initiate the process, as outlined in Figure 3. The new information will cause focused attention on the body part that is suspected to harbor the disease. A cycle of worry and expectation of symptoms will ensue. Everybody knows this phenomenon: if you injure your foot all your attention is directed towards the foot, which then is examined for symptoms and changes. This will cause new sensations/symptoms to surface and to be interpreted in the light of external or internal sources. Thus you will either become reassured or more nervous that the sensations/symptoms may be signs of illness. The process can be cumulative, because the patient may wrongfully ascribe the physical arousal accompanying the nervousness or the anxiety to disease.

The Patient's Illness Perception

The patient's illness perception and illness model are crucial to his or her morbidity and functional level. This also applies to severe physical diseases in which the patient's self-perception may be decisive for the prognosis for subjective well-being, functional level, and use of health care services⁵⁸.

A patient's illness perception may be seen as consisting of at least five main elements⁵⁹:

1. The identity of the illness: What does the patient think is wrong?
2. The cause: Is the patient convinced that the condition is caused only by organically founded problems, are psychosocial factors of any importance, or do other causes play a part?
3. Time frame: Does the patient think it will be short lived or does he or she fear a chronic disorder?
4. The consequences: Does the patient believe that he or she will be able to work again, that she will be troubled, or that he will depend on sickness benefit, etc.?
5. Recovery and control: Does the patient believe he or she will recover and that treatment will help? Does the patient feel he can control the illness to a certain extent, or does she feel helpless?

Future research will most likely uncover further details of our illness perception.

The patient's symptom perception and illness understanding

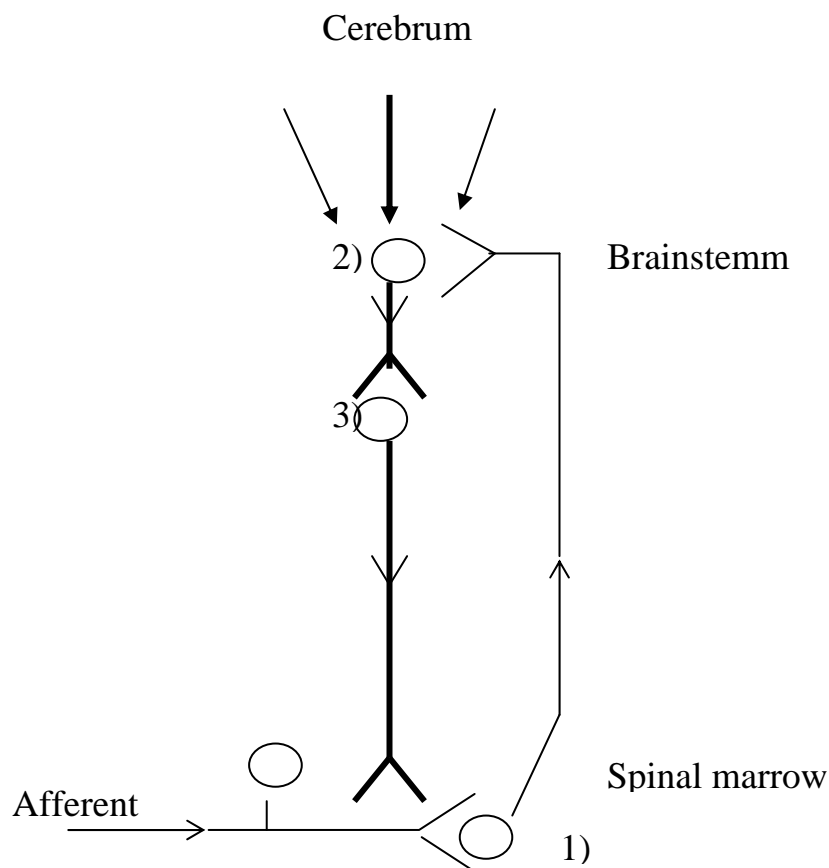
1. Everybody experiences daily spontaneous bodily sensations, but the perception and interpretation of these sensations vary.
2. The perception of the symptoms depends on the tonus of the nervous system and the patient's emotional state. Attention to one symptom may strengthen this perception.
3. Genetic factors may also influence the perception of the bodily sensations.
4. Internal evaluation of the symptoms determines the primary understanding of the condition, which is based on upbringing and previous experience. The well-known phenomenon that focusing on one body part can unveil new symptoms (i.e., previously unnoticed) may have a cumulative effect.
5. External evaluation most often takes place when the internal evaluation is not sufficient. Information can be gathered from family members, books, weekly magazines, dictionaries, etc. The patient regards the physician as just one expert among many others. New information in the media may be seen as more correct than the physician's expert opinion.
6. The symptom interpretation can be seen as a continuum that depends on learning during upbringing, family myths, prior experience, state of mind, and how the treatment system responds to the condition.
7. The patient's own perception of the illness influences the course and prognosis, that is, the patient's own hypothesis about the consequences and feeling of control of the illness.
8. Illness behavior is of great importance for the use of health care and the severity of the symptoms. The illness behavior is foremost controlled by the patient's own interpretation of the illness and the symptoms.

3.4. Section 3: Biological Basis of Somatization

Together with other factors, the hereditary predisposition in somatoform disorders supports the existence of a biomedical component in the disorder^{60;61}

Some people subjected to severe stress – for example, in a combat situation or accident - can suppress even severe pain. In such cases, psychological factors alter the threshold of the individual's perception via biological mechanisms. In contrast, the multisymptomatic illness pattern encountered in somatizing patients may be caused by the patients' intensification of all bodily sensations; that is, afferent stimuli to the brain are not suppressed. The result is that all sensations or symptoms, which are continuously evaluated in the unconscious part of the mind, will suddenly surface to the conscious level. It could be said that the filter function is insufficient⁶² (Figure 4).

Figure 4. Outline of somatosensory lines and control



The activity of the cortifugal system can be hampered or increased.

Positive feedback: Afferent information is increased, because everything has existing influence.

Negative feedback: Afferent information is blocked at 1), as the descending system from 3) is hampered at 2)

Tonic activity: 3) increases or hampers activity

James et al.⁶³ suggest the presence of a fundamental neuronal and physical dysfunction in the attention processes of somatizing patients. In EEG examinations with evoked potentials they found that somatizing patients responded in the same way to both relevant and irrelevant stimuli. In other words, the somatizing patients were unable to ignore the irrelevant stimuli.

The results from a study that used PET-scanning showed significant changes in the somatizing patients that closely matched the changes found in depressed patients (H. Karlsson, personal communication).

Numerous other studies have indicated that biological mechanisms and pathophysiological changes may be contributing factors in somatizing conditions³¹.

The biological basis of somatizing

1. A certain hereditary predisposition for somatizing has been demonstrated.
2. Neurophysiological studies have indicated that the somatizing patients lack a normal filter function, resulting in the patients being unable to ignore irrelevant stimuli.
3. PET scanning of somatizing patients differs very much from normal scanning.
4. Other biological mechanisms have also been suggested.

3.5. Section 4: How the Physician Becomes more Comfortable with the Somatizing Patient

When working with the somatizing patient it is of foremost importance to structure and plan the treatment and to make clear agreements. This is done to secure that everything is open and above board. It is, moreover, imperative that the physician makes the diagnosis and knows and understands the nature of somatoform disorders in order not to be in constant doubt about the diagnosis.

Chronically somatizing patients can be particularly burdensome. In some cases these patients would be better treated (or better managed) by the shared care of the family physician and specialized psychiatric health care. Unfortunately, this is rarely an option. Much frustration among physicians as well as patients may be avoided by adopting the advice on *management* and handling of somatizing patients outlined in Section 7.

Do Not Accept Responsibility that Is Not Yours

The doctor-patient relationship often fails because the physician accepts that somatizing patients hand him or her all the responsibility for their health, a responsibility that the doctor in no way can live up to. A British study on a gynecological ward analyzed consultations due to gynecological problems without organic basis by comparing the consultations that lead to hysterectomy with those that did not³⁸. It was characteristic that the patients focused on their subjective inconveniences and the consequences for their lives and their quality of lives. They were sometimes almost aggressive when demanding that the gynecologist should do something immediately. The patient were able to put pressure on the physician by referring to earlier unsuccessful treatment attempts and devaluating previous physicians and treatment implying, “if you do not help me you are just as bad”, and “nothing has helped me; you must make an effort and help me”. Consultations that lead to hysterectomy in spite of lacking indications on the basis of biomedical facts were characterized by the fact that the gynecologist accepted that the consultation was conducted on the patient’s terms. The topic of these consultations was the subjective consequences and inconveniences the disorder was causing. These are areas in which the patient is the absolute expert. Inversely, when consultation did not lead to hysterectomy, the gynecologist stood firm, maintaining that he or she had “looked inside the patient” and with his or her own eyes had seen that there was nothing wrong with the uterus and would therefore not perform a hysterectomy. The physician maintained his or her field of competence - that is, organic changes and physical diseases - and also that he or she had examined the patient and found no signs of organ changes. The gynecologist referred patients with psychosocial problems due to their symptoms to treatment elsewhere.

It is important to bear in mind that it is the patient and not the physician who has a problem, and the patient only can be helped through factual guidance. The patient cannot question the physician’s field of expertise and expert decision that there is no organic problem to treat. The physician must therefore not accept it if the patient tries to make the physician responsible for the patient’s health by demanding treatment that is not indicated but instead should offer the patient help in finding other possibilities, when the possibility they endorsed – that is, medical or surgical treatment – is not an option.

Communication

Patients with somatoform disorders often focus on their subjective illness story and its consequences. The patient’s *psychosocial communication* may cause the partners to talk at cross-purposes – the physician talks about facts and the patient about feelings. Thus, the

patient does not feel understood or the conversation will be one sided. If the patient is in charge, the communication will often be limited to emotions and demands for actions (“I hurt, do something!”). Recognizing the reality of the symptoms and communicating emphatic understanding of the patient’s emotional problems/statements, combined with the insistence of diagnosing and appropriate treatment, will contribute to finding a common ground for communication.

If the patient tries to make the physician responsible for his or her problems by insisting that the problem is only physical and, as such, one the physician should be able to handle, it is important for the physician to maintain that this is his or her field of expertise. The physician must communicate that there are no organ pathologic findings to indicate an organic disease or to perform surgical or medical interventions. It is important to insist on the mainly psychosocial nature of the problem, as when dealing with apoplectic patients disabled by paresis. Such patients can be offered neither medical nor surgical treatment but may be helped through psychosocial measures.

Accepting the Limits of Medicine

Somatizing patients seek treatment among others because they expect medicine to have a cure for their problems. Patients may believe they have an undiagnosed disease because “the physicians cannot find out what is wrong”. It is essential for the physician at an early stage to elucidate the patient’s illness perception and any myths the patient may have and at the same time empathically inform the patient about what the evidence suggests is wrong and what may be the best and most effective treatment approach. It will often be advantageous to offer a physiological explanation for the patient’s symptoms, and it is necessary to outline the limits of medical treatment.

If the physician has asked the patient about his or her expectations during the consultation, it will be easier to keep the allotted time and avoid being stressed by the knowledge of a full waiting room. If the patient’s illness perception and reluctance to accept nonbiomedical explanations suggests that mutual understanding may be hard to reach, the physician should schedule a new appointment and allow for due preparation.

Time pressure may often cause the physician to seek easy solutions. However, this approach will often, in the long run, turn out to be time consuming, because the untreated patient may return time and again with ongoing symptoms and renewed worries.

Becoming more comfortable with the somatizing patient

1. Establish a firm diagnosis.
2. Structured and clear agreements about consultations and treatment will prevent insecurity and make it easier to manage the patient.
3. Do not assume responsibility that is not yours.
4. Do not let psychosocial issues be the sole focal point of the conversation: The somatizing patient will communicate his or her suffering and expectation for the physician to take action at any cost. The physician should exercise empathy and insistence when communicating the professional indications for intervention or nonintervention.
5. The physician should assist the patient in establishing a realistic attitude to the possibilities and limitations of medicine.

3.6. Section 5: Assessment and Treatment

3.6.1. Considerations Before the Consultation

The physician's familiarity with the patient will often give him or her a gut feeling in advance whether the patient will present with functional symptoms. The physician may find it useful to devote extra attention to this feeling in an effort to fully understand it before the consultation. Somatization should be considered if the patient previously has presented a vague or complicated illness story, if the patient has not responded as expected to treatment, if symptom patterns repeat themselves in an incomprehensible manner, or in cases where something does not really add up.

Table 5. Consider the following before the consultation

- Similar reactions previously? Is this a repeated pattern?
- Indications of/information about previous mental disturbances or disorders?
- Does the patient have a low threshold for consulting the physician?
- Is the condition chronic? If yes, consider to schedule a status consultation

Patients with somatoform disorders often complain of grave subjective suffering and discomfort. The physician may feel forced to do something immediately, with the result that the consultation will focus solely on the most urgent problems, as defined by the patient. It can be very frustrating always to feel one step behind and feel manipulated by the patient's apparently severe and urgent symptoms. The physician may avoid this situation by being prepared for the consultation with a potentially somatizing patient (please refer to Table 5). Consideration of the listed questions will allow the physician to prepare a mental agenda before the consultation and to decide on a strategy, an approach that will be proactive rather than reactive.

3.6.2. Assessment and the Art of Making the Patient Feel Heard and Understood

General Techniques

One of the most important psychological aspects of the treatment program is to make the patient feel heard and understood. To achieve this, the physician must know a number of general rules of communication, which are listed in Table 6. Central to these rules is that the spirit matters more than the technique. It is more important to be attentive and to have eye contact with the patient than to remember a special technique. Avoid hiding behind instructions, lab-test forms, the patient's case notes, etc.

Socratic Questioning

The central element in Socratic questioning is curiosity. The task lies in coming to understand how the patient thinks, feels, and perceives the situation. At this stage, use active listening skills, show genuine interest in the patient's problems, be open and do not attempt to find premature explanations or to make corrections and give advice. Interesting at this point is not the factual state of affairs but the patient's subjective perception of the situation. Exact knowledge of the patient's perceptions makes this much easier and may be a fundamental prerequisite to correcting misunderstandings and misinterpretations. In general, people are afraid to appear ignorant and to say something that will sound stupid to the expert. Advice

offered at the wrong moment may cause the patient to feel stupid, and in the worst case, that he or she is ridiculed or loses face.

It is important to be neutral, because the patient may withdraw if the physician's opinion becomes known. The physician must refrain from giving advice and explanations, because no matter how well intended these may be, the patient is unable to use them unless they in agreement with the patient's own understanding. In the seventeenth century, Pascal Penesees wrote, "People are generally better persuaded by the reasons which they have themselves discovered, than by those which have come into the mind of others" – words that are still valid.

Table 6. Main rules for interviewing

Less desirable

- Closed questions (questions that can be answered by yes/no)
- Advice
- Premature corrections
- Arguments and confrontations
- The patients should not just be persuaded, because ideas generated by the patients themselves are much more convincing

More desirable

- Socratic questioning
 - Be neutral and sincerely curious
 - Use open questions
 - Use encouragement (facilitating)
 - Keep the focus
- Make frequent summaries
- Empathy/emotional feedback
- Roll with resistance ("rope-a-dope")
- Support empowerment – let the patients find their own suggestions to a solution and support the patients' feeling of power

In the consultation, use open questions such as, "What do you think?" or "What is going through your head when you feel like this?" By using closed questions, namely questions that can only be answered with yes or no, the physician controls the dialogue and takes on the responsibility. The physician may feel that this amounts to a burden, especially if he or she is insecure about what to do with the patient or which direction to take. The patient, too, may feel under pressure because of all the questions. Many patients describe that they feel more relaxed and reassured when they can use their own words. The patients will feel more satisfied to be able to discuss what they feel are important and are allowed to express their own understanding of a specific situation. Patients will feel the physician is listening, and this will make them feel understood.

Physician can encourage patients to express themselves by making supporting utterances or grunts (facilitation) such as, “Aha...”, “really”, “continue”, and “tell me more about that”.

The physician should not remain passive and let the patient control the whole dialogue. The patient rightly expects the physician to keep the time and to make sure that he or she receives the necessary information. However, it is also possible to control or focus the dialogue through the use of open questions and to clarify what the patient means by frequent summaries, perhaps combined with relevant closed questions. If the patient spends too much time on irrelevant information, try to keep the focus by asking, “it is fun to hear about the football match, but please tell me more about ...”.

Socratic questioning does not necessarily take more time than the use of closed questioning. Actually, quite the opposite may be true, because it may require many closed questions to reach the same answers. Furthermore, you are more certain that the patient has told what he or she really came for and thus avoid many of the so-called doorknob questions⁴⁸. It may be important to use closed questions in some cases, for example if you want to be certain of the nature of a symptom.

Summaries

Summaries present a simple but very effective method of making the patient feel understood. Summaries can be classified into three types: repetition, in which the patient’s own words are used; rephrasing, in which other words are used but with the same meaning; and interpretation, in which other words with another meaning are used as explanations. Repetition of the patient’s experiences and expressions affords the physician the possibility of checking that he or she has correctly understood the patient, and it hopefully gives the patient the feeling of having been heard and understood. Repetition also serves to clarify (or reinforce) the patient’s experiences and the patients may come to see the problem in a different light and to better understand the problem. An entirely different situation results when you hear your own experiences expressed by someone else, even if your own words and meanings are used. Just think of the comment, “it does sound strange when I hear you saying it.”

Summaries will also serve to expose many of the paradoxes or inconsistencies in the patients’ way of thinking. If the patient becomes aware of such contradictory thoughts and ambiguities, it will make him or her wonder and with great certainty make changes.

During summaries, the physician can use the following expressions, “did I understand you correct; you mean...”, “I want to be sure that I have understood you correctly”, “you are saying (or mean) ...”, “if I have understood you correctly, you are saying...”, “I hear you say...”, “on one side ... and on the other..”.

Express Empathy (Emotional Feedback)

By the physicians’ expressing empathy, the patient will feel heard and understood. Empathy could be expressed by saying, for example, “I can tell it has been hard on you (or caused you trouble)”, “I understand you find it unpleasant”, or “I can see this is disagreeable”.

It is important to bear in mind that understanding and empathy do not equal agreeing with or accepting the patient’s explanations and actions.

Assessment techniques

1. If possible, review and summarize previous reactions, patterns, psychiatric history and chronic problems prior to the visit (Table 5).
2. Try to be proactive instead of reactive.
3. During the process of assessment, it is critical to use Socratic questioning (curiosity, open questions, and facilitation) and to avoid premature explanations, corrections, and judgmental manners (Table 6).
4. It is vital that the patient feels understood. Thus use, for example, frequent summaries and empathy or emotional feedback.
5. Remember: the spirit is more important than the technique!

3.6.3. TERM Model Step 1: Understanding**TERM Model**

1. Understanding
2. Physician's expertise and acknowledgement of illness
3. Negotiating a new model of understanding
4. Negotiating further treatment

The different steps in the assessment of patients who present with medical unexplained symptoms are illustrated in Table 7. This method of structured assessment may also be very useful when dealing with other patients.

Assessment of Symptoms

The physician must insist on a clarification of symptoms as well as on the identification and description of specific symptoms, even in cases where it is obvious that the physical symptoms presented are not rooted in physical disease. This is not only fundamental to correct diagnosing; it will also give greater weight to the physician's words when he or she explains the absence of an organic basis of the symptoms to the patient. On the basis of the physician's knowledge as an expert, which cannot be disputed by the patient, it is easier later on to have a qualified discussion of the patient's health beliefs and fears.

Patients with functional disorders almost always focus on their subjective suffering caused by the symptoms and on the negative consequences on their lives and quality of life. It is therefore often difficult for the patients to be specific when describing their symptoms. A thorough review of all the symptoms may help the patient get a general, overall view of the symptoms, something that may otherwise be difficult, and hence alleviate the fear that springs from their profusion. In some cases, this approach alone can be therapeutic. It may be of great value to have the patient describe a "typical pain/symptom day".

Explore Emotional Clues

Patients often tell about the emotional trouble their physical difficulty is causing them, as reflected in common statements such as, "I am so depressed because it won't go away" or "if

it doesn't improve soon, I'll kill myself". Without either disputing or confirming the causality, the physician may invite the patient to elaborate on how his or her feelings in the following way, "tell me more about this" or "you say that you feel everything is confusing (the patient's own words) – try to tell me more about that (about how you feel)". Be emphatic and do not be sparing with emotional feedback; reply, for example, by saying, "I do understand this is difficult for you".

This will allow the discussion of other issues than physical symptoms and will change the focus of conversation while sending the signal that emotional factors are important. Also, the patients see it as a sign of genuine interest in their well-being.

Attention should also be paid to nonverbal emotional clues that, if present, could be brought into the open by asking, "you look quite tense, is that how you feel?"

Ask Directly about Symptoms of Anxiety and Depression

The physician should use general and open questions and words such as, "how is your general mood?", "how do you feel about yourself?", "are you able to relax?", or "do you feel stressed?". This may be more acceptable than asking whether the patient is "depressed" or "anxious".

If the patient confirms these screening questions, a more direct question may be asked about symptoms of depression and anxiety disorders, maybe by use of a questionnaire.

Explore Life Events, Stress and Other External Factors (Social, Work-Related and Family)

Functional physical symptoms are often a reaction to psychosocial distress. Likewise, a patient's problems caused by authentic physical diseases may be worsened by psychosocial distress and in stressed situations. Patients may be reluctant to tell about such problems, because they may erroneously believe that the physician deals only with physical matters. It is therefore advisable to screen for such stressors as a routine. Often the patients themselves have wondered whether there might be a connection, and the physician's questions might therefore confirm the patient's own hypothesis. Chronically somatizing patients may be particularly reluctant to reveal thoughts about the impact of psychosocial factors to the physician, fearing that the physician will focus exclusively on this and not take their physical problems seriously and not examine them properly.

Below are stated some short, generally valid screening questions to elucidate this situation⁶⁴:

- Background: "What else is happening in your life (in general)?"
- Affect: "How do you feel about this?"
- Trouble: "What causes you the most trouble?"
- Coping: "How do you handle this?" or "How did you cope with this?"
- Empathy: "It must be difficult for you" or "I can tell"

Some physicians are reluctant to ask these questions, because they feel that it will take up too much time. However, our present knowledge strongly indicates that such questioning is a necessary precondition for good clinical practice. It does save time to make direct inquiries during the consultation, because you may avoid the so-called doorknob questions⁴⁸.

It is important to ask about psychosocial circumstances and relationships early on in the assessment. The patient may otherwise feel that the physician is trying to dismiss the symptoms as being "all in the mind", because he or she cannot find anything else wrong.

Table 7. TERM model**1. Understanding**

Take a full symptom history (seek clarification, identify accompanying symptoms, describe a typical symptom day)

Explore emotional clues

Inquire directly about symptoms of anxiety and depression

Explore life events, stress, and other external factors (social, workrelated, and family)

Explore functional level (physical, social, and family)

Explore the patient's health beliefs

Explore the patient's expectations to treatment and examinations

Make a brief, focused physical examination and, if indicated, nonclinical examination

2. The physician's expertise and acknowledgement of illness

Provide feedback on the results of the physical examination

Acknowledge the reality of the symptoms

Make clear that there is no (or that there is indeed) indication for further examination or nonpsychiatric treatment.

3. Negotiating a new model of understanding (Reframing)

Negotiate with the patient a new model of understanding of his or her illness

Simple explanations

Physical symptoms are common reactions to, for example, stress and strain/nervousness

Depression lowers the threshold of pain ("you are more sensitive when depressed")

Muscular tension in anxiety and nervousness causes pain

Demonstrations

Practical (hyperventilation, muscular tension)

Establish the association between physical discomfort, emotional reactions, and life events.

"Here and now" (nervous over consulting the physician)

Severe cases

Known phenomenon with a name; somatization

Basically the cause is unknown, but nothing indicates a hidden physical disease.

Biological explanation: some are bodily more sensitive than others, which explains their more intense symptoms.

Individual symptom coping and reactions determine one's future well-being.

4. Negotiating further treatment

Sum up agreements made during the consultation

Agree on specific objectives, contents and form of the future course.

Acute cases: no further appointments

Subacute cases: therapy sessions, regular scheduled appointments.

Chronic: consider status consultation, regular scheduled appointments
(see practical advice)

Consider referral to psychiatrist, psychologist, or specialist service.

Explore the Patient's Functional Level and How He or She Copes with the Illness

The physician should ask the patients how the symptoms have affected their work, family life, and social interactions, for example: "how has this affected your ability to do this or that?", "how do you cope with this?", or "how did you usually cope with this?"

Explore the Patient's Health Beliefs (and Do Not Reveal Yours Right Away)

Recent years have seen general recognition of the importance of the patient's own illness perception and illness models to his or her morbidity and functional level and to the patient's reactions and coping when faced with symptoms (please refer to the section about symptom perception and illness understanding). It is therefore important to uncover the patient's health beliefs. The physician could, for instance, ask, "what thoughts do you have about your condition", "... and about the cause", "have you thought of a particular disease?", or "you must have had some thought of what..."

If necessary, use a few guiding questions, because the patient may, out of fear, be reluctant to bring up the subject or he or she may not want to sound ignorant.

It is vital to avoid the temptation to correct the patient and to interrupt with an explanation, even though this may seem the obvious thing to do to the physician. Instead, listen to the patient and ask questions out of genuine interest while keeping the focus. What is interesting at this point is not the factual state of affairs but the patient's subjective perception of the situation, knowledge of which is the key to later efforts to help the patient change his or her way of thinking.

Explore the Patient's Expectations of Treatment and Examination

Ask the patient about his or her expectations of the consultation. This may be instrumental in uncovering veiled motives, including emotional ones, for seeking consultation and it may facilitate the working relationship between the physician and the patient. Knowledge of the real wishes and expectations of the patient will also help the physician meet and consider these expectations, and it will be easier to agree on treatment plans and goals.

Patients with functional disorders often have unrealistic ideas about (nonpsychiatric) treatment options and about the diagnostic possibilities in medicine. In other words, they do not have a realistic understanding of the limits of medicine (as is also the case for some physicians!). Patients may think that something must be organically wrong, that is, "if only I am examined thoroughly, they will find out what is wrong with me and I will be treated and become well again".

This may be one of the reasons why patients with functional disorders often consult a physician and may continue to consult different physicians ("doctor shopping"). Patients who have not accepted the limits of medicine may even conclude that it is the physician who will not examine or treat them properly.

Ask the patient, "what are your thoughts about what is going to happen now/what treatment should be initiated?", or "what are your expectations of this visit?"

Brief Focused Physical Examination and Indicated Nonclinical Examinations

For many years, it has been a widely held misunderstanding that a physical examination of the somatizing patients should be shunned in order not to afford the patient any chance of secondary gains. However, patients with functional disorders have the same right to careful examination as other patients. Even though the patient's symptom description does not raise suspicion of organic pathology, it may serve a valid psychological purpose to physically examine the relevant organ, for example, performing a heart stethoscopy if the patient complains of "heart trouble". This reassures the patient that he or she is being taken seriously and that the physician is careful and meticulous: "Nothing in your description makes me think

that there may be something wrong with your heart. However, I would like to listen to it anyway.” If the patient demands repeat examination, the physician may suggest a psychological explanation, “I can see it worries you, so I would like to listen to your heart.”

Especially when dealing with chronically somatizing patients, it is important to focus on objective symptoms and signs and certain findings and not on subjective symptoms and provoked findings. In chronic cases further diagnostic procedures and laboratory tests should be avoided, unless they are based on certain findings or an illness history that points to a well-defined physical disease.

3.6.4. TERM-Model Step 2: The Physician’s Expertise and Acknowledgement of the Reality of the Symptoms

Provide Feedback on the Results of the Examination

When the medical history has been taken and the patient has been examined clinically, the result should be summed up for the patient. It is important to mention both positive and negative findings to the patient. *Never say that there is nothing wrong with the patient.* You may, instead, use phrases such as, “I have now examined your stomach (or the organ system in focus) and I have found no signs of changes (causing your pains). The tenderness you feel in the left side is often seen in muscular tension and it is completely harmless”.

It is important to speak as an authority and to communicate expert knowledge that rests on facts obtained by – so to speak – “looking inside” the patient during the clinical examinations and nonclinical examinations, etc. The patient cannot justly claim or assess such knowledge and, by implication, therefore cannot dispute the information received³⁸.

Acknowledge the Reality of the Symptoms

It is important on one hand to inform the patient about the absence of any signs of organ-pathological or pathophysiological changes in a manner that bars the patient from challenging the physician’s expert judgement. On the other hand, it is also crucial to acknowledge that the patient’s symptoms are real, because the physician in fact cannot dispute the patient’s feeling of being ill. The patient is the authority on illness – that is, the subjective experience of not being well - whereas the physician is the authority on medical terms, disease, and disorder. The patient may take a remark that nothing is wrong to indicate that the physician believes that he or she is a malingerer. The physician should therefore always, almost automatically, acknowledge that the symptoms are real and troublesome whenever it is mentioned that the symptoms are organically unfounded. A possible wording is “I can see you are very troubled by your pains (symptoms). Fortunately, for your reassurance, I can tell you that nothing indicates a serious physical disease. Perhaps we could try together to look for other possible explanations for your pains.”

Stress the Absence of Indications for Further Tests or Physical Treatment

It must be made absolutely clear to the patient that neither the physician’s expertise nor the examinations (clinical as well as nonclinical, etc.) provide any basis for further diagnostic tests or procedures, and that no relevant medical or surgical treatment can help relieve the symptoms. This will serve to stop the patient immediately after the consultation from entertaining the idea that some test could have been forgotten. Likewise, it emphasizes that the decision is made because the limits of medicine have been reached and not because of the physician’s reluctance or negligence.

“I can find no indication for making further tests and there is no medical or surgical treatment that will help you.” It is important to base the wording on the illness(es) the patient fears or the treatment he or she believes could help him or her.

Feedback cushioned in authoritative or metaphorical language will often prove highly effective. Greater effect and better comprehension is achieved through metaphorical expressions that convey the impression that the physician has "seen into the patient", for example, by scopes or diagnostic imaging techniques, and found everything to be normal than through statements such as "we have found nothing abnormal". It also carries greater weight if you have "seen or tested the kidney or the liver" through blood tests and the organs were functioning normally than simple statements like, "the blood tests did not show anything abnormal."

3.6.5. TERM-model Step 3: Negotiating a New Model of Understanding (Reframing)

Physical symptoms are commonly assumed to be caused by physical diseases, that is, caused by organic changes or pathophysiological dysfunction. This assumption defies the fact that this seems to be the exception rather than the rule²⁹. The either-or-thinking is widespread and comes to life in expressions such as "if the symptoms do not have an organic cause then the cause must be found in something psychological". This is often viewed as sheer imagination, and it communicates the attitude that the patient should pull him- or herself together or just stop it. The implication carried in this attitude is that the patient produces the symptoms on purpose and thus is to be blamed.

If these patients sense that other people and, notably, the physician, believe it is their own fault, treatment will more or less be impossible. Rightly, the patients cannot understand this and they will feel rejected and powerless⁶⁵. Helping these patients to get a deeper understanding of their illness, which is more in line with the actual facts, is therefore a most pertinent issue. The objective is to make the patients feel that they understand what is wrong with them, that it is not their fault, that they can do something themselves, and that they have a certain amount of control over their illness/symptoms (empowerment).

The principal purpose at this stage is hence to reframe the complaints, that is, localize the complaints in new contexts and give the patients a new frame of understanding. As was mentioned before, it is very important that they do not feel corrected, and it would be very effective if the patients themselves could reach some of the conclusions. Particularly crucial is that the patients are offered explanations that do not clash with their own understanding, and that the physician does not force the pace of the reframing process. However, it is important not to simply accept the patient's suggestions, but also to try to facilitate or even suggest other possible alternative explanations, even if the patient is reluctant.

Before going into steps 3 and 4 of the model (see items 3 and 4 in Table 7), we will present some general rules of communication below (see also Table 6).

Avoid Resistance

In some cases, it is not possible to change the patient's perception about an organ-pathological basis of the complaints, and it is important not to enter a locked and confrontational discussion. "Rope-a-dope" (a professional boxing expression) or "go along" with the patient's resistance. "I can hear (or see) you are convinced you have heart trouble (or another organ). However, I can find no signs of changes of your heart, which is why we cannot offer surgical or medical treatment that will make the symptoms go away. On the other hand, there are several things you can do to feel better, which would also be the case if you did suffer from an actual heart condition. Would it be okay to take a closer look at these measures?" Depending on the problem, one should discuss relevant possibilities. The physician may, for example, say "it is a fact that exercise is important for your health condition; this also applies to people suffering from a heart disease. How does this sound to you?" "Many people are afraid that the heart may be harmed when exercising or that it may

even kill you. Did you worry about this? I can reassure you that this is not the case. However, you will certainly feel worse if you do not exercise - try to keep busy, even though I do understand you may find it difficult.”

Support Self-Efficacy and Empowerment

It is vital to support the patient’s feeling of being able to do something him or herself and of controlling the illness and its symptoms. This can be accomplished by showing the patient in practice what to do (see below) and by helping the patient to a new understanding of his or her illness and a general understanding of what is taking place.

This is also called “empowerment” or “self-efficacy”. Contrary to what we as physicians are often induced to believe, the patient sees him or herself and not the physician as the highest authority. The physician is more likely to be seen as a consultant and often in competition with alternative therapists, magazines, friends, family, etc.⁶⁶. The patient may use the physician to test hypotheses and thoughts about illness relations or to be confirmed of the validity of his or her own ideas. If the physician wishes to change the patient’s perception, it is necessary to fit new ideas into the patient’s own world of ideas and not to conflict with these that have been tested and evaluated by the patient - who is “the final authority”. This goal is best achieved by facilitating the patient in finding possible solutions, for example by deploying the summarizing technique whereby the physician may discreetly guide the patient via the emphasis and focus of the summary. It is important that the patient does not feel that the physician rejects his or her opinion but that he or she is taken seriously. The ideal is a dialogue in the form of a conversation between physician and patient. The patient’s thoughts can be recognized by statements like, “I understand what you are saying. However, you could also see it this way...” or “I can follow your thoughts. However, I do not understand ...”.

Studies have shown that the time used in supporting patient self-efficacy and empowerment is time saved in the long run and that successful empowerment is reflected in greater patient satisfaction and less somatization⁶⁵.

Simple Explanations

Try to explain that tension or mental stress is commonly accompanied by physical symptoms and/or that it may worsen existing physical symptoms. Physical symptoms are quite rarely caused by organic or pathophysiological dysfunction, for example, “all people might react with physical symptoms and trouble when having problems or feeling tense or stressed”, “it is harmless, but I do understand it worries you and it is unpleasant”, or “I often see such symptoms in stressed or tense persons; could this also be the problem in your case?” In some cases, it is hard for the patient to believe this. This approach often induces a radical change in the patient’s perception of the symptoms’ cause, and the patient may therefore need time to adjust to the idea. The most successful way of doing this is by giving the patient a chance to express his or her own thoughts and ideas and by helping the patient to weigh the pros and cons.

Examples of simple explanations could be:

- You may experience palpitations, breathlessness, and other physical symptoms when frightened or nervous over something. Most patients have experienced this themselves and therefore understand this explanation (Table 3).
- When depressed, you are more sensitive to physical symptoms.
- When you are frightened or stressed you tighten your muscles. This can result in pain that may increase the tension and give more pains. Thus you are trapped in a vicious circle.

Demonstrations

Practical exercises and demonstrations may effectively illustrate the link between physical symptoms and behavior. It is crucial that these exercises and demonstrations allow the patients to experience that they can influence the symptoms themselves and that the symptoms are not beyond their control.

- Muscle pains can be demonstrated by asking the patient to tighten the muscles, for example, in an arm (lift a book with the arm outstretched), which will almost always be painful after a while: even a minor muscular tension can quickly cause muscle pain. Logically, even minor muscular tension will cause muscle pains if it persists almost day and night. In some cases tension headache can be demonstrated by pressing the patient's tight occipital muscles.
- It is often possible to connect emotional reactions and life events with physical reactions. The patient is gradually guided into speaking about their physical trouble when experiencing straining and stressing events. The physician presumably has relevant information from the patient's medical history. The best effect is obtained by using the patient's own examples, "You told me before that you were especially troubled last Monday; that was also the day your spouse came home very late. I wonder whether this is linked somehow: what do you think?"
- Finally, spontaneous situations may be used to good effect, "I can see you feel bad when we talk about this; it must be hard on you." The patient has often been nervous about the visit, and the physician may enquire whether the visit has caused a worsening of the physical symptoms.

Severe Cases

In more severe cases of somatizing, it is necessary to help the patient to a meaningful understanding of his or her illness.

The patients often believe that they are the only ones in the world who have a particular type of illness and are therefore afraid that the physician has overlooked something. The patients must be told that this is a known phenomenon called somatization. It could be phrased, "Many people feel like you do. It is in no way a rare condition." "We have a name for it; somatization or functional symptoms/disorders." (The patient will in most cases ask what it is?).

The physician may continue by explaining that the fundamental cause is unknown, as is also the case for many other illnesses (e.g., essential hypertension). You could say, "We do not know the actual cause or the mechanisms behind it, but it is subject to a lot of research" or "We do know with great certainty that it is not caused by any hidden physical disease and neither traditional medical nor surgical treatment will help, but may actually worsen the condition".

To take away the patient's sense of guilt, it is advisable to state the likelihood of a biological basis for the disorder, which is supported by scientific evidence (just as today it is quite certain that depressions do have a biological substratum). The physician could, for instance say, "Several studies indicate that the reason is changes in the brain and the nervous system and some people are more bodily sensitive than others. In other words, they do not filter physical sensations and symptoms as well as others, and are therefore more troubled by the different symptoms". The physician may assist the patient's understanding by using wellknown examples such as when you think about fleas and lice, you start itching. The senses and your attention are sharpened. In somatizing the increase in attention is just much stronger. Furthermore, it could also be mentioned, "we know that for some it runs in the family".

The physician should explain to the patient that how he or she acts and reacts to symptoms is important for his or her future well-being. The patient must learn how to cope with illness, that is, to function as well as possible in spite of the trouble the he or she is experiencing and that it is important not to become physically unfit, which will just make things worse. It is also important for the patient to understand that he or she should not expose him- or herself to unnecessary tests or treatments (i.e., accepting the limits of medicine), because this may harm the patient even more.

3.6.6. TERM Model step 4: Negotiating Further Treatment

At the end of the visit, the result is summed up, for example, by asking the patient, "what is your outcome from this visit?", "is there something you can use?", "would it be reasonable to do (such and such)?", or "could we agree ... ?".

In some cases – especially chronic cases – it is not possible to change the patient's belief that the illness is caused by a physical disease. It is important in this situation not to engage in deadlocked, confrontational discussion (see Table 11 in Section 7 about advice on chronic cases).

The further course of the treatment is negotiated with the patient. The physician may mention the existence of other possibilities of treatment than orthodox medical or surgical ones. Suggest looking into this together with the patient and to find out what he or she can do to feel better, no matter what the cause of the problem is.

The following four courses should be considered:

1. Acute cases: no further appointments
2. Sub-acute cases: agree to have therapy sessions in the form of regular, scheduled appointments.
3. Chronic cases: consider a status consultation. Agree to have regular, scheduled appointments (see practical advice)
4. Consider referral to psychiatrist, psychologist, or special service.

Please note the paramount importance of regular, scheduled appointments!

Acute Somatization

This group of patients includes those who present with medically unexplained symptoms and who are not subacute or chronically somatizing patients according to their medical history. After having used the general model during the consultation, the patients are normally discharged. However, it may in some cases be suitable to agree that the patient return, if necessary.

Subacute Somatization

This group includes acutely somatizing patients, who are consulting the physician again or who have already consulted the physician because of illness worrying or functional symptoms that they have been feeling for a period of less than 6 months.

Agree on a short series of regular, scheduled appointments. If the physician already has learned and mastered a method or the technique for brief psychotherapy, this can be used in combination with TERM model elements. Another possibility is the use of the technique of problem solving described below.

In many cases, it could be beneficial to use the advice aimed at chronically somatizing patients also on patients with a shorter duration of illness.

Chronic Somatization

Please refer to Section 7 regarding treatment and management of chronic somatizing conditions.

Referral

The possibilities of referral depend on the services available in the local area. The reason for a referral could be formulated as follows, as not to offend the patient:

Referral to psychiatrist

"I am glad to say that we have excluded that your symptoms are caused by serious bodily disorder. However, I understand that your pain (or another symptom) is still a big problem. The problems you have at home and how tense they make you worries me, and this is definitely not contributing toward making you feel better.

I have a colleague, who is a psychiatrist, who is interested in chronic pain (or another symptom) and who often gives me advice on patients with this kind of problem. I would therefore appreciate hearing his opinion about the best way to proceed."

(Quotation from C. Bass)⁴³

3.7. Section 6: Follow-up Appointments

General Advice About Follow-Up Consultations

Do not avoid asking about the patient's physical symptoms (Table 8). However, this should not take up too much time and should not become the focal point of the consultation. The patient's need to discuss his or her symptoms will often diminish as treatment progresses. The physician should seek to focus the conversation on the factors that cause the problems and that maintain the patient's symptoms and behavior.

Concentrate on current tangible and specific problems, not childhood and past problems. It may be relevant to work with childhood during long-term psychotherapy, but it is seldom a good idea in other situations, rather the opposite is true. A patient with many skeletons in the closet can become totally absorbed and paralyzed. For them, it would be a great help to be kept in the present and focused on practical specific problems. Other patients may use speaking about childhood as an escape from dealing with present-day problems.

The consultation should take the form of a dialogue. As was mentioned above, it is crucial for the physician and the patient to reach a common understanding, an end that may be reached by use of the Socratic questioning technique. The aim is, through negotiation, to help the patient solve the problem him or herself. It is ultimately the patient's choice where to step in. The physician may help the patient in making this choice by engaging in a joint brainstorming that produces a number of different possible solutions to the problem.

Termination of therapy should be planned well in advance, preferably 2-3 appointments before the actual conclusion. As soon as the final appointment is set, the dialogues will automatically change character and become more forward-looking ("How do I manage new problems from now on – from whom can I expect to get help?" etc.).

Further Assessment

Although the patient has acquired insight into the relation between mental and physical factors, it is far from certain that he or she can immediately see which factors influence the symptoms. During the scheduled follow-up visits it may therefore be necessary to continue the exploration of the symptoms.

Provoking and relieving factors can be explored via a diary or weekly chart (see Appendix). The result of this exploration is used directly in the cooperation between the patient and the physician for finding strategies the patient may use in coping with his or her symptoms and problems.

- Which factors would normally worsen the condition?
- Which factors would normally relieve the symptoms?
- How did the onset of the symptoms affect the patient's functional level?
- How does the patient function (i.e., cope) when having symptoms?

Training

Impairment due to functional symptoms should be relieved by gradually resuming activities. It is important to be empathic with the patient's fear of the exercises and to explain that it will do with one small step at a time and that the next step will always be manageable. The patient is often seized with overweening confidence when things start falling into place again. They may therefore risk defeat and lose confidence in possible treatment. Gradual introduction and gentle progression of the challenges is hence of utmost importance. The patient should proceed from easy to gradually more and more difficult problem-solving exercises.

Table 8. Follow-up consultations**In general**

- Present-day, specific, and tangible problems. Not childhood or the past.
- The consultation should have the form of a dialogue
- A fixed time frame is always allotted (e.g., 10, 20 or 30 minutes) and is always kept
- Help the patient find solutions by themselves, i.e., through negotiation. It is the patient who chooses
- Agree and negotiate conclusion of the sessions well in advance, preferably 2-3 appointments before the actual conclusion

Further assessment

- Provoking and relieving factors (focus on a single symptom)
- How can the patient function in spite of symptoms (coping)

Problem solving technique

- Set the agenda. Discuss tasks from the last appointment
- Identification of the current problem
- Set realistic targets
- Let the patient break down overall targets into realistic and manageable subtargets. (Elucidate every single active step to be able to reach the subtargets)
- Formulate different solutions for each step – consider pros and cons
- Agree upon the preferred solutions and agenda for problem-solving
- Consider possible hindrances
- Sum up the problem-solving program

Next time evaluate progress. Targets and measures are adjusted if necessary

Problem-Solving Therapy

Problem-solving therapy has been effective and easy to use when treating somatizing patients in general practice⁶⁷. It is a suitable method that allows the therapist, in a structured way and in a few sessions, to help the patient explore and solve problems that used to be difficult to manage. The patient learns to use his or her own abilities and use this experience to handle both present and future problems. The physician will function more as a consultant and trainer than as an expert.

A problem-solving session normally lasts more than the 10-12 minutes usually allotted for a consultation⁹ and it is therefore recommended to use a regular therapy session.

The patient may find it a boundless undertaking to face the entire problem complex at once, so individual sessions should address a single problem at a time.

Always start by making an agenda and revising the result of the homework and exercises since the last session. The seven steps of the problem-solving model are examined for each problem addressed:

1. Identification and clarification of a present problem, for example, the patient isolates him or herself and does not get out of his or her home.
2. Clarification of alternative targets and choice of one concrete goal, for example, being able to go shopping.
3. Formulate together possible solutions (brainstorming). It is important at this point not to exclude any solutions beforehand.
4. Each solution's pros and cons are evaluated. Choose the solution model that seems most feasible after evaluation. It is important that the patient feels that he or she is the one who chooses the solution.
5. The solution model is broken down into steps, each of which can realistically be managed. Each step is elucidated in terms of method, time frame, and initiation; for example, start the first week by taking small walks with the dog.
6. The patient summarizes the plan for the solution of the problem, and this agenda may be perceived as a sort of a contract. The physician's providence may greatly help the patient, as may advance, joint consideration of possible hindrances.
7. At the next appointment, evaluate progress and adjust target and measures if necessary.

In the beginning, the patient will often find the method difficult and may come to the appointments without having tried to use the agreed problem-solving method. Try to be relaxed about this and avoid at any cost becoming admonitory toward the patient. Discuss, instead, what was difficult and find out what hinders the patient from progressing.

3.8. Section 7: Treatment and Management of Chronic Somatization

The more severe cases of chronic somatoform disorder present a lifelong illness that may seriously disable the patient. In many cases, it is therefore more realistic to use the term “management” rather than treatment, which is to say that the instituted therapy will not have a curative intent but will aim at giving the patient the best possible life, as when dealing with other chronic physical or mental disorders. Some take the view that the most severe cases of chronically somatizing patients can only be managed through long continual ambulatory contact with a psychiatric specialist. A physician who deals with a chronically somatizing patient often faces a rather bewildering scenario of illness images and may find it impossible to get a clear picture of the condition of a patient who has gone through a plethora of tests and futile attempts at treatment. The scenario often presents a difficult mixture of different probable pathological findings and signs and obviously medically unexplained symptoms. The patient will not be less confused. The physician may think, “Is it her again. What shall I do? Could there be anything I have overlooked in the extensive case history?” The physician can feel insecure about seeing the patient and must brace him or herself when spotting the patient in the waiting room. Agreement with the patient to have status consultations is a method the physician may resort to in order to obtain a general overview of a complex case and to get on top of the chronic somatizing condition.

3.8.1. Status Consultation

Before the Consultation

Allot the necessary time to go through the patient’s case. This may seem boundless and demands great effort, but later it will definitely be worth the effort, both because it saves time and because it improves the relationship with the patient (Table 9).

Table 9. Before status consultations

- Allot the necessary time to go over the patient’s case
- Review the patient’s medical history on the basis of case notes, discharge summaries, etc.
- Sum up in a few main groups or subjects the symptom patterns the patient has presented with and which have been assessed
- Sum up which examinations and treatments the patient has gone through, e.g., for each illness picture, including any positive and negative findings
- Look for any patterns over time in intensity of illness in relation to psychosocial distress and life events
- Look for indications of mental disorders

Go through the patient’s medical history on the basis of case notes, commentaries, etc. *Sum up* in a few main groups or subjects *the symptom groups* the patient has presented with and has been examined for. Sum up the *examinations and treatment trials* the patient has gone through, including any positive and negative findings.

A one- to two-page outline based on these summaries will clarify the illness picture and make the physician feel on safer grounds. Both positive and negative results must be covered so that the patient will not feel that one half has been overlooked. Also, be aware of any

patterns over time in the intensity of the illness and complaints in relation to external stress and life events.

Look for psychiatric disorders. Physical and emotional symptoms often both occur and worsen simultaneously. The patient may, for example, focus only on bodily symptoms of a depression, even in cases where symptoms have disappeared with the treatment of the depression. This correlation can be rendered probable to the patient, which may in turn mediate a dialogue about the subject.

During the Status Consultation (Table 10)

The reason for the status consultation is explained to the patient. An explanation could be that the patient has gone through many examinations and treatments but has not become better, that the patient has come often, is very tormented, and the physician can tell that the patient is not feeling very well. It is therefore obvious that orthodox medical treatment, indeed, has not helped. The physician and the patient could therefore try jointly to approach the matter from a different angle, as it is unsatisfactory with all the examinations and treatment attempts that do not help. The physician could give the patient the following offer, "Could we together try to find new ways to make you feel better?" "Unfortunately, there are many illnesses that we cannot treat so that they disappear completely. However, certain things could be done to mitigate the inconveniences". "There are no miracle cures". "An objective could be to stop all these unnecessary examinations, because they are not helping you anyway". "I will, of course, be observant in case you show signs of a physical disease".

Present the summary of the medical history as neutral facts: It is important that both positive and negative findings are emphasized and discussed with the patient. A careful and systematic summary should make it clear to the patient that he can safely leave it to the physician to oversee that a future physical disease is not overlooked.

The limits of medicine: We physicians must acknowledge that the biomedical model allows us to explain only a small part of the illnesses and disabilities caused by physical symptoms and to cure an even smaller part. This recognition has only been reached by few people, which may explain why somatizing patients will continue to seek treatment. It should be borne in mind that this recognition applies not only to somatoform disorders, but also to many physical diseases. Essential hypertension could be an analogous example, as the aim of the treatment of this disorder also is to avoid secondary damage.

Table 10. During the status consultation

- Explain the reason for the status consultation to the patient
- Present the summary of the medical history as neutral facts. If necessary, "read" the case notes together with the patient
- Explore the patient's expectation of medical care
- On this basis, conclude that orthodox medical treatment (by its own) has failed
- Offer the patient a partnership trying to find a new way to help the patient to get better
- Use the general advice for communication technique and management of chronic somatization

Table 11. General advice on the management of chronic somatization**Physical**

1. Make a brief physical examination focusing on the organ system from which the patient has (new) complaints
 - Look for signs of disease instead of symptoms
 - Avoid tests and procedures, unless indicated by objective signs of disease or a well-defined (new) clinical illness picture
2. Reduce unnecessary drugs, do not use on-demand prescriptions, and avoid habit-forming medication

Psychological

3. Make the diagnosis and inform the patient that the disorder is known and has a name
4. Acknowledge the reality of the patient's symptoms
5. Be direct and honest with the patient about the areas you agree on and those you do not agree on, but be careful as not to make the patient feel ignorant or not respected
6. Be stoic; do not expect rapid changes or cures
7. Reduce expectations of cure and accept the patient as being chronically ill. Aim at containment and (iatrogenic) damage limitation, i.e., use management rather than treatment
8. Perceive worsening of or new symptoms as emotional communication rather than as a manifestation of a new disease
9. Apply a specific therapeutic technique (refer to the TERM-model step 1-3 and follow-up appointments) and consider referral to specialized treatment.

Psychopharmacological treatment

10. Consider treatment with psychoactive medication (primarily antidepressant or Buspirone)
11. Choose non habit-forming medication and, if possible, choose medication that can be serum monitored
12. Start with a smaller dosage than usual and increase slowly. Be stoic about side effects
13. Take regular serum values because of compliance issues and for validating complaints of adverse effects
14. Treat any co-existing psychiatric disorders according to usual guidelines

Administrative

15. Be proactive rather than reactive. Agree on a course with fixed, scheduled appointments with 2- to 6-week intervals and avoid consultations on patient demand (if needed, accept on demand a maximum of one phone appointment per week)
16. If the patient has a job, avoid giving him or her sick leave if at all possible
17. Try to become the patient's only physician and minimize the patient's contact to other health care professionals, doctors on call, and alternative therapists
18. Inform your colleagues of your management plans and develop contingency plans for when you are not accessible
19. Inform the patient's nearest relative and try to co-opt a relative as a therapeutic ally
20. If necessary, arrange support/supervision for yourself
21. If necessary, motivate the patient to receive psychiatric treatment

3.8.2. General Advice - Management of Chronic Somatization (Table 11)

1. Make a brief *physical examination* that focuses on the organ system to which the patient's new complaints are referring. This contributes to making the patient feel that he or she is taken seriously and not superficially as may otherwise be the case. In the examination and in the whole assessment of the patient, it is important to *emphasize objective findings* instead of subjective complaints. Perceive the complaints as primarily emotional communication and not as a sign of a physical disease. *Avoid investigations and tests* if there are no indications based on objective findings or a well-defined (new) clinical illness picture. If the patient is a chronic somatizing patient, the possibility of finding a disease explaining the illness is very small (less than 1%-2%)^{31;41}. However, somatizing patients have the same risk as everybody else of getting a (independent) genuine physical disease.
2. *Rationalize medication. Avoid habit-forming medication.* The typical chronically somatizing patient uses several different types of medication. Consider whether medication, both the psychoactive and other types, is doing more harm than good. Many somatizing patients have a high potential for misuse. Medication can cause physical damage, it is expensive for the patient, and he or she will often become emotionally dependent and may use the medication as proof of the illness both toward other people and him or herself. The patients will often resist withdrawal of their medication. It is important to explain the reason for the change: "You have been taking this medication for a long time, and I can see that it has not helped you very much, because you still complain of I therefore think we should try phasing it out." Warn the patient that inconveniences may occur during a transition period. It can be harder to reduce the patient's consumption of psychoactive medication and painkillers than to reduce other kinds of medication. An explanation could be, "I can imagine you are afraid to give up the medication and you feel that it is helping you somewhat. I am sure when you have adjusted to not taking the medication you will feel better, because it also sedates you and you can become dependent on it, which will cause you more trouble than now (i.e., medication is only helpful during the short term)". Be firm but not hard or punishing when rationalizing medication. Prevention is better than treatment, which emphasizes that it is better to avoid medication that may be habit-forming.
3. Make the diagnosis and inform the patient that the disorder is known and has a name. It is important to realize the diagnosis, because keeping this in mind makes one think twice before initiating new tests or treatments (see paragraph 1). Thus, it is also easier to resist the pressure the patient may put on the physician. Furthermore, unfamiliar things often involve anxiety and insecurity for both physician and patient. When "the enemy is known" and has a name, it is easier for the patient to relate and fight against it. This reduces anxiety⁵⁰.
4. Acknowledge the reality of the patient's symptoms. This is crucial, because it is a precondition for the patient's acceptance and cooperation.
5. Be direct and honest about the areas you agree in and those you do not, but be careful as not to make the patients feel ignorant or disrespected. "I can see you find it difficult to believe what I am saying."
6. Be stoic; do not expect rapid changes or cure. Hesitate a while before you evaluate whether treatment has helped or not.
7. Reduce expectations about cure and accept the patient as being chronically ill. Try instead to aim at containment (iatrogenic) and damage limitation. The therapeutic focus is, in other words, more on management than on treatment, in the same way as in other chronic physical or mental disorders.

8. Understand worsening and new symptoms as emotional communication rather than as a manifestation of a new disease. The physician who knows the patient could, for example, say, “nothing of what you are telling me makes me think you have contracted a new disease ...” or “we have talked about your inclination to react with strong physical symptoms when something upsets you and I was wondering whether something has come up or anything specific is worrying you at the moment?”
9. Consider specific therapy (TERM-model step 1-3 and follow-up appointments) and consider referral to specialized treatment if such is available.
10. Consider psychopharmacological treatment. There are no randomized studies of the effect of various psychoactive drugs for somatizing conditions. It is the clinical impression that many somatizing patients benefit from antidepressants or Buspirone, and this should be considered, even though the patient denies symptoms of depression or anxiety. Be cautious to discontinue the medication if it has no effect when used in sufficient dosage and for a sufficient period (Table 11).
11. Treat any coexisting psychiatric disorders according to usual guidelines. In chronic cases more than 50% of the somatizing patients also have another mental disorder. Start with smaller dosage than usual and increase slowly, because the somatizing patient often has a low threshold and low tolerance for side effects. Be stoical and try to hold on to the initiated treatment until the patient has gone through a sufficient treatment regime. Preferably choose medication that can be serum monitored, because these patients can be very unstable in their medication habits and in their compliance. Furthermore, by choosing this medication the physician does not depend only on the patient’s subjective information about adverse effects.
12. Be proactive instead of reactive. Agree on a course with fixed, scheduled appointments with 2- to 6-week intervals and avoid visits on patient demand (if needed, accept on demand one phone call per week). This is an absolute must for any treatment or management of patients with functional symptoms with a certain severity. If you cannot accomplish this, you may as well give up the treatment.
13. If the patient has a job, avoid giving him or her sick leaves if at all possible. Somatizing patients are predisposed toward being trapped in the sick role and get caught in self-perpetuating vicious circles that confirm them in their ill health and how little they can accomplish. It is important to formulate the reason for not letting the patient go on sick leave, so that the patient does not feel rejected or misunderstood. There is presumably no risk involved in a short-time sick leave for a well-defined genuine physical disease such as fractures in a somatizing patient. This could be explained by the clinical observation that the patient surprisingly seems able to distinguish even though they are not conscious of this distinction³¹.
14. Try to become the patient’s only physician and minimize the patient’s contact with other health care professionals, physicians on call, and alternative therapists as much as possible. The health care system (and the gray market) has a significant responsibility for the somatizing patients becoming chronic and disabled, because in this market the patients are often treated and examined in the same way as patients with genuine physical disorders. Many examinations and treatments involve considerable risk of physical damage as well as personal and financial costs for the patient.
15. Inform your colleagues of your management plan and develop contingency plans for when you are off duty, on leave, etc. A physician who does not know the patient will often be driven into a corner by a severely somatizing patient, because his or her medical history is often boundless and the physician only hears the patient’s own perception. Providing colleagues with necessary information and, preferably, instructions to make them able to manage the patient and to withstand the pressure they may be exposed to is

therefore of utmost importance.

16. Inform the patient's nearest relatives and try to co-opt relatives as therapeutic allies. Especially chronically somatizing patients often have a very close symbiotic familial interplay. In many cases the whole family life revolves around the patient and his or her illness, and changes can be directly opposed by the family because of misunderstandings or a fragile balance of power within the family. Changes will thus interfere deeply with the whole family life, and it can be very complicated to change such patterns. It is necessary that the family accepts, better yet, supports the patient in going through treatment and making the necessary behavioral changes. Actual family therapy demands specialist knowledge, but it is always possible to have a talk with the patient and his or her family. If possible, consider co-opting a health counselor and to get help from the local psychiatric system.
17. The physician may also wish to arrange support/supervision for him or herself. Chronically somatizing patients often belong to the group of patients that it is most difficult to treat and manage. The physician is often exposed to almost constant pressure to make examinations and attempts at physical treatment. Because the patients are often very active in their search for treatment, many other health care professionals may try to interfere in the management and suggest inappropriate treatment or unnecessary examinations because they lack knowledge of the patient. It is advisable to find a close colleague with whom you can discuss the problems.
18. If relevant, motivate the patient for psychiatric treatment. It may be a question of assessment and exclusion of another coexisting mental disorder, reduction of unnecessary drugs, mobilization and activation, behavioral therapy and family therapy, etc. This is usually best done in a psychiatric setting. Moreover, many hold the opinion that continual, ambulatory psychiatric treatment is superior to other types of treatment when dealing with the most severe cases. Unfortunately, many psychiatrists are disinclined to care for these patients.

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Appendix - TERM

Patient forms

1. Weekly form for registration of symptoms/problems
2. Form for registration of symptoms, emotions and thoughts (4-column form)

A copy can be given to the patient.

1. Weekly form for registration of symptoms

On this form you note for each day of the week how many and which symptoms you have had. Together with your physician you can decide which symptoms to note, if there are many symptoms troubling you.

For every note write a headword about the situation you were in when the symptoms occurred.

E.g.: “in the bus”, “at work” or the like.

Symptom/problem registration

Weekly form Registration of symptom/problem	Monday date:	Tuesday date:	Wednesday date:	Thursday date:	Friday date:	Saturday date:	Sunday date:
<p>Morning</p> <p>(Note symptoms and situation for each day/time of day)</p>							
<p>Afternoon</p>							
<p>Evening</p>							
<p>Night</p>							

2. Form for registration of symptoms, emotions and thoughts

This form is to be helpful when exploring symptoms and their severity

Column 1: Symptom:

In this column you describe your symptoms and their severity. 0 (zero) is when there are no symptoms and 10 are when the symptoms are so severe as they could possibly be.

Column 2: Situation:

In this column you describe the situation you were in when you observed your symptoms. Sometimes it can be specific situations that you can relate to unpleasantness and the symptoms, while at other times you might suddenly have thought of something that in the situation totally preoccupied you.

Column 3: What did you feel?

State how you were feeling at the time you describe. It could be emotions of sadness, anger, melancholy, loneliness, anxiety, happiness or the like. This column is for registration of your emotions, not your thoughts. Remember, thoughts are actually words, expressions or sentences we say to ourselves.

Column 4: What was on your mind?

Most people believe it is the situation that creates the emotion. Actually it is just as much our thoughts about the situation that leads to the emotion. In this column please describe which thoughts went ahead of the symptoms and the emotions you felt.

Registration of symptoms, emotions and thoughts (4-column form)

Date	Symptom (How bad: 0-10)	Situation (What were you doing or thinking of?)	What did you feel? (How bad: 0-10)	What was on your mind? (How convinced were you: 0-10)

Chapter 4

Effect of short-time training on general practitioners' attitude towards somatisation - a randomised controlled trial

Marianne Rosendal, Flemming Bro, Ineta Sokolowski, Per Fink, Tomas Toft, Frede Olesen

Submitted

Abstract

Objective

This study aimed to evaluate the effect of a novel, multifaceted training programme on general practitioners' attitude towards somatisation.

Design

A cluster randomised controlled trial with practices as randomisation unit and with a follow-up period of 12 months.

Setting

General practices in Vejle County, Denmark.

Participants

43 general practitioners from 27 practices.

Intervention

A cognitively oriented educational programme on assessment, treatment and management of somatisation (The Extended Reattribution and Management Model).

Main outcome measures

The general practitioners' attitude toward somatoform disorder and somatisation in general was measured by the means of questionnaires at baseline and follow-up. The primary outcome was a change in responses. This was supplemented by factor analyses.

Results

Baseline values confirmed previous findings that general practitioners find it difficult to deal with somatising patients. Compared with the control doctors, intervention doctors' attitudes towards patients with somatoform disorders had changed significantly 12 months after training, on parameters related to the general practitioners' feelings ($p=0.001$). Doctors now felt more comfortable in dealing with somatising patients. Attitudes about other parameters related to aetiology and course of somatisation changed in the expected direction, but these changes were not statistically significant.

Conclusion

A short-time multifaceted training programme focussing on somatisation was accompanied by a significant change in general practitioners' attitude towards patients with somatoform disorders. Future research should look at the impact of this change on doctor-patient interaction and patient care during routine clinical work.

Keywords

Somatoform disorders, health personnel attitude, primary health care, education - continuing, randomised controlled trial.

4.1. Introduction

Somatising patients are highly prevalent in primary care (25% of patients)¹⁻³ and general practitioners (GPs) often express their frustration in dealing with them. A negative attitude, missed diagnoses and lack of treatment not only frustrate GPs, but may also affect patient care.^{4:5}

GPs rate about 15% of patient encounters as being difficult.^{6:7} Reported predictors for difficulty and frustration have included somatisation and a poor attitude towards psychosocial issues.⁷⁻⁹ Nevertheless, most GPs believe that patients with medically unexplained symptoms should be managed in primary care.¹⁰

Previous intervention studies focusing on doctor-patient relationships or psychiatric disorders in general have explored various ways of changing GPs' attitude. A pilot study of GPs participating in a Balint group demonstrated a positive effect on GPs' attitude towards patients with somatoform disorders.¹¹ Long training may also influence GPs' attitude towards psychiatric disorders in general.¹² Brief training increased GPs' confidence in dealing with depression in a before-and-after study,¹³ but a recent randomised controlled trial of cognitive behavioural therapy taught to GPs showed no major effect on GPs' attitude towards depression.¹⁴

The present intervention study targeted somatisation, which was defined both narrowly as *somatoform disorders* (according to ICD-10)¹⁵ and more broadly as *somatisation* according to Lipowski's definition (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).¹⁶

We aimed to evaluate the effect of a novel, multifaceted training programme on GPs' attitude towards somatising patients.

4.2. Methods

4.2.1. Setting

The study was performed in Vejle County, Denmark, which is a mixed rural and metropolitan area served by 121 practices (227 GPs). The assessment of GPs' attitude was performed as part of a larger study examining the effects of 'The Extended Reattribution and Management Model'.^{17:18}

4.2.2. General practitioners and randomisation

All GPs registered with the Vejle County health insurance were invited. Inclusion criteria were: Participation of at least 50% of GPs from a practice and minimum working hours of 2½ day per week. Enrolled practices were stratified by number of GPs per practice and by proportion of participating GPs in relation to the total number of GPs in practices (0.5, 0.75, 1.0). After inclusion was completed, the practices in each stratum were allocated to intervention or control (figure 1, table 1). A person not involved in the study performed the randomisation by drawing non-transparent lots containing code numbers. GPs were informed about their randomisation group.

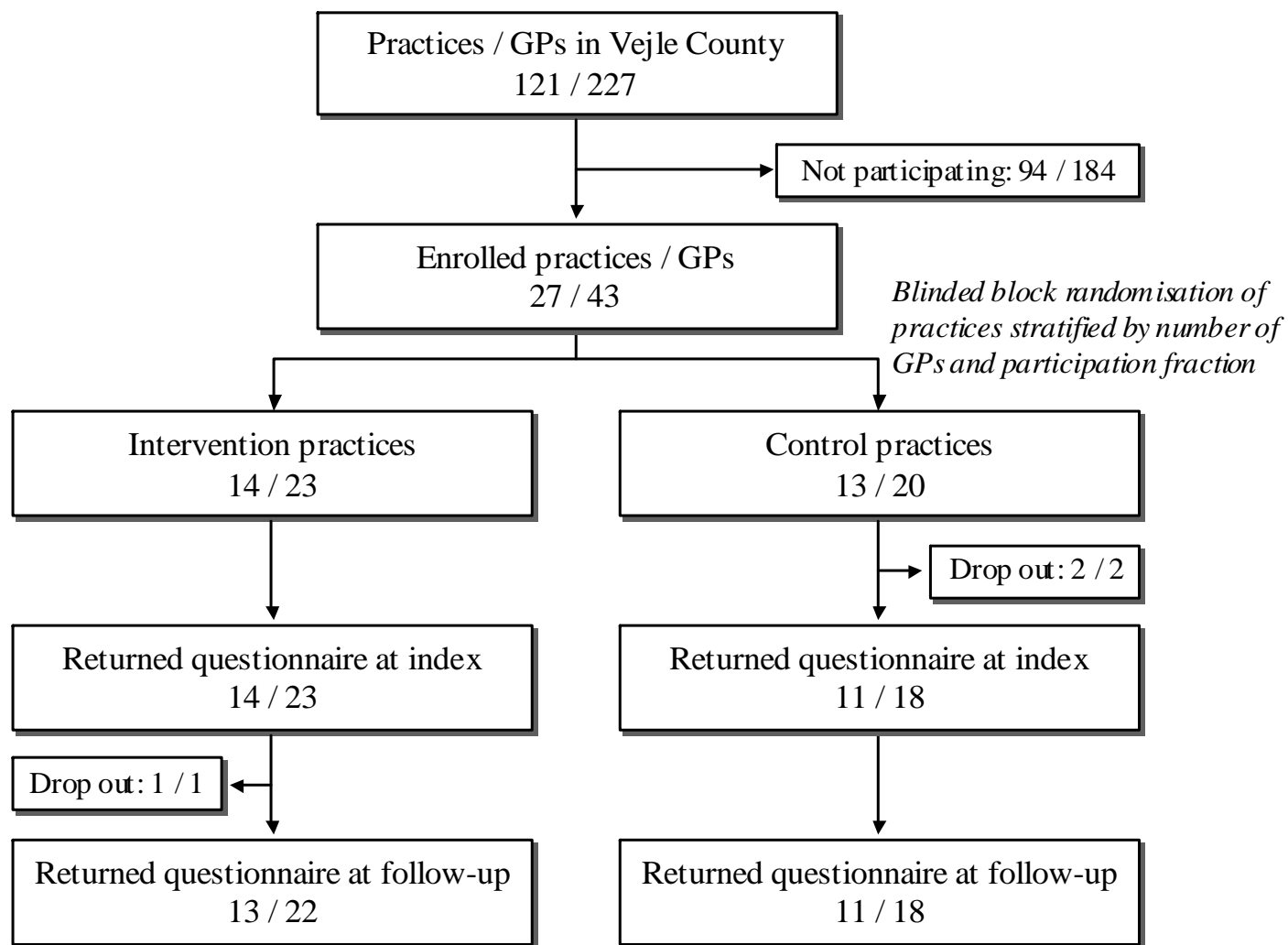
Figure 1. Flow of general practitioners through the trial

Table 1. Baseline characteristics for participating general practitioners

	Intervention n=23	Control n=18	p-value
Gender - men, n (%)	16 (69.6)	12 (66.7)	0.843 ^a
Age, mean (SD)	49.4 (7.9)	47.5 (4.5)	0.248 ^b
Seniority as GP, mean (SD)	12.5 (9.8)	7.9 (6.9)	0.130 ^b
Type of practice - partnership, n (%)	14 (60.9)	12 (66.7)	0.702 ^a
Practice geography - urban, n (%)	22 (95.7)	18 (100.0)	0.370 ^a
Number of GPs in practice, median (25-75% percentiles)	2 (1-4)	2 (1-2.25)	0.273 ^b
Number of listed patients per GP, mean (SD)	1492 (288)	1599 (238)	0.120 ^b
Previous longer courses, n (%) [*]	8 (34.8)	9 (50.0)	0.326 ^a
Previous supervision, n (%) [*]	10 (45.5) ^{**}	10 (55.6)	0.525 ^a

2 GPs dropped out from the study and are not included in this table.

^{*}Supervision and courses of at least 3 days duration concerning communication skills and psychiatric training

^{**}4.3% (n=1) missing within the intervention group

a) Chi-square test

b) Mann-Whitney's U test

4.2.3. Sample size

Power analyses were performed for the entire study.¹⁸ These analyses resulted in a desired sample size of 22 GPs in each arm (type 1 error 0.05 and type 2 error 0.20), which would be sufficient to show a 20% difference in this part of the study.

4.2.4. Intervention

Intervention consisted of a multifaceted educational programme on assessment, treatment and management of somatisation described in detail in a previous publication.¹⁷ Training started in April 2000 and several strategies were applied (figure 2). Control GPs were only informed about the definitions of somatisation. They were offered training after completion of the trial.

4.2.5. Outcome measures

We evaluated GPs' attitude towards somatisation using a self-administered questionnaire consisting of two parts (table 2). The first part was based on a previously used questionnaire concerning *somatoform disorders* and consisting of 9 items and a 7-point Lickert scale.¹¹ The second part was based on a validated questionnaire dealing with depression.¹⁹ The questions were adapted to *somatisation* generating 20 items with 10-cm visual analogue scales (VAS). The entire questionnaire was pilot tested by GPs not otherwise involved in the study. Five items were removed either because they were repeated within the questionnaire or because they seemed incompatible with the concept of somatisation.

Participating GPs were asked to answer this questionnaire one month before training (March 2000) and 12 months after training. Non-responders were reminded after two weeks, and if they still did not respond they were contacted by telephone.

Questionnaires were rated in two ways.

- Item rating: Items were analysed for all GPs before training. Differences between follow-up and baseline data were assessed for every GP and randomised groups were compared.
- Component rating: Items were combined in exploratory factor analyses for each part of the questionnaire. Factor differences between follow-up and baseline were calculated for every GP and analysed.

4.2.6. Statistics and software

Questionnaire data were processed using TELEform.²⁰ 'Intention to treat' analyses could not be performed as lost GPs did not provide necessary information. Although randomisation was carried out at practice level, individual GPs were chosen as the analytic unit because the intervention was targeted at individual GPs and because GPs within practices were found to change attitudes differently.

Chi-square tests, two-tailed T-tests and Mann-Whitney's U tests were used to compare randomised groups. Exploratory factor analyses including principal component analysis and Promax rotation procedures were performed separately for Lickert and VAS scales in order to summarize the relationship between items (minimum loadings of 0.3. applied).²¹ Statistical analyses were performed using SPSS²² and STATA²³.

4.2.7. Ethics and approvals

This study was approved by the local Ethics Committee, the Data Surveillance Authority and the Scientific Research Evaluation Committee of the Danish College of General Practitioners.

4.3. Results

Enrolment comprised 27 (43 GPs) practices randomised to intervention or control (figure 1). Two practices dropped out before the intervention. They were solo practices with male GPs (mean age 57 years). Participants completing the study did not differ from non-participants on selected parameters (table 1), except for urban doctors being in majority.

Randomised groups did not differ significantly (table 1). Training was completed by 22 GPs in the intervention group (residential course and minimum 2 follow-up meetings) and 20 GPs accepted the outreach visit.

4.3.1. GPs' attitude towards somatisation before training

GP attitudes did not differ significantly between randomisation groups before training. GPs generally scored low on attitudes on the Lickert scale (table 2, first column). However, the score reached at least 4 (=some) for 51% of GPs on the statement 'these patients take up too much of my time', for 44% on 'feeling unsure', 37% on 'enjoyment', 24% on 'worry', 17% on 'anxiety', and 13% on 'anger'. In the second part of the questionnaire, the 95% confidence intervals (CI) were placed outside the 5-cm area on the VAS for a number of items: GPs *agreed* to the influence of 'life conditions' and some of the proposed aetiologies (items 9, 14 and 15), but they *disagreed* on the existence of biochemical abnormality, that psychotherapy would be more beneficial than current treatments, that psychotherapy should be left to specialists, and that somatisation was not amenable to change. GPs found it difficult to differentiate self-limiting somatisation from somatisation requiring treatment. A score above 5 cm was seen in 90% of GPs for the statement 'working with somatising patients is heavy going'.

Figure 2. *The educational intervention*

Part of training programme	Contents	Time schedule
Residential course	<p>Didactic sessions</p> <p>Theory and evidence about somatisation</p> <p>Introduction to exercises</p> <p>Video clips of a trained GP applying skills in a consultation</p> <p>In groups of 8 with 2 supervisors</p> <p>3 rounds of group discussions</p> <p>8 modules of micro skills training in pairs and with amateur actors</p> <p>8 video supervisions of consultations performed with actors</p>	2 x 8 hours
Follow-up meetings	<p>Weekly meetings in groups of 8 with 2 supervisors</p> <p>Video supervision of consultations from practices</p>	<p>3 x 2 hours</p> <p>The weeks following the residential course</p>
Booster meeting	Small group discussions	2 hours after 3 months
Outreach visit	<p>A facilitator paid visits to practices aiming at a reinforcement of the learning process.</p> <p>The dialogue with GPs focused on incentives, barriers, strengths, weaknesses, opportunities and threats concerning the 'TERM-model' applied in routine clinical practice²³.</p> <p>Facilitators were supervisors from the course.</p>	½ hour after 6 months
Posted information	A letter describing the overall experiences from the outreach visits	After 9 months
Total time spent on course for each participant:		25 hours

4.3.2. Effects of training on GPs' attitude

Intervention entailed a significant decrease in GPs' negative attitudes towards patients with *somatoform disorders* and an increase in their professional satisfaction (table 2, figure 3). All answers changed in the expected direction.

The GPs' attitudes to *somatisation in general*, however, did not change to the same degree (table 2, figure 3). The largest observed difference in the control group was 0.7 cm, whereas differences in the intervention group exceeded 0.7 cm and went in the expected direction for 7 out of 17 items. The largest and only statistically significant change was found in item 16 showing that GPs felt more comfortable in dealing with somatising patients after training. Items 8 and 18 may not have been relevant in relation to the accomplished training.

Analyses of items at practice level using mean values for partnership practices confirmed the tendencies and statistical test results.

4.3.3. Factor analyses of questionnaires

Principal component analysis retained one component on the first part of the questionnaire, which was in accordance with our interpretation of the items. Items were summarized (item 4 reversed) and divided by the number of items. A low score reflected positive attitudes. Differences in component scores between individual GPs had a mean value of 0.1 (95% CI [-0.2; 0.4]) in the control group and -0.7 (95% CI [-1.0; -0.3]) in the intervention group (p -value = 0.001).

Analysis of the second part of the questionnaire was affected by the high number of items compared with the number of participants. Item 8, 18 and 20 were removed, as they fitted with no category either conceptually or during the analyses. Three possible components were identified: 'Inevitable course' (-item9 +item10 +item22 -item24), 'Aetiology' (-item11 -item13 -item14 -item15), and 'Professional unease' (+item12 -item16 +item17 +item19 -item21 +item23) (negative signs means that scales were reversed). Low scores indicated positive attitudes. Item 17 was thought to belong to 'Inevitable course' but was correlated with items 16 and 23 and thus kept in 'Professional unease'. Changes from baseline to follow-up showed a significant difference for 'Professional unease' between controls (mean 0.0, 95% CI [-8.5; 8.2]) and trained GPs (mean -1.1, 95% CI [-16.3; -5.0]) ($p=0.029$). Statistical analyses of other components showed no statistically significant difference between the groups.

4.4. Discussion

GPs expressed worry, uncertainty and frustration in relation to patients with somatoform disorders and they found working with somatising patients hard. Short-term multifaceted training of GPs induced a positive change in attitude. In particular, GP attitude saw a decline in negative and a rise in positive feelings.

Randomisation of practices combined with assessment of attitude before and after training provides strong evidence that the observed changes in attitude were related to the intervention. There was no indication of selection bias as only few GPs dropped out, and randomisation was successful according to baseline values. The time period of 12 months from training to evaluation ensured that the measured outcome reflects a sustained effect of training and not just a short-lived rapture.

Table 2. General practitioners' attitudes towards somatising patients

Results from questionnaires before and 12 months after training.

	Before training			Differences (after - before training)						
	(N=41)			Control (N=18)		Intervention (N=22)		p-value		
	n	Mean	Median	n	Mean	95% CI	n		Mean	95% CI
Questionnaire on 'Patients with Somatoform Disorder'										
'How do you typically react when you see a patient with somatoform disorder in your consultation?'										
Item 7. These patients take up too much of my time (<i>Much time</i>)	41	3.5	4	17	0.1	[-0.6; 0.8]	22	0.0	[-0.8; 0.7]	0.750 ^b
Item 2. I worry about missing physical disease and being sued (<i>Worry</i>)	41	2.9	3	17	-0.1	[-0.6; 0.3]	22	-0.6	[-1.2; 0.0]	0.197 ^b
Item 5. I feel anxious (<i>Anxiety</i>)	41	2.2	2	17	0.4	[-0.1; 0.9]	22	-0.6	[-1.1; -0.2]	0.019^b
Item 1. I feel angry (<i>Anger</i>)	40	2.0	2	17	0.2	[-0.2; 0.7]	21	-0.7	[-1.3; -0.0]	0.009^b
Item 4* I enjoy working with these patients (<i>Enjoyment</i>)	41	3.0	3	17	-0.2	[-0.9; 0.5]	22	0.9	[0.4; 1.3]	0.002^b
Item 3. I often feel unsure of what to do (<i>Unsure</i>)	41	3.4	3	17	-0.1	[-0.8; 0.5]	22	-1.0	[-1.5; -0.5]	0.008^b
Item 6** (I don't like seeing these patients in the consultation)										
Possible answers = 'not at all' (1) to 'very much' (7) on a 7 point Lickert scale										
Questionnaire on 'Somatising patients'										
'Please indicate a point on each line which best reflects your daily clinical experience'										
Component=Inevitable course										
Item 9* The majority of somatising conditions in general practice originate from patients' conditions of life (<i>Life conditions</i>)	41	6.5	[5.8; 7.2]	17	-0.6	[-1.9; 0.7]	22	-0.2	[-1.5; 1.2]	0.626 ^c
Item 10. Most somatising conditions in general practice improve without treatment (<i>Improve spontaneously</i>)	40	4.5	[3.7; 5.3]	16	0.3	[-1.0; 1.6]	21	-0.2	[-1.1; 0.7]	0.504 ^c
Item 24* If psychotherapy were freely available, this would be more beneficial for somatising patients than the current treatment (<i>PTH beneficial</i>)	41	4.1	[3.3; 4.9]	16	-0.1	[-1.3; 1.1]	22	0.3	[-1.1; 1.7]	0.662 ^c
Item 22. Psychotherapy does not seem to help somatising patients (<i>PTH no help</i>)	40	4.4	[3.7; 5.1]	15	-0.6	[-1.7; 0.5]	22	-1.3	[-2.4; -0.2]	0.345 ^b
Component = Aetiology										
Item 15* Somatising patients are more likely to have experienced deprivation in early life than other people (<i>Deprivation</i>)	41	6.8	[6.2; 7.3]	16	-0.3	[-1.1; 0.4]	22	0.0	[-0.8; 0.7]	0.613 ^c
Item 13* It is possible to distinguish two main groups of somatisation: stress induced and more genuine somatisation disorders (<i>Distinguish cause</i>)	40	5.3	[4.5; 6.1]	15	0.0	[-1.1; 1.4]	21	0.2	[-1.1; 1.5]	0.836 ^c
Item 14. Somatising is a way that people with poor stamina deal with life difficulties (<i>Dealing with difficulties</i>)	41	7.3	[6.7; 7.9]	17	0.4	[-0.2; 1.1]	21	-0.3	[-1.2; 0.6]	0.200 ^c
Item 11* An underlying biochemical abnormality is at the basis of severe cases of somatisation (<i>Biochemical</i>)	41	2.0	[1.3; 2.7]	17	0.1	[-0.8; 1.0]	22	1.3	[-0.1; 2.6]	0.865 ^b
Component = Professional unease										
Item 23. Psychotherapy for somatising patients should be left to specialists (<i>Specialist</i>)	41	3.8	[3.0; 4.7]	16	0.4	[-0.8; 1.7]	22	-0.5	[-1.7; 0.7]	0.275 ^c
Item 19. Working with somatising patients is heavy going (<i>Heavy going</i>)	41	6.8	[6.2; 7.4]	17	0.3	[-1.1; 1.6]	21	-0.7	[-1.4; 0.1]	0.190 ^c
Item 17. Somatisation reflects a characteristic response in patients which is not amenable to change (<i>No influence</i>)	41	3.7	[3.0; 4.4]	17	-0.2	[-1.3; 0.9]	22	-0.8	[-2.0; 0.3]	0.441 ^c
Item 12. It is difficult to distinguish self-limiting somatisation from somatisation that needs treatment (<i>Distinguish management</i>)	41	7.0	[6.4; 7.7]	16	-0.5	[-1.6; 0.6]	21	-0.9	[-1.9; 0.1]	0.568 ^c
Item 21* It is rewarding to spend time on somatising patients (<i>Rewarding</i>)	41	5.1	[4.5; 5.8]	16	-0.1	[-1.6; 1.4]	22	1.3	[-0.0; 2.5]	0.158 ^c
Item 16* I feel comfortable in dealing with somatising patients (<i>Comfort</i>)	41	4.5	[3.7; 5.2]	17	-0.3	[-1.6; 1.0]	22	2.2	[1.2; 3.2]	0.002^c
Others										
Item 8. During the last 5 years, I have seen an increase in the number of somatising patients (<i>Prevalence</i>)	41	5.2	[4.4; 6.0]	17	0.7	[-0.7; 2.1]	21	0.1	[-1.0; 1.3]	0.508 ^c
Item 18. A practice nurse who could support somatising patients would be useful (<i>Nurse</i>)	41	5.0	[4.2; 5.9]	17	0.7	[-0.8; 2.2]	22	0.6	[-0.8; 1.9]	0.909 ^c
Item 20. There is little to be offered to those somatising patients who do not respond to what their GPs do (<i>No alternatives</i>)	41	5.2	[4.4; 5.9]	17	0.2	[-1.3; 1.6]	21	-1.6	[-3.1; -0.1]	0.081 ^c
Possible answers='strongly disagree' (0) to 'strongly agree' (10) on a 10 cm visual analogue scale										

Items have been ordered according to factor analyses and size of effect in the intervention group. The item number reflects the original order in the questionnaire.

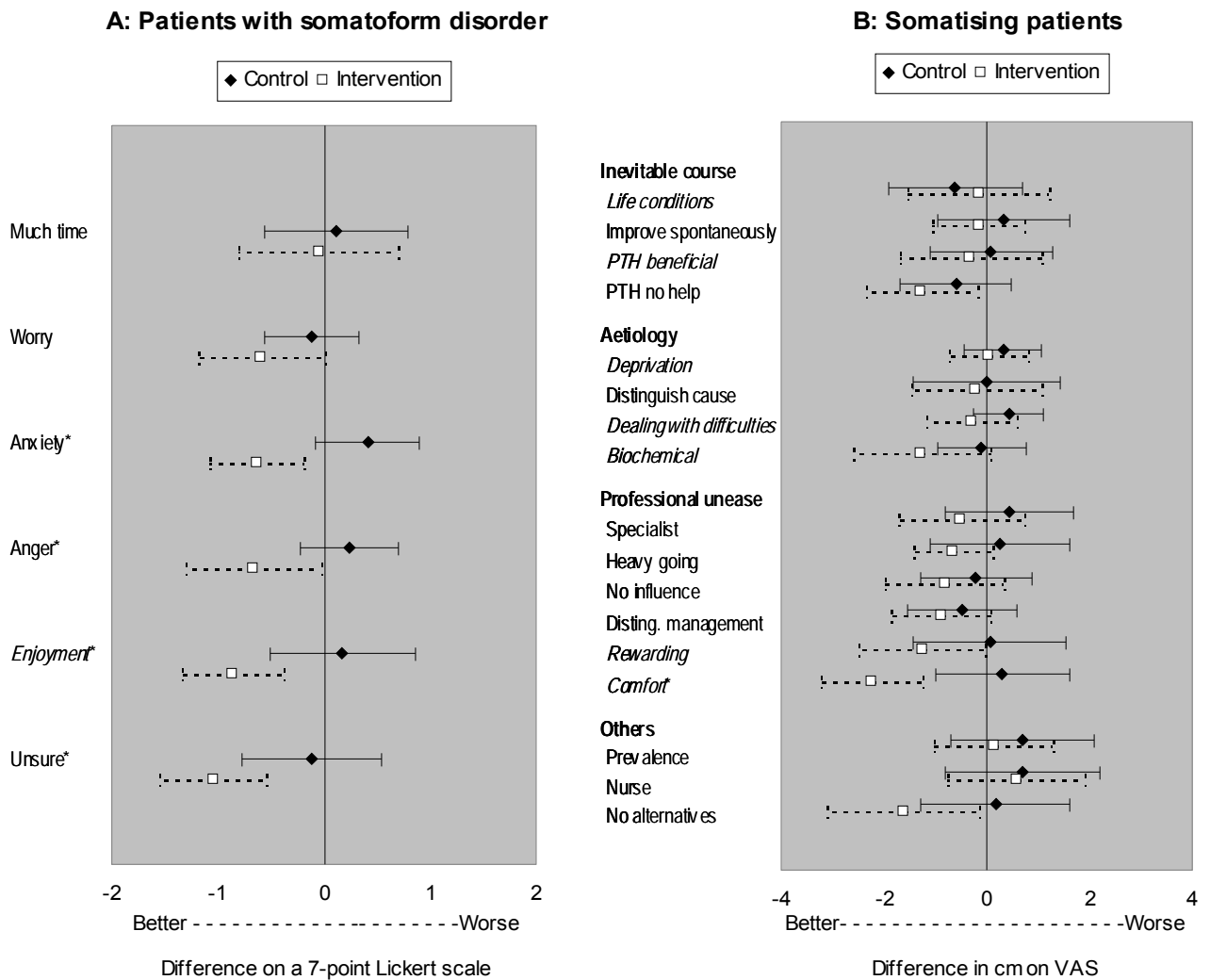
*Response values were expected to rise due to intervention

**Removed as the question during the translation into Danish became double negated and was impossible to answer unequivocally

b) Mann-Whitney's U test

c) T-test with equal variances

Figure 3. Change in GPs' attitudes towards patients with somatoform disorders (A) and somatising patients (B)



Differences in responses were calculated by subtracting baseline values from values 12 months after training and are illustrated with 95% confidence intervals.

Results for enjoyment, life conditions, psychotherapy beneficial, deprivation, distinguish cause, dealing with difficulties, biochemical, rewarding, and comfort have been reversed in the figures above.

- A. Somatoform disorder was defined according to ICD-10.
- B. Somatisation was defined according to Lipowski as ‘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’.

*Significant difference between groups (p<0.05)

A large and representative proportion of GPs in Vejle County participated in this study, which would seem to indicate that results may be generalised to general practice in similar settings. We can, however, not rule out that enrolled GPs took greater interest in somatisation than non-participants. Such a selection would not affect the overall conclusion on the effect of intervention, but it would bias baseline values and could question the generalisability of the effect size. A fact speaking against selection is that no difference was found between participants and non-participants on previous training in communication and psychiatry, though information was available for 60% of non-participants only.

The questionnaires used in this study were not validated in Denmark, but they were based on questionnaires used in previous studies of GPs' attitude and many questions were directed at themes that were raised during training. Furthermore, the validity of the results was supported by a concomitant qualitative study of participating GPs.²⁴

Multiple testing of the questionnaire items posed a problem of possible mass significance. However, all item responses went in the expected direction and component analyses supported the statistical results found in the item analyses.

Our study agrees with previous studies that GPs find it difficult to handle somatising patients⁶⁻⁸ and with the few studies that have indicated an effect of training on GPs' attitude.^{11;12} However, a recent randomised controlled study in the UK showed no effect on attitude towards depression six months after training.¹⁴ The second part of our questionnaire was developed from the questionnaire used in that study and demonstrated a statistically significant change in one item. This difference may be rooted in the different disorders targeted and the different interventions applied. Our data would seem to largely corroborate those of the British study concerning changes in attitudes towards illness course and aetiology.

4.4.1. Implications

According to this study, a short-term multifaceted training programme is able to produce a sustained change in GPs' attitude towards somatisation. GPs become more confident and find it less frustrating to deal with medical uncertainty. Seen in the light of problems with burnout in primary care, this is an important result. An altered and more positive attitude towards somatising patients is also a necessary step in the direction of better patient care. Future research should look at the impact of this change on doctor-patient interaction and patient care.

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What is already known on this topic

Somatising patients are highly prevalent in primary care, but general practitioners often express their frustration in dealing with them.

Educational interventions targeting mental disorders have shown a possible effect on general practitioners' attitude but only in small or uncontrolled studies. A recent randomised controlled trial failed to show any effect of training on general practitioners' attitude towards depression.

What this study adds

A short-term multifaceted educational programme produced a sustained change in general practitioners' attitude towards somatisation in a randomised controlled trial with 12-month follow-up.

Our study suggests that trained general practitioners may become more confident and find it less frustrating to deal with somatising patients.

Future research should look at the impact of an attitudinal change on doctor-patient interaction and patient care.

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Chapter 5

General practitioners' diagnosis of somatisation - effect of an educational intervention in a cluster randomised controlled trial

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Summary

Background

Somatisation is highly prevalent in primary care (25% of visiting patients) but often goes unrecognised. Non-recognition may lead to ineffective treatment, risk of iatrogenic harm and excessive use of health care services.

Aim

To examine the effect of training on general practitioners' (GPs') diagnosis of somatisation in routine clinical practice.

Design of study

A cluster randomised controlled trial with practices as randomisation unit.

Setting

27 general practices (43 GPs) in Vejle County, Denmark.

Method

Intervention consisted of a multifaceted training programme (the TERM-model). Patients were enrolled consecutively during 13 workdays. Psychiatric morbidity was assessed by means of a screening questionnaire. GPs categorised their diagnoses in another questionnaire. Primary outcome was the GPs' diagnoses of somatisation and agreement with the screening questionnaire.

Results

GPs diagnosed somatisation less frequently than previously observed but with much variation between GPs. The difference between groups in the number of diagnosis of somatisation fell short of significance at a 5% level ($p=0.094$). However diagnoses of medically unexplained physical symptoms were twice as high in the intervention group as in the control group (7.7% and 3.9% respectively, $p=0.007$). Examination of the agreement between GPs' diagnoses and screening questionnaire revealed no significant difference between groups.

Conclusion

Brief training increased GPs' awareness of medically unexplained physical symptoms. Diagnostic accuracy according to a screening questionnaire was not affected but was difficult to evaluate as a golden standard for somatisation in general practice is not agreed upon.

Keywords

Somatoform disorders, diagnosis, primary health care, education-continuing, randomised controlled trial, evaluation studies.

5.1. Introduction

Every day general practitioners (GPs) see patients presenting physical symptoms for which there is no specific diagnosis and for which medicine does not provide cure. The profusion of labels, like 'medically unexplained physical symptoms', 'somatisation' and 'hypochondria', testifies to the prevailing diversity in how these symptoms are conceived. We defined somatisation as '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' – as described by Lipowski¹. This definition encompasses the broad spectrum of disorders met in general practice.

Somatoform disorder may be diagnosed in 20-30% of primary care patients according to psychiatric standard interviews²⁻⁵. GPs only recognise about 50% of patients diagnosed by psychiatrists^{2,5}. Unrecognised cases may be left without proper treatment and risk iatrogenic harm and disablement in the course of ruling out physical disease^{6,7}.

A review of controlled interventional studies on mental disorders found that 18 of 23 trials showed improvement of diagnosis but none of the studied specifically addressed somatisation⁸. Educational interventions have increased GPs' detection rates of emotional distress⁹⁻¹¹ but failed to improve GPs' detection of depression in a recent randomised controlled study¹². Studies on somatisation have shown that training may improve interviewing skills¹³ and that implementation of new skills in daily clinical practice is feasible¹⁴. Interventions targeting diagnostic skills only may, however, be insufficient. Improving recognition also depends on improved possibilities of handling patients¹⁵.

This intervention study aims to evaluate the effect of a novel, multifaceted training programme on GPs' diagnosis of somatisation during routine clinical practice¹⁶. We hypothesised that trained GPs would recognise a larger number of somatising patients and agree better with psychiatric rating scales than control GPs.

HOW THIS FITS IN

What do we know?

Somatisation affects 20-30% of primary care patients; yet about half of these cases remain unrecognised. Training may improve general practitioners' interviewing skills and their recognition of emotional distress in general, but little is known about the effect of training on their diagnosis of somatisation in routine clinical practice.

What does this paper add?

A brief educational training in assessment, treatment and management of somatisation did not affect the overall number of diagnoses of somatisation but increased the general practitioners' awareness of medically unexplained physical symptoms. Intervention did not significantly affect agreement between the general practitioners and a screening questionnaire for somatisation.

5.2. Method

5.2.1. Setting

The study was performed in Vejle County, Denmark, which is a mixed rural and metropolitan area with 350,000 inhabitants served by 121 practices/227 GPs. The Danish health care system is tax-financed and 98% of Danes are listed with one general practice.

5.2.2. General practitioners and randomisation

GPs registered with the Vejle County Health Insurance were invited to participate in November 1999. Inclusion criteria were: Participation of at least 50% of GPs from a practice and minimum working hours 2½ day per week. Enrolled practices were stratified by number of GPs per practice (1-4) and proportion of participating GPs in relation to total number of GPs in practices (0.5-1.0). After ended inclusion practices in each stratum were allocated to intervention or control (Figure 1, Table 1). A person not involved in the study performed the randomisation by drawing non-transparent lots containing code numbers. Practices could not be blinded, but were asked NOT to inform patients about their grouping. All GPs received reimbursement for participation.

5.2.3. Patients

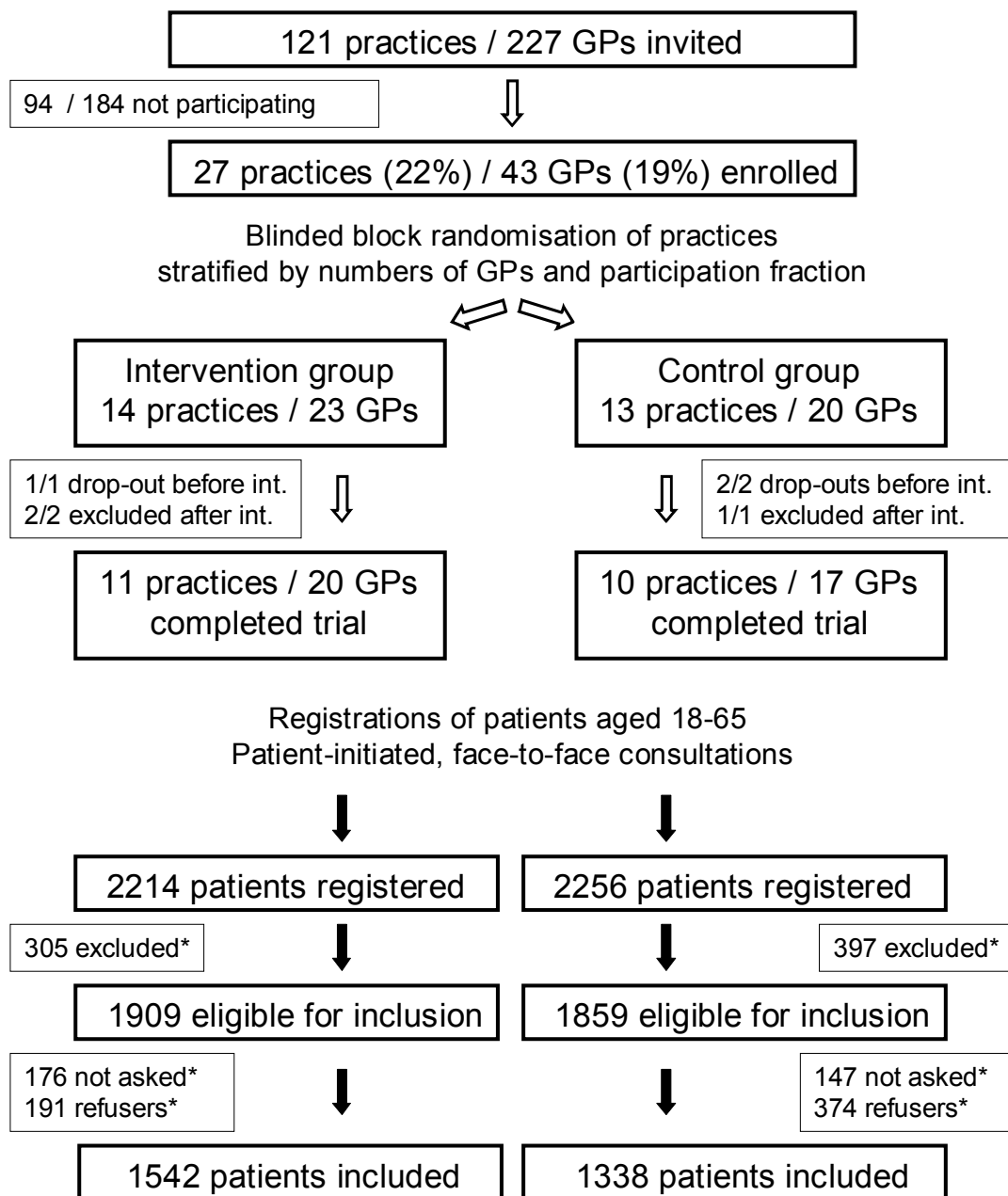
Practice secretaries enrolled patients consecutively during 13 working days (May 2000). Inclusion criteria were: 18-65-year-old consulting for a new health problem. Exclusion criteria were: acute severe disease, mental handicap, non-Scandinavian descent, not listed with participating GP, previously enrolled and participation not possible for other reasons (error in registration number, forgotten glasses, etc.) (Figure 1). Practice secretaries and GPs made registrations independently.

5.2.4. Sample size

The level of GP diagnoses was assessed from previous studies (20%). Standard power calculations showed that 1733 patients were to be included in each arm to obtain a minimum required difference in diagnoses of 20% (type 1 error 0.05, type 2 error 0.20). On average GPs would include 80 patients each yielding a desired sample size of 44 GPs in total. Subsequent power analysis based on the observed cluster adjusted standard error of diagnostic difference indicated a need for doubling of the GP sample size.

5.2.5. Intervention

Intervention consisted of a multifaceted educational programme on assessment, treatment and management of somatisation (the TERM-model), which rests on present theoretical and scientific knowledge about somatisation and adopts a cognitive oriented approach. It is described in detail elsewhere¹⁶ and is summarised in Figure 2. The education included positive criteria for somatisation and skills training in bio-psycho-social history taking. GPs in the intervention group were trained in April 2000. Control GPs were informed in writing and during meetings with the project head about the definitions of somatisation. They were offered the training programme following completion of the trial.

Figure 1. Practice randomisation and patient registration

*Excluded were patients with acute severe disease (19) or mental handicap (38), patients of non-Scandinavian descent (311), patients not listed with included GP (53) and patients who could not be included for other reasons (error in registration number or procedures, not able to read or write because of forgotten glasses or arm problems, one of the above but not specified, etc.) (281). A small number of visiting patients were not asked to participate by mistake (not asked) and some patients refused to participate when asked (refusers).

Table 1. *Baseline characteristics for participating general practitioners in Vejle County.*

	Participating GPs (N=37)		p-value
	Intervention n=20	Control n=17	
Gender - men, n (%)	15 (75.0)	11 (64.7)	0.495 ^a
Age, mean (SD)	48.1 (7.7)	47.9 (5.3)	0.729 ^b
Seniority as GP, mean (SD)	12.0 (9.8)	7.6 (7.0)	0.220 ^b
Type of practice - partnership, n (%)	14 (70.0)	12 (70.6)	0.969 ^a
Practice geography - urban, n (%)	19 (95.0)	17 (100.0)	1.000 ^a
Number of GPs in practice, median (25-75% percentiles)	3 (1-4)	2 (1-3)	0.125 ^b
Number of listed patients per GP, mean (SD)	1526 (291)	1645 (185)	0.141 ^b
Previous longer courses, n (%) [*]	6 (30.0)	8 (50.0) ^{**}	0.221 ^a
Previous supervision, n (%) [*]	9 (47.4) ^{**}	8 (50.0) ^{**}	0.877 ^a

^{*}Supervision and courses of at least 3 days duration concerning communication skills and psychiatric training

^{**}Missing information on one GP

a) Chi-square test

b) Mann-Whitney's U test

Figure 2. *The training accomplished in the intervention group before the patient inclusion.*

Residential course

(2 x 8.5 hours including breaks)

Didactic sessions (3 hours in total)

Theory and evidence about somatisation

Introduction to exercises

Video clips of a trained GP applying skills in a consultation

In groups of 8 with 2 supervisors (11 hours in total)

3 rounds of group discussions

8 modules of micro skills training in pairs and with amateur actors

8 video supervisions of consultations performed with an actor

Follow-up meetings

(3 x 2 hours following the residential course, minimal attendance of 2 meetings required)

Weekly meetings in groups of 8 with 2 supervisors

Video supervision of consultations from practices

Total time spent on training was 23 hours per participant

5.2.6. Outcome measures

Baseline characteristics on GPs were obtained from the Vejle County Health Insurance and from questionnaires on GPs' postgraduate training. Included patients completed a screening questionnaire in the waiting room prior to their consultation. Independent hereof the GP filled in a questionnaire after the consultation. Results from questionnaires were only revealed to the project head.

Two ratings were made.

- GP diagnosis: GPs were asked to classify the main problem presented by the patient in one of five categories (Table 2). During analyses diagnoses were dichotomised into 'physical disease' or 'somatisation'.
- Psychometric assessment: A somatisation subscale from the Hopkins Symptoms Check List (SCL-SOM)¹⁷ and a scale for illness worrying and conviction (Whiteley-7)¹⁸ were applied. Patients were asked about symptoms during the past 4 weeks. Answers were given on a 5-point Likert scale. Both scales were dichotomised between 'a little bit' and 'moderately', and cut points used were 3/4 for SCL-SOM and 1/2 for Whiteley-7. Compared to a standardised interview (Schedules for Clinical Assessment in Neuropsychiatry) sensitivity, specificity, and positive predictive values for any somatoform disorder were 0.378/0.833/0.586 for SCL-SOM and 0.311/0.856/0.574 for Whiteley-7 (personal communication FIP-study, 25/10 2002). Screening was positive if scoring was high on at least one scale.

Primary endpoints were the GPs' diagnosis of somatisation and their diagnostic agreement with rating scales.

5.2.7. Statistics and software

Questionnaire data were processed using TELEform formulas¹⁹. 'Intention to treat' analyses at GP level could not be performed, as lost GPs did not provide necessary information. At patient level information was missing for 15% of refusers. Consequently, analyses were performed using complete data only. Analyses at patient level were adjusted for patient gender and clusters. Although randomisation was carried out at practice level, clustering within GPs was thought to be of greater importance for diagnoses than clustering within practices. Chi-square test was applied to dichotomous data and t-test or Mann-Whitney's U test to continuous data. We used general linear models with identity link for Bernoulli family, i.e., modelling the risk differences, when adjusting analyses. This was supplemented by the Wald test in a combined analysis of diagnostic categories. The intra-cluster variation was assessed by the one-way ANOVA for random-effects model. Statistical analyses were performed with STATA SE 8.0 and SPSS 10.0 for Windows^{20;21}.

5.2.8. Ethics and approvals

This study was approved by the Ethics Committee for Funen and Vejle County, the Data Surveillance Authority and the Scientific Research Evaluation Committee of the Danish College of General Practitioners.

5.3. Results

Twenty-seven practices/43 GPs were enrolled and randomised to intervention (14 practices/23 GPs) or control (13 practices/20 GPs) (Figure 1). Three practices dropped out before

intervention and another three were excluded because of low rates of patient inclusion. Participants completing the study had practiced family medicine for fewer years than non-participants (10.0 compared to 12.8, $p=0.038$) and were from urban areas (97.3% compared to 56.0%, $p<0.001$) but did not otherwise differ from non-participants on parameters listed in Table 1. Randomised groups did not differ significantly on selected parameters (Table 1).

Participation was refused by 15% of patients eligible for inclusion and 9% were not asked by mistake (Figure 1). Refusers were older than participants (mean 45.3 compared to 39.7 years, $p<0.001$) and more of them were diagnosed by GPs as somatisers (19.5% compared to 12.6%, $p<0.001$).

82.3% of participating patients had symptom duration of less than 6 months and 32.0% scored positive on the screening questionnaire. Randomised groups only differed in two respects at patient level: the inclusion rate was 81% in the intervention group, 72% in the control group. Men accounted for 41.3% in the former group, 35.0% in the latter ($p<0.001$).

5.3.1. Effect of intervention on the GP's classification

Dichotomisation of diagnoses into 'physical' and 'non-physical' (somatisation) revealed that 14.2% of the main problems were classified as 'non-physical' by intervention GPs compared with 10.8% by control GPs (diagnostic difference 3.5%, 95% Confidence Interval (CI) [-0.6-7.5], $p=0.094$, adjusted for patient gender and clusters). Clustering was found to have a strong impact on results as the estimated intra-cluster correlation coefficient was 0.027 (95% CI [0.008-0.045]) and clusters were large. The proportion of patients diagnosed as somatisers varied much among GPs, even within practices with mean 13.5% (range 3.3%-33.9%) in the intervention group and mean 10.3% (range 2.5%-21.9%) in the control group. This variation could not be accounted for by disparities between GPs' patient populations assessed by scores on the screening questionnaire (for details please consult the table and figure for the electronic version).

Analyses of the original five-item questionnaire revealed a significant difference in the overall classification ($p=0.049$, adjusted for patient gender and clusters). GPs in the intervention group classified twice as many patients with 'medically unexplained symptoms' than control GPs ($p=0.007$) and fewer with 'physical disease' ($p=0.085$) (Table 2).

Subgroup analyses showed no relation between classification and GPs' gender, age, number of listed patients, participation in previous courses or supervision. However, numbers in subgroups were small.

The skewed patient inclusion necessitated separate analysis of refusers. Like participants, refusers were more often classified as somatisers in the intervention group (22.1%) than in the control group (18.3%) (adjusted diagnostic difference: 3.0, 95% CI [-6,8-12,7], $p = 0.551$).

5.3.2. Effect on classification compared with rating scales

In both groups GPs diagnosed more patients as somatisers if the screening questionnaire was positive (19.5%) than if it was negative (9.3%). The agreement between GP assessments and screening questionnaire results did not differ significantly between groups (Table 3).

For each GP we calculated sensitivity and specificity using the score from the screening questionnaire as reference. The sensitivity varied considerably between GPs with a mean of 19.9% (SD 11.1) in the intervention group and 16.6% (SD 8.9) in the control group. The specificity mean was 89.9% (SD 7.1) and 92.2% (SD 5.1), respectively.

Table 2. The general practitioner's classification of the main problem presented by the patient in

Numbers of patients are presented according to classification and randomisation group.

Classification category	Intervention		Control		Adjusted diagnosis	
	Number	%	Number	%	$\Delta\%^{**}$	95% CI
1. Physical disease	960	68.2	918	74.0	-6.2	[-13.3 - 0.9]
2. Probable physical disease	247	17.6	188	15.2	2.8	[-3.1 - 8.7]
<i>Subtotal physical</i>	(1207)	(85.8)	(1106)	(89.2)		
<hr style="border-top: 1px dashed black;"/>						
3. Medically unexplained symptoms	109	7.7	48	3.9	4.0	[1.1 - 6.9]
4. Mental illness	29	2.1	35	2.8	-0.8	[-3.2 - 1.6]
5. No physical symptoms	62	4.4	51	4.1	0.2	[-2.2 - 2.6]
<i>Subtotal non-physical (somatisation)</i>	(200)	(14.2)	(134)	(10.8)		
Total	1407	100	1240	100		
Missing	135	9.6	98	7.9		
					Combined analysis	
					p=0.001	

*All analyses were **adjusted** for patient gender and clustering of patients within GPs

**The diagnostic difference was calculated by subtracting percentage in control group from percentage in intervention group

***Comparisons of each classification category against the sum of others.

† Comparison of all classification categories in one analysis

The GPs' diagnoses were dichotomised around the broken line for the diagnosis of somatisation

Table 3. *The general practitioner's classification of the patient's main problem as 'somatisation' or 'physical disease' compared with results from a patient screening questionnaire*

GP classification	Screening questionnaire				Total
	Positive ¹		Negative ²		
	Number	%	Number	%	
GP+					
Intervention	98	21.0	97	10.5	195
Control	66	17.6	68	8.0	134
$\Delta\%$ agreement*	3.4 [-3.4 - 10.1]				
p-value*	0.327				
GP-					
Intervention	368	79.0	829	89.5	1197
Control	308	82.4	787	92.0	1095
$\Delta\%$ agreement*	-2.5 [-6.1 - 1.0]				
p-value*	0.161				
Total intervention	466	100	926	100	1392
Total control	374	100	855	100	1229

GP+: Dichotomised classification by general practitioner = medically unexplained symptoms, mental illness or no physical symptoms

GP-: Dichotomised classification by general practitioner = physical or probable physical disease

- 1) The dichotomised score on Whiteley-7 OR SCL-SOM was positive
- 2) The dichotomised score on Whiteley-7 AND SCL-SOM was negative

*Analyses were adjusted for patient gender and clustering of patients within GPs.

The diagnostic difference was calculated by subtracting percentage in the control group from percentage in the intervention group.

259 included patients (9.0%) had missing information on either GP diagnosis or screening questionnaire

Subgroup analyses indicated effect modification by gender and previous longer courses, but not by GP age, number of listed patients or previous supervision. The difference in agreement between intervention and control group was 3.01 for female GPs compared with -6.04 for male GPs (difference between gender: 9.05, 95% CI [3.11–14.99], $p=0.003$). For GPs who previously had attended courses, the difference was 1.70 compared with -6.39 for other GPs (difference = 8.09, 95% CI [0.14–16.03], $p=0.046$). Results from subgroup analyses must be interpreted with caution, as this study was not designed to investigate the effect of GP factors.

5.4. Discussion

5.4.1. Summary of main findings

A large and representative number of GPs in Vejle County participated indicating that the results may be generalized to a similar setting. GPs diagnosed somatisation less frequently than observed in previous studies, but inter-GP variation was substantial. Our intervention did not significantly affect the overall classification of symptoms but it increased GPs' awareness of medically unexplained physical symptoms. Intervention failed to improve diagnostic accuracy assessed by the use of rating scales.

5.4.2. Strengths and limitations of this study

The study was carried out as a randomised controlled trial during routine practice, making even small effects valuable. The intervention addressed both diagnosis and treatment of the whole spectrum of somatisation as previously recommended¹⁵. To strengthen the study even more, cluster randomisation was performed at practice level limiting contamination of the control group.

The effect of the intervention may have been overestimated as 'intention to treat' analyses could not be performed. The numbers of GPs leaving the study were, however, identical in both groups indicating non-differential drop out. Selection bias may also have contributed to the difference. Despite successful GP randomisation, the control group included fewer patients than the intervention group and refusers were more likely to be diagnosed as somatisers. On the other hand, the effect of the intervention may also have been underestimated by 1) GPs being forced to make only one diagnosis despite being taught the complexity of problems, 2) the intervention targeting treatment more than diagnostic criteria for somatisation, and 3) the fact that changing GPs' behaviour is a complex process that may take much longer than the limited time available in this study. A Hawthorne effect would have been present in both groups and would tend to reduce the magnitude of differences. Furthermore, the number of enrolled GPs and patients did not reach the planned sample size and the cluster effect turned out to be considerable, both of which served to make the study underpowered.

Estimating diagnostic accuracy poses several problems: Most patients in this study presented symptoms of less than 6 months' duration making application of the ICD-10 diagnosis for somatoform disorder unsuitable. Furthermore, diagnoses in general practice are made over time, whereas the assessment of accuracy is often cross sectional²². We chose rating scales for measuring accuracy. They are subject to a large degree of uncertainty and do not always reveal whether a problem noted is related to the reason for encounter. Finally, GPs' diagnosis of somatisation has previously been shown only to be weakly associated with questionnaires based on psychiatric diagnostic classifications²³. Currently, these scales are, however, our best tools for rating somatisation by the use of questionnaires.

5.4.3. How and why our study agrees or disagrees with the existing literature

Only 12.6% of patients were diagnosed as somatisers compared with 20-30% in previous studies²⁻⁵. This could be a result of our dichotomisation. Altering the dichotomy to 'entirely physical disease' and 'others' would yield numbers close to those previously found but would not be consistent with our conception of somatisation. Another reason for the low diagnostic rates could be that participants represented a large proportion of GPs from Vejle County also including those without special interest in mental disorders. Finally, a diagnostic rate similar to ours was reported by Weich et al, when they looked at the number of patients having emotional distress of relevance to the reason for encounter²⁴.

Previous studies have shown that GP training may affect diagnosis of mental disorders and interviewing skills⁸, but a recent study on depression failed to show any effect of education on recognition¹². In the same study members of the UK Royal College of General Practitioners showed increased sensitivity in diagnosing depression. Like indicated in our study this was at the cost of decreased specificity when compared to rating scales²⁵. The possible increase in sensitivity is consistent with previous results on somatisation in follow-up studies¹³ and our study adds the certainty of a cluster-randomised design.

5.4.4. Implications for future research or clinical practice

Training of GPs may increase their awareness of medically unexplained physical symptoms in relation to patients' reason for encounter. This has, to our knowledge, not been demonstrated in a randomised controlled trial before. However, the accuracy of an increased number of diagnoses of medically unexplained symptoms is uncertain and needs further investigation. Assessment of GPs' diagnoses depends on the establishment of a golden standard for somatisation applicable to general practice and should be supplemented by evaluation of longitudinal diagnoses.

Acknowledgements

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Supplementary table for the electronic edition

General practitioners' classification of the main problem presented by the patient in the consultation.

The ratio of patients with a diagnosis of somatisation is presented for each GP.

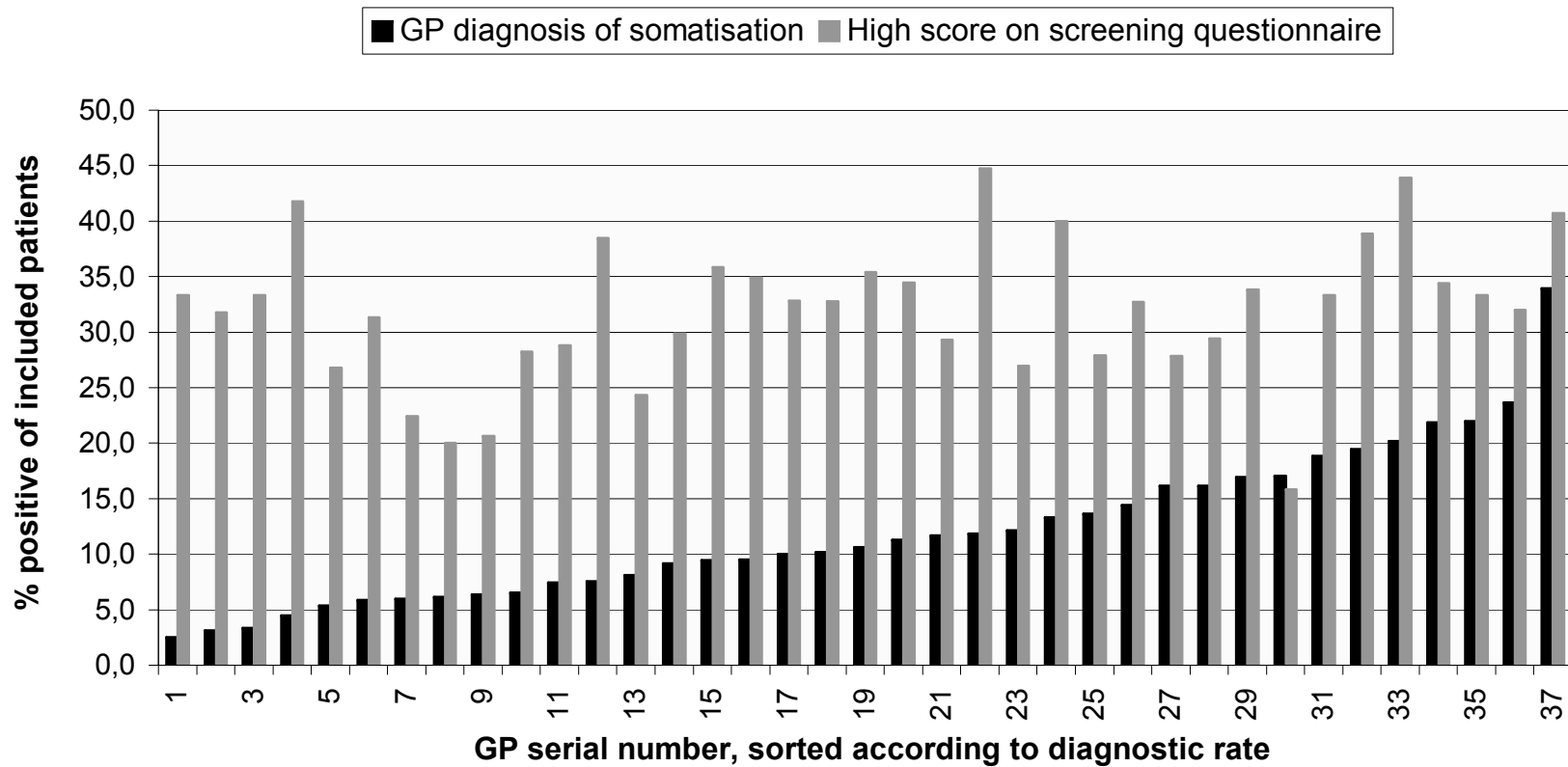
GP from practice	Intervention group			Control group			
	Number of patients Included	GP+	% GP+	GP from practice	Number of patients Included	GP+	% GP+
A	60	2	3.3	E	79	2	2.5
*	67	3	4.5	E	64	2	3.1
B	68	4	5.9	*	56	3	5.4
A	65	4	6.2	*	50	3	6.0
*	46	3	6.5	F	63	4	6.3
C	53	4	7.5	G	67	5	7.5
*	63	6	9.5	*	74	6	8.1
A	59	6	10.2	H	87	8	9.2
D	62	7	11.3	*	53	5	9.4
C	76	9	11.8	H	70	7	10.0
*	66	8	12.1	E	66	7	10.6
A	60	8	13.3	E	77	9	11.7
D	99	16	16.2	G	88	12	13.6
*	68	11	16.2	*	111	16	14.4
*	82	14	17.1	F	65	11	16.9
*	72	14	19.4	*	106	20	18.9
B	109	22	20.2	G	64	14	21.9
B	100	22	22.0				
B	76	18	23.7				
D	56	19	33.9				
Sum	1407				1240		
Mean (SD)			13.5 (7.7)				10.3 (5.4)

GP+: Dichotomised classification by general practitioner = medically unexplained symptoms, mental illness or no physical symptoms

*Single handed practice

Supplementary figure for the electronic edition

General practitioners' classification of the main problem presented by the patient in the consultation as 'somatisation' compared with results from a patient screening questionnaire for somatisation.



Chapter 6

Does general practitioner training targeting somatisation affect patient outcome? A cluster randomised controlled trial

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Prepared for publication

Summary

Background

Somatising patients are highly prevalent in primary care but many go unrecognised. General practitioners are often unable to provide proper treatment and patients therefore risk iatrogenic harm and poor health.

Objectives

Our aim was to evaluate the effect on patient outcome of a short-term educational programme focussing on general practitioners' assessment and treatment of somatising patients.

Methods

Evaluation was performed during routine clinical care in a cluster randomised controlled trial with practices as randomisation units. Practice secretaries included patients consecutively and those with a high score on rating scales for somatisation were selected for follow-up. Follow-up was conducted three and twelve months after inclusion using questionnaires measuring quality of life (SF-36), disability days (WHO-DAS), somatisation (Whiteley-7 and SCL-SOM) and patient satisfaction (EUROPEP). We analysed differences from baseline to follow-up between intervention and control groups.

Results

The somatisers' self-reported health improved in both intervention and control groups during follow-up, but changes were small. Statistically significant differences between groups were only observed for 'bodily pain' and 'social functioning', and the changes were most pronounced in the control group (not corrected for mass significance). Other differences between groups fell short of statistical significance, including our primary outcome 'physical functioning'. Patients in the intervention group tended to be more satisfied at follow-up than those in the control group.

Conclusion

Data from the present patient sample showed no statistically significant effect of general practitioner training on clinical outcome or patient satisfaction with care.

Keywords

Somatoform disorder, education-continuing, primary health care, randomised controlled trial, evaluation studies, quality of life, intervention studies, family practice, mental health, disability evaluation, patient satisfaction, medically unexplained symptoms.

6.1. Introduction

General practitioners (GPs) attend many continuing medical education activities (CME). How these activities influence patient outcome during routine practice is, however, seldom evaluated.

GPs have expressed a need for CME-activities addressing somatisation¹. The GPs' need and a necessity for improved care for somatising patients have been met with the launch of an educational programme entitled 'The Extended Reattribution and Management Model'².

Somatisation may be defined as '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' (Lipowski, 1988)³. This definition encompasses the broad spectrum of somatisation met in general practice and it includes somatoform disorders according to the diagnostic classification systems (the American Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) and the WHO's International Statistical Classification of Diseases and Related Health Problems (ICD-10)).

Somatisation is highly prevalent in general practice where 20-30% of patients fulfil the criteria for somatoform disorders according to standard psychiatric interviews^{4,5,5-7}. Despite its high prevalence, somatisation often goes unrecognised^{5,6,8}. The default use of biomedical approaches causes iatrogenic harm and disablement to the somatising patients^{9,10}, and previous studies have demonstrated significant health problems¹¹.

Treatment of somatising patients has been evaluated in a number of studies, but few have centred on primary care undertaken by GPs. A review on primary care interventions aimed at improving treatment of mental disorders reported a positive effect on clinical outcome in eight of sixteen studies of which only three specifically targeted somatisation¹². Another review found a consistent effect of cognitive behavioural therapy (71% of 31 controlled trials) on physical health in somatising patients. In these studies treatment was, however, provided by mental health specialists¹³.

Primary care treatment for somatisation has taken two main directions¹⁴. One approach has been shared care, where mental health specialists have offered GPs patient assessment and treatment guidelines. Another approach has been to educate GPs to improve their management of somatisation within their own setting. Such a programme ('The Reattribution Model') has been tested in before-after studies and showed a possible effect after three months on the patients' physical functioning and psychiatric disorders, but only for somatisers who believed their symptoms to have a partial physical cause¹⁵. The patients' illness attribution and satisfaction also improved¹⁶. A related programme was tested in a randomised controlled trial and showed a significant effect on subjective health and sick leave after two years¹⁴. In this study GPs were told which patients they were supposed to apply the model to; an approach that is difficult to implement in routine practice.

'The Extended Reattribution and Management Model' was developed to address the whole spectrum of patients with medically unexplained symptoms seen in general practice². Our aim was to evaluate the effect of routine application of this short-term educational programme on patients' physical health, mental health and satisfaction with care.

6.2. Methods

6.2.1. Setting

The study was performed in Vejle County, Denmark, which is a mixed rural and metropolitan area with 350,000 inhabitants served by 121 practices (227 GPs). The Danish health care system is tax-financed and 98% of Danes are listed with one general practice.

Key learning points

Background: Somatisation is highly prevalent in general practice but may go unrecognised. General practitioners feel poorly educated in this field and are often unable to provide effective treatment. There seems to be a potential for improving management of somatisation in primary care for the benefit of patients, general practitioners and the health care system.

The present study was conducted to investigate the effect on patient outcome of a recently developed educational programme ('The Extended Reattribution and Management Model') designed to improve care for patients presenting with medically unexplained physical symptoms (somatisation) in general practice.

The overall changes in self-reported health measured on the SF-36 subscales, the SCL-8 and disability days were small and so were changes in scores for somatisation (Whiteley-7 and SCL-SOM). Training of general practitioners had no statistically significant effect on patient outcome in terms of physical function, quality of life, disability days, symptom scores, illness worry or satisfaction after one-year of follow-up.

New skills can only be brought to use if the general practitioners actually recognise somatising patients. We therefore analysed the subgroup of patients who were diagnosed by their doctors. The diagnostic rates in practices were surprisingly low and the subgroup analyses therefore threw no new light on the possible effects of education on patient outcome.

Only a few interventional studies have been conducted focussing on treatment of somatisation by general practitioners. Our results differ from some of the previous studies and it remains an important issue whether and how professional education affects patient outcome.

6.2.2. General practitioners and randomisation

GPs registered with the Vejle County Health Insurance were invited to participate in November 1999. Inclusion criteria were: Participation of at least 50% of GPs from a practice and minimum working hours of 2½ day per week. Enrolled practices were stratified by number of GPs per practice (1-4) and proportion of participating GPs in relation to the total number of GPs in practices (0.5-1.0). After inclusion was completed, practices in each stratum were allocated to intervention or control (Figure 1). A person not involved in the study performed the randomisation by drawing non-transparent lots containing code numbers. Participating GPs could not be blinded but were asked *not* to inform patients about their grouping. All GPs received reimbursement for participation

6.2.3. Patients

Practice secretaries enrolled patients consecutively during 13 working days (May 2000). Inclusion criteria were: 18-65-year-old consulting for a new health problem. Exclusion criteria were: acute severe disease, mental handicap, non-Scandinavian descent, not listed with participating GP, previously enrolled and participation not possible for other reasons (error in registration number, forgotten glasses, etc.) (Figure 1).

Follow-up was conducted for *somatising patients, defined as patients with a positive score on one of two rating scales for somatisation (SCL-SOM¹⁷, Whiteley-7¹⁸)*. Items in the two rating scales were dichotomised between “a little bit” and “moderately”. Scales were scored using cut points 3/4 for SCL-SOM and 1/2 for Whiteley-7. Somatising patients were sent a questionnaire three and twelve months after inclusion. This also included patients, who left Vejle County (approximately 3%) or changed their listing with practices (approximately 1%) during follow-up. If patients did not respond to questionnaires, reminders were sent after three weeks.

6.2.4. Sample size

Power analyses were performed for the entire study producing a desired sample size of 22 GPs in each arm (type 1 error 0.05 and type 2 error 0.20)¹⁹. Renewed standard power analyses for the outcome ‘physical functioning’ based on estimates from previous studies (mean 44, standard deviation 20) showed that 78 somatising patients were to be included in each arm to obtain a 20% difference in functioning. These analyses did not allow for clustering of patients within GPs. Subsequent analysis taking GP clusters into account yielded an intra-class correlation coefficient for differences close to zero and thus a minimal cluster effect.

6.2.5. Intervention

Intervention comprised a multifaceted educational programme on assessment, treatment and management of medically unexplained physical symptoms (the TERM-model)² (Table 1). The programme included positive criteria for somatisation, skills training in bio-psycho-social history taking, a general treatment model for somatisation and advice on management of chronic cases. GPs in the intervention group were trained during April 2000.

Control GPs were only informed about the definitions of somatisation in writing and during meetings with the project head. They were offered the training after completion of the trial.

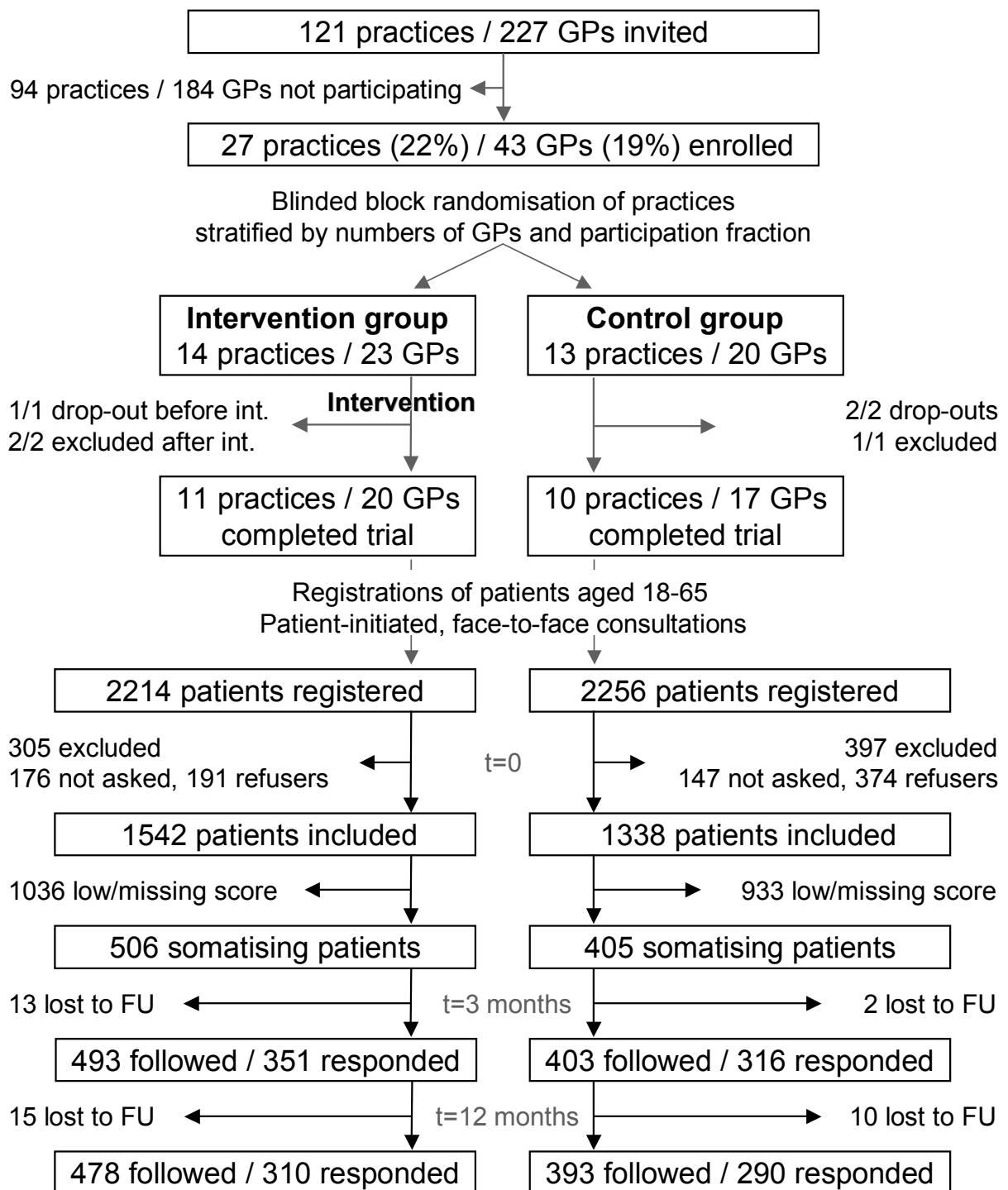
6.2.6. Outcome measures

GP Baseline characteristics were obtained from the Vejle County Health Insurance and from questionnaires on their postgraduate training in communication and psychiatry.

Included patients completed a self-administered screening questionnaire in the waiting room prior to their consultation. Follow-up was performed by postal questionnaires three and twelve months after inclusion. All of the patient questionnaires included the following measures:

- SF-36 (Medical Outcomes Study short-form)²⁰
This brief measure of quality of life comprises eight dimensions for which *high scores* indicate *better* quality of life. Subscales and summary components were scored according to guidelines²⁰. The primary outcome measure was physical health.

Figure 1. Randomisation of practices, patient registration and follow-up of patients with high score on a patient screening questionnaire



Excluded were patients with acute severe disease (19) or mental handicap (38), patients of non-Scandinavian descent (311), patients not listed with included GPs (53) and patients who could not be included for other reasons (error in registration number or procedures, not able to read or write because of forgotten glasses or arm problems, one of the above but not specified etc. (281)). A small number of visiting patients were not asked to participate by mistake (not asked) and some patients refused to participate when asked (refusers).

Table 1. *The educational intervention*

Part of training programme	Contents	Time schedule
Residential course	<p>Didactic sessions</p> <p>Theory and evidence about somatisation</p> <p>Introduction to exercises</p> <p>Video clips of a trained GP applying skills in a consultation</p> <p>In groups of 8 with 2 supervisors</p> <p>3 rounds of group discussions</p> <p>8 modules of micro skills training in pairs and with amateur actors</p> <p>8 video supervisions of consultations performed with actors</p>	2 x 8 hours
Follow-up meetings	<p>Weekly meetings in groups of 8 with 2 supervisors</p> <p>Video supervision of consultations from practices</p>	<p>3 x 2 hours</p> <p>The weeks following the residential course</p>
Booster meeting	Small group discussions	2 hours after 3 months
Outreach visit	<p>A facilitator paid visits to practices aiming at a reinforcement of the learning process.</p> <p>The dialogue with GPs focused on incentives, barriers, strengths, weaknesses, opportunities and threats concerning the 'TERM-model' applied in routine clinical practice²³.</p> <p>Facilitators were supervisors from the course.</p>	½ hour after 6 months
Posted information	A letter describing the overall experiences from the outreach visits	After 9 months
Total time spent on course for each participant:		25 hours

- WHO-DAS (WHO's Disability Assessment Schedule)
We used only one question from the WHO's questionnaire: 'in the past 4 weeks, for how many days were you totally unable to carry out your usual activities or work because of any health condition?'
- Whiteley-7¹⁸
This short version of the Whiteley index measures illness worry and conviction.
- SCL-SOM (Hopkins Symptom Checklist¹⁷)
This is a 12-item subscale measuring somatisation by symptom score.
- SCL-8 (Hopkins Symptom Checklist¹⁷)
This 8-item subscale measures mental illness in general.

In the scales Whiteley-7, SCL-SOM and SCL-8 patients were asked about symptoms during the past four weeks and answers were given on 5-point Lickert scales. *High scores* indicated *poor* mental health. When used as outcome measures, mean values were calculated for each scale by summarising item scores and dividing by number of answered items. If more than half of the items within a scale were missing, all items were set missing.

The follow-up questionnaires also included:

- EUROPEP²¹
This instrument measured patient satisfaction with primary health care. EUROPEP consists of 23 items grouped as: doctor-patient relationship, medical-technical care, information and support, and organization of service. The first three groups were related to our intervention and were analysed. Items were also analysed separately. Analyses of categories were based on dichotomisation of single items²¹ and subsequent dichotomisation of groups between 'all items answered positively' and 'at least one item answered negatively', corresponding to the 75% percentile.

The GPs answered questionnaires on eligible patients immediately after the index consultations. GPs were asked to classify the main problem presented by the patient in one of five categories, later dichotomised into 'physical disease' or 'somatisation'¹⁹.

Applied questionnaires were pilot tested before the trial in non-participating general practices.

6.2.7. Statistics and software

Questionnaire data were processed using TELEform 6.1. 'Intention to treat' analyses at GP level could not be performed, as lost GPs did not provide the necessary information. At patient level information was missing for non-responders. Consequently, analyses were performed using complete data only. 'Intention to treat' analyses were, however, applied to responders who left the county or were listed with another GP during follow-up.

Chi-square or Mann-Whitney's U test were applied to data concerning GPs. Analyses at patient level were performed using linear regression or logistic regression. At this level 95% confidence intervals (CI) and tests of longitudinal changes within groups were adjusted for GP clusters. Tests of differences between randomised groups were adjusted for patient gender, patient age and GP clusters. The intra-cluster variation was assessed by the one-way ANOVA for random-effects model. Statistical analyses were performed with SPSS 10.0 and STATA SE 8.0 for windows.

6.2.8. Ethics and approvals

This study was approved by the Ethics Committee for Funen and Vejle County, the Data Surveillance Authority and the Scientific Research Evaluation Committee of the Danish College of General Practitioners.

6.3. Results

6.3.1. General practitioners

Enrolment comprised 27 practices (43 GPs) randomised to intervention or control group (Figure 1). Three practices dropped out before intervention and another three were excluded because of low rates of patient inclusion. Participants completing the study had practiced general medicine for fewer years than non-participants (10.0 compared with 12.8, $p=0.038$) and were from urban areas (97.3% compared with 56.0%, $p<0.001$) but did not otherwise differ from non-participants on parameters listed in Table 2.

Randomised groups did not differ significantly on selected parameters (Table 2). The GPs in the intervention group who completed the trial all accomplished training by participation in the residential course and at least two follow-up meetings. Nineteen of twenty GPs accepted the outreach visit.

6.3.2. Patients at baseline

Participation was refused by 15% of the eligible patients and 9% were not asked by mistake (Figure 1). Refusers were older than participants (mean 45.3 vs. 39.8 years, $p<0.001$) and more were diagnosed by GPs as somatisers (19.5% vs. 12.6%, $p<0.001$).

The intervention group saw a higher inclusion rate (81%) than the control group (72%). Scores on the screening questionnaire for somatisation were positive for 33% in the intervention group and 30% in the control group. Patients included for follow-up scored lower on the SF-36 subscales at baseline than the Danish normal population, except for 'role-emotional'²⁰ (Table 2).

Ceiling and floor effects were analysed for the SF-36 and WHO-DAS. They were generally low and were all below 50%.

Randomised groups differed on two of the listed parameters (Table 2). Somatising patients in the intervention group were more often unskilled and had poorer ratings for 'general health' than patients in the control group.

6.3.3. Follow-up of somatising patients

Twelve-month follow-up questionnaires were sent to 94% of somatising patients (i.e. patients with high scores for somatisation) in the intervention and 98% in the control group. The response rates were 71% and 78% at three months and 65% and 74% at twelve months. Deaths amounted to four in each group.

Each group was analysed separately for changes in outcome measures over time. Individual changes varied widely, but overall changes were small both at three and twelve months (Table 3). An improvement was observed in both groups for most parameters after twelve months. 'Role-physical', 'bodily pain', 'the physical component summary', the transition question, Whiteley-7, SCL-SOM, and SCL-8 improved statistically significantly in both groups. 'General health', 'vitality', 'social functioning' and disability days only improved significantly in the control group.

Table 2. Baseline characteristics for participating general practitioners and patients included for follow-up

	Control	Intervention	P-value
Characteristics for general practitioners			
No of participants	17	20	
No (%) of men	11 (64.7)	15 (75.0)	0.495 ^a
Mean age	47.9 [45.2; 50.6]	48.1 [44.5; 51.7]	0.729 ^b
Mean seniority as GP	7.6 [4.0; 11.2]	12.0 [7.4; 16.6]	0.220 ^b
No (%) of partnership practices	12 (70.6)	14 (70.0)	0.969 ^a
No (%) of urban practices	17 (100.0)	19 (95.0)	1.000 ^a
Median (25-75% percentiles) number of GPs per practice	2 (1-3)	3 (1-4)	0.125 ^b
Mean number of listed patients per GP	1645 [1550; 1740]	1526 [1390; 1662]	0.141 ^b
No (%) of GPs having attended previous longer courses [#]	8 (50.0)*	6 (30.0)	0.221 ^a
No (%) of GPs having attended previous supervision [#]	8 (50.0)*	9 (47.4)*	0.877 ^a
Patient characteristics			
No with a high score on SCL-SOM or Whiteley-7	405	506	
No (%) men	127 (31.4)	192 (37.9)	0.099 ^c
Mean age	42.2 [40.9; 43.4]	41.6 [39.6; 43.6]	0.599 ^c
No (%) with symptom duration < 6 months	283 (76.1)	355 (76.5)	0.915 ^c
No (%) diagnosed as somatisers by GP	66 (17.7)	98 (21.0)	0.330 ^c
Socio-demographic characteristics			
No (%) living with partner or spouse (v living alone or with parents)	279 (69.4)	337 (67.8)	0.660 ^c
No (%) having accomplished primary school only (v further school education)	231 (57.8)	295 (60.7)	0.447 ^c
No (%) unskilled (v accomplished formal education)	111 (28.9)	175 (36.8)	0.023^c
No (%) employed (v students, unemployed, pensioners, etc.)	240 (61.5)	273 (57.6)	0.295 ^c
SF-36, subscales (0-100)			
Physical functioning, median (25-75% percentiles)	84.2 (65.0-95.0)	80.0 (61.1-95.0)	0.608 ^c
Role-physical, mean	50.3 [44.3; 56.3]	49.9 [45.3; 54.6]	0.930 ^c
Bodily pain, mean	48.0 [44.8; 51.1]	49.6 [46.8; 52.4]	0.414 ^c
General health, mean	58.8 [56.1; 61.6]	54.3 [52.1; 56.5]	0.005^c
Vitality, mean	50.0 [47.3; 52.7]	48.3 [46.2; 50.3]	0.262 ^c
Social functioning, median (25-75% percentiles)	75.0 (62.5-100)	75.0 (62.5-100)	0.642 ^c
Role-emotional, median (25-75% percentiles)	100 (33.3-100)	100 (33.3-100)	0.666 ^c
Mental health, mean	67.0 [64.4; 69.5]	65.6 [63.4; 67.8]	0.382 ^c
SF-36, component summaries and transition question			
Physical component summary, mean	41.6 [40.2; 43.0]**	41.6 [40.1; 43.0]**	0.975 ^c
Mental component summary, mean	47.4 [45.8; 49.0]**	46.4 [44.9; 47.9]**	0.342 ^c
Health compared to 1 year ago, mean	3.2 [3.1; 3.3]	3.2 [3.1; 3.3]	0.683 ^c
Disability days			
Median number of disability days (0-28) (25-75% percentiles)	1 [0; 8]	0 [0; 7]**	0.559 ^c
Psychological screening			
SCL-SOM score (1-12), median (25-75% percentiles)	2.3 (2.0-2.6)	2.3 (1.9-2.6)	0.565 ^c
Whiteley-7 score (1-7), median (25-75% percentiles)	2.0 (1.6-2.5)	2.1 (1.7-2.6)	0.438 ^c
SCL-8 score (1-8), median (25-75% percentiles)	1.9 (1.5-2.6)	2.0 (1.5-2.8)	0.636 ^c

Information was missing on less than 10% of patients except when marked**

Mean values are stated with 95% confidence intervals in []

[#]Supervision and courses of at least 3 days duration concerning communication skills and psychiatric training

*Missing information on one GP

**Missing information on 10-15% of patients

a) Chi-square test

b) Mann-Whitney's U test

c) Logistic regression adjusting for GP clusters

Baseline values for patients not responding at the twelve-month follow-up were analysed separately. Non-responders were younger (39.4 vs. 43.1 years, $p < 0.001$), more of them were men (42.3% vs. 31.8%, $p = 0.001$) and unskilled (39.0% vs. 30.0%, $p = 0.001$), and fewer were living with a partner (63.0% vs. 71.7%, $p = 0.039$). They did not differ from responders with regard to the other parameters listed in Table 2.

Non-responders did not differ between randomised groups except for their larger number in the intervention group. However, responders at twelve months were healthier at baseline in the control group than in the intervention group according to SCL-SOM ($p = 0.045$) and 'general health' ($p = 0.018$).

6.3.4. Effect of intervention on physical and mental health

A large number of items was analysed to examine the possible effect of intervention (Table 3). After three months no statistically significant differences or definite pattern in the differences between groups were observed. At twelve months the overall pattern of differences between randomised groups appeared to favour the control group, though most differences were small (Figure 2). Two patients in the intervention group having extreme negative differences (-73 and -85) could explain the larger improvement in the control group. Removing those patients from the analyses changed outcome on physical functioning to favour the intervention group (adjusted difference 0.4, 95% CI [-2.4-3.1]). Most differences between intervention and control groups, including our primary outcome 'physical functioning' and 'physical component summary', fell short of significance. Statistical significance was only observed for 'bodily pain' and 'social functioning'.

The number of patients having no disability days during the past 28 days increased from 50.2 at baseline to 55.3 after twelve months in the intervention group compared with 47.8 and 55.3 in the control group.

Supplementary analyses were performed at the twelve-month follow-up on the subgroup of somatising patients who were also diagnosed by their GPs (Figure 2). The GPs' diagnostic rate was lower than expected, and numbers produced for analysis were small (41 to 58). The physical functioning improved 1.4 units (95% CI [-5.9-8.2]) and the physical component summary improved 2.2 units (95% CI [-1.8-6.2]) more in the intervention group than in the control group ($p = 0.271$). There was no specific pattern in the differences between randomised groups (Figure 2) and none of them were statistically significant. Disability days decreased 1.7 days in the control group (95% CI [-4.3 - 1.0]) and increased 1.0 day in the intervention group (95% CI [-2.4 - 4.4]), an insignificant difference ($p = 0.212$).

Furthermore, we analysed subgroups of patients according to age (dichotomised at 45 years) and gender. These analyses showed similar results, i.e. an inconsistent pattern of positive and negative differences between groups with few significant differences.

6.3.5. Effect of intervention on somatisation

Our somatisation measures were SCL-SOM and Whiteley-7. Improvements in scores were very small in both groups and randomised groups did not differ significantly.

Supplementary analyses of somatising patients diagnosed by their GPs showed that patients in the intervention group improved more on Whiteley-7 and SCL-SOM than patients in the control group: for the intervention and control group changes were -0.3 (95% CI [-0.5-0.0]) and -0.2 (95% CI [-0.4-0.1]), respectively, for Whiteley-7 and -0.2 (95% CI [-0.4-0.0]) and -0.1 (95% CI [-0.3-0.1]) for SCL-SOM. These differences, however, fell short of statistical significance.

Table 3. Differences in scores on patient questionnaires at follow-up compared with baseline for somatising patients.

3 months follow-up ÷ baseline	Control		Intervention		Adjusted difference [#]	
	N	Mean 95% CI*	N	Mean 95% CI*	Δ Mean 95% CI*	P-value**
SF-36 - 8 subscales (0-100)						
Physical functioning	311	-0,3 [-2.2; 1.6]	328	-0,1 [-2.3; 2.2]	0,3 [-2.6; 3.1]	0,854
Role-physical	300	5,8 [2.6; 9.1]	326	3,4 [-0.6; 7.5]	-2,5 [-7.4; 2.4]	0,307
Bodily pain	311	8,2 [4.6; 11.8]	339	5,0 [2.9; 7.0]	-3,5 [-7.4; 0.5]	0,087
General health	310	-0,7 [-3.1; 1.7]	317	1,0 [-0.6; 2.6]	1,6 [-1.2; 4.3]	0,252
Vitality	309	-0,6 [-2.5; 1.3]	336	-0,9 [-2.8; 1.0]	-0,2 [-2.9; 2.5]	0,852
Social functioning	317	1,0 [-1.0; 2.9]	342	-1,1 [-3.7; 1.5]	-2,3 [-5.4; 0.8]	0,138
Role-emotional	298	0,4 [-5.9; 6.7]	321	0,5 [-4.1; 5.2]	0,1 [-7.5; 7.6]	0,989
Mental health	311	0,8 [-1.4; 3.1]	336	-0,7 [-2.4; 1.0]	-1,5 [-4.3; 1.2]	0,253
SF-36, component summaries and transition question						
Physical component summary (0-100)	272	1,5 [0.4; 2.6]	280	1,1 [0.3; 1.9]	-0,4 [-1.7; 0.9]	0,484
Mental component summary (0-100)	272	-0,1 [-1.4; 1.2]	280	-0,6 [-1.7; 0.5]	-0,5 [-2.1; 1.1]	0,548
Health compared with 1 year ago (1-5)	316	-0,1 [-0.3; 0.0]	338	-0,1 [-0.2; 0.0]	0,1 [-0.1; 0.2]	0,417
Disability days						
WHO-DAS (0-28)	294	-0,7 [-1.6; 0.1]	302	-0,3 [-1.4; 0.8]	0,5 [-0.8; 1.8]	0,460
Psychological screening						
Whiteley-7 (1-7)	314	-0,3 [-0.4; -0.2]	348	-0,3 [-0.4; -0.2]	0,0 [-0.1; 0.1]	0,975
SCL-SOM (1-12)	315	-0,2 [-0.3; -0.2]	351	-0,2 [-0.2; -0.1]	0,1 [0.0; 0.1]	0,210
SCL-8 (1-8)	314	-0,2 [-0.3; -0.1]	348	-0,1 [-0.2; -0.0]	0,1 [0.0; 0.2]	0,193
Respondents, n (response rate)	317 (78%)		352(71%)			
12 months follow-up ÷ baseline						
SF-36 - 8 subscales (0-100)						
Physical functioning	284	0,8 [-0.9; 2.6]	288	0,5 [-1.7; 2.8]	-0,1 [-2.9; 2.7]	0,890
Role-physical	271	9,3 [5.1; 13.4]	289	4,6 [0.7; 8.5]	-4,6 [-9.9; 0.7]	0,085
Bodily pain	287	10,5 [8.5; 12.5]	293	6,5 [3.8; 9.3]	-4,1 [-7.4; -0.8]	0.015
General health	277	1,9 [-0.3; 4.1]	286	0,5 [-1.1; 2.2]	-1,3 [-3.9; 1.4]	0,341
Vitality	282	1,9 [-0.5; 4.4]	300	-0,4 [-2.4; 1.6]	-2,3 [-5.3; 0.7]	0,128
Social functioning	290	2,6 [-0.2; 5.4]	303	-1,5 [-4.0; 1.0]	-4,2 [-7.8; -0.6]	0.022
Role-emotional	271	1,9 [-3.4; 7.2]	286	-2,4 [-7.8; 2.9]	-4,2 [-11.3; 3.0]	0,244
Mental health	283	1,0 [-1.9; 3.8]	299	0,4 [-1.9; 2.6]	-0,5 [-4.1; 3.0]	0,756
SF-36, component summaries and transition question						
Physical component summary (0-100)	247	2,7 [1.8; 3.5]	245	2,0 [1.0; 2.9]	-0,7 [-1.9; 0.5]	0,247
Mental component summary (0-100)	247	0,2 [-1.4; 1.8]	245	-0,6 [-1.8; 0.6]	-0,8 [-2.7; 1.1]	0,416
Health compared with 1 year ago (1-5)	287	-0,5 [-0.6; -0.3]	299	-0,4 [-0.5; -0.3]	0,1 [-0.1; 0.2]	0,205
Disability days						
WHO-DAS (0-28)	272	-1,1 [-2.1; -0.2]	270	-0,9 [-2.0; 0.2]	0,3 [-1.1; 0.2]	0,708
Psychological screening						
Whiteley-7 (1-7)	285	-0,4 [-0.4; -0.3]	307	-0,3 [-0.4; -0.2]	0,1 [-0.1; 0.2]	0,367
SCL-SOM (1-12)	284	-0,2 [-0.3; -0.2]	304	-0,2 [-0.2; -0.1]	0,1 [0.0; 0.2]	0,229
SCL-8 (1-8)	285	-0,2 [-0.3; -0.1]	306	-0,1 [-0.2; 0.0]	0,1 [-0.1; 0.2]	0,317
Respondents, n (response rate)	290 (74%)		311(65%)			

For the SF-36 subscales and summaries a high score reflects well-being and a positive adjusted difference indicates better outcome in the intervention group, except for the transition question.

For the SF-36 transition question, disability days and psychological screening, a low score reflects well-being and a negative adjusted difference indicates better outcome in the intervention group.

[#]Mean[†] specifies the mean of differences for patients' scores at follow-up minus scores at baseline. 95% confidence intervals are stated in []

[#] Differences are calculated by subtracting the mean value in the control group from that of the intervention group. They have been adjusted for patient gender, patient age and GP clusters

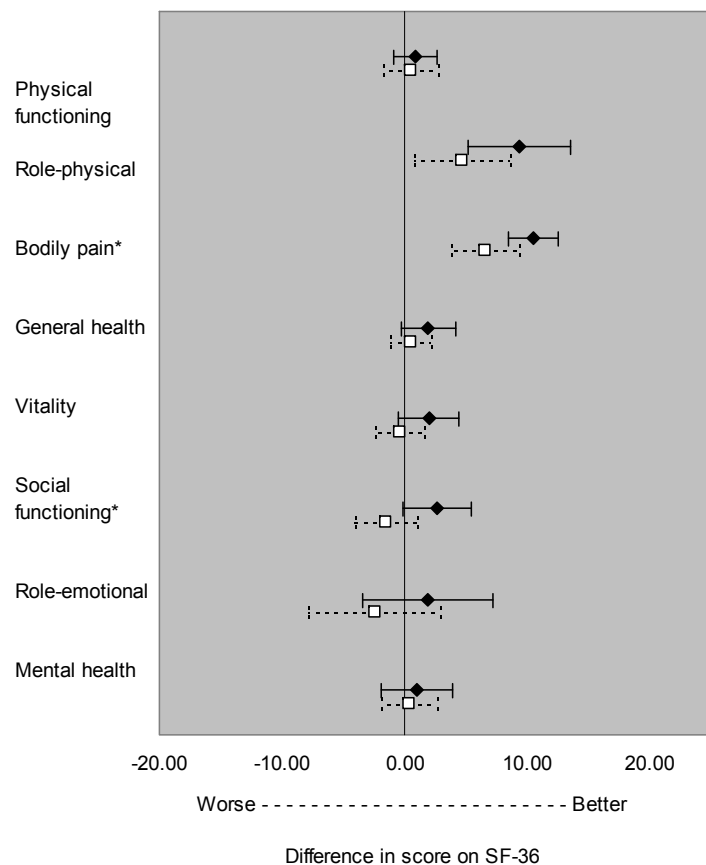
* Confidence intervals are adjusted for GP clusters

**Linear regression adjusting for patient gender, patient age and GP clusters

Figure 2. Mean differences in scores on the eight subscales of the SF-36 for somatising patients according to randomisation group.

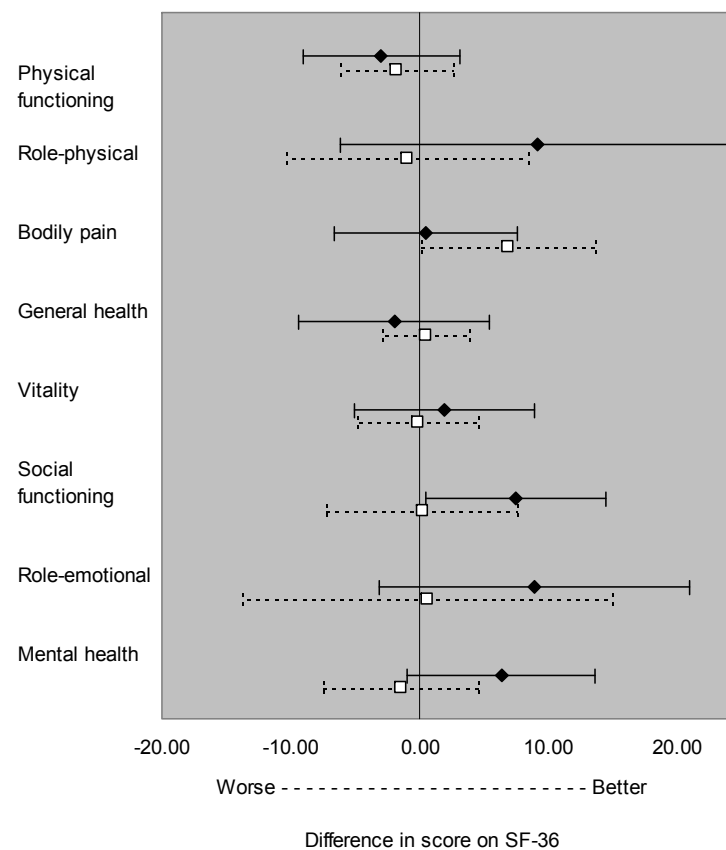
A: All somatising patients

◆ Control (n=271-290) □ Intervention (n=286-303)



B: Somatising patients diagnosed by GPs

◆ Control, GP+ (n=41-44) □ Intervention, GP+ (n=53-56)



Scores at baseline were subtracted from scores at 12 months follow-up (possible values for differences are -100 to 100)

* p<0.05

6.3.6. Effect of intervention on patient satisfaction with care

Patient satisfaction was only measured at three and twelve months and could not be directly compared as we asked for satisfaction for different time intervals (the past three and the past twelve months, respectively). No statistically significant differences were observed at either time. Analyses of single items showed no specific pattern.

At twelve months, 38.8% of patients in the intervention group compared with 36.5% in the control group were satisfied with the doctor-patient relationship ($p=0.567$), 29.0% vs. 24.7% with medical-technical care ($p=0.237$) and 36.8% vs. 30.6% with information and support ($p=0.069$). These differences did not reach statistical significance, but patients in the intervention group were clearly more satisfied in all of the three groups than patients in control practices.

6.4. Discussion

6.4.1. Summary of main findings

The large and representative participation of GPs in Vejle County indicates that the results may be generalised to similar settings. The overall changes in self-reported health, symptom score and illness worry were small during one-year follow-up for patients with high scores on a screening questionnaire for somatisation. Training of GPs had no statistically significant effect on patient outcome regarding physical function, quality of life, disability days, somatisation or satisfaction with care after twelve months of follow-up.

6.4.2. Strengths and weaknesses of the study

The study was carried out during routine practice as a randomised controlled trial with follow-up. This is a robust design that makes even small effects valuable. Furthermore, randomisation was performed for clusters of practices limiting contamination of the control group. A large number of patients was included compared with previous studies and follow-up was performed on all but a few patients and with satisfactory response rates. Patients were included and answered baseline questionnaires before consulting the GPs, which ensured that baseline values were not affected by intervention. Finally the instruments chosen to measure outcome had previously been validated and produced low ceiling and floor effects in this study.

Changes in health measures were small and even tended to be lower in the intervention group than in the control group after one year. These findings were unexpected since intervention was based on principles that had previously had promising effects at patient level, and GPs' attitudes changed in a positive direction in the present study^{22,23}. The surprising nature of these results may be ascribed to 1) inclusion bias, 2) the sampling method, 3) inadequate instruments for measuring outcome, 4) a minimal effect of training within the first year, and 5) unchanged clinical practice in the intervention group.

Inclusion bias may have been present as the intervention practices had a higher inclusion rate and included a higher proportion of somatisers than control practices. Furthermore, their baseline scores on the SF-36 were poorer than those in the control group for included patients and for responders at the twelve-month follow-up. Somatisation may hence have been more chronic in the intervention than in the control group. Increased chronicity is correlated both with a poorer spontaneous improvement and with a poorer responsiveness to applied intervention. Bias may have been small, but if we also consider the fact that it took only two patients with extreme values to change the overall patterns, the bias may have been sufficient to produce the observed results.

Patients were included by the use of questionnaires in order to obtain a large sample. The applied screening questionnaires (SCL-SOM and Whitley-7) are, however, subject to a large degree of uncertainty. They have been validated against the ICD-10 diagnoses for somatoform disorders, but perform only moderately; in particular, the sensitivity was rather low. Furthermore, the diagnostic criteria of ICD-10 are not applicable to somatisation in general practice and GPs' diagnoses of somatisation are only weakly associated with questionnaires based on psychiatric classifications^{19,24}. Currently, these scales are, however, our best tools for rating somatisation by the use of questionnaires.

The included patients presented a wide spectrum of somatisation. Changes in outcome may, however, have occurred to different degrees and at different speeds in distinct subgroups of patients. Our choice of inclusion made it difficult to identify the relevant subgroups of patients that may have gained most from intervention.

We used previously validated questionnaires to measure outcome. The responsiveness of the SF-36 has been established in common clinical conditions²⁵. This general health measure was supplemented by specific measures for somatisation (SCL-SOM, Whiteley-7). These specific measures have primarily been developed for cross-sectional studies of mental disorders and their responsiveness is poorly described. Furthermore, possible positive changes in patients' illness attributions might have affected their answers to some of the psychological items in the questionnaires negatively.

We know only little about how the TERM-model was implemented in clinical practice. Previous studies have demonstrated that taught skills are learned and applied^{14,26}, and a qualitative study of the TERM-model rendered probable the implementation of parts of the model in routine practice²³. The time period for implementation may, however, have been too short and reinforcement too weak, as the acquisition of complex skills may not be straightforward for GPs. Finally, GPs must recognise somatisation to apply a new treatment. The GPs' diagnostic rates were low¹⁹, which resulted in small numbers for analyses and consequently in poor statistical test strength.

The questionnaires contained a large number of items yielding multiple statistical analyses. The few significant values found disappeared if corrected for mass significance.

6.4.3. Comparison with other studies

Some scores on the SF-36 subscales and scores on the psychological screening improved statistically significantly during follow-up. These results agree with a before-and-after study by Morriss et al¹⁵. Morriss et al, however, only found effect on the subgroup of patients who were not true somatisers, whereas our improvements applied to all patients sampled. Though changes in our scores on the SF-36 were statistically significant, they were, however, small and not clinically impressive²⁷.

Changes were small compared to previous interventional studies on somatisation. We did, however, use different questionnaires for the sampling of patients. In our study, patients generally produced better baseline scores on the SF-36, had fewer disability days, and most of them had a symptom duration of less than six months, whereas previous studies have been concerned with persistent somatisation. Blankenstein¹⁴ and Smith et al²⁸ observed a significant effect of intervention on clinical parameters in randomised controlled trials. Our results do not support those findings, but there are some important differences between the studies that should be addressed. The randomised controlled study by Smith involved assessment by an acknowledged psychiatrist, and GPs were given diagnosis and treatment instructions for selected patients²⁸. In Blankenstein's study, the GPs also knew exactly which patients they had to apply the new treatment to, as patients were selected for the GP by a research assistant (minimum 15 GP visits in the previous three years and somatisation

according to a questionnaire). Furthermore, treatment was reinforced by the use of GP protocols and patient diaries¹⁴.

The FIP-study, which is closely related to this study and applies the same inclusion, intervention and outcome measures, performed identical analyses and could not confirm the trend of a negative effect observed in this study (personal communication, July 2003). On the contrary, the FIP-study reports a statistically significant improvement in 'physical functioning' for patients with somatoform disorders according to both psychiatric diagnostics and the GP (personal communication, July 2003).

A recent study on depression failed to demonstrate improved patient outcome upon brief training of GPs and showed the same overall negative trend as our study²⁹. Their conclusion that it may be difficult for GPs to learn necessary skills in a short time is in line with a recent review of treatments stating that 'treatment seem to be more effective in patients in secondary care than in primary care'³⁰.

6.4.4. Meaning of the study and implications for future research

It is an important issue whether and how educational interventions affect patient outcome. It may, however, be difficult to measure significant changes at patient level, as small but important effects are watered down when a broadly defined group of patients is to benefit in routine clinical care. For the evaluation of educational interventions such as the TERM-model we may have to consider an approach where well-defined cases of somatisation are observed and GP recognition of cases is ensured. Such an approach would be methodologically stronger, but would suffer from the disadvantage of being less applicable to routine clinical practice.

Future research in the field of medically unexplained symptoms and somatisation would also gain from the development of improved illness-specific measuring instruments.

The time dimension must also be addressed in studies evaluating educational intervention. It may be that GPs require more time to acquire the complex skills needed for the management of somatisation, just as somatising patients may need more time for the process of change.

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Chapter 7

General discussion of methods

7.1. Introduction

This thesis set out to develop an educational programme for GPs in assessment and treatment of somatisation (Chapters 2 and 3). The effectiveness of the programme was evaluated at different outcome levels (Chapters 4-6). The applied methods and results have been discussed in detail during their presentation in the Chapters 2-6. This chapter will discuss the methods applied across chapters, but separately for the two parts of the study.

7.2. Development of the educational programme

Ideally, this programme should contain modules on evidence of somatisation, opportunities for attitudinal changes, and skills necessary to perform assessment and treatment of somatisation in general practice. To ensure implementation, multiple strategies should be applied [Chapter 1, Changing professional behaviour, page 11], and Grol et al has recommended that,

‘Any attempt to bring about change should first involve a ‘diagnostic analysis’ to identify factors likely to influence the proposed change.’¹

Such an explorative approach would serve to identify incentives and possible barriers to behavioural change in routine care.

We did not make a formal ‘diagnostic analysis’ of the GPs targeted, but we abided by the intentions of such an analysis by developing the TERM-model and the educational programme in a highly structured way [Chapter 3, Introduction, page 29] including:

- A literature search and expert knowledge retrieval in the process of programme drafting
- Contact to existing research groups working with ‘The Reattribution Model’ in order to learn from their experiences
- Adjustment of the outlined educational programme in continuous dialogue with a multidisciplinary research group with an overweight of GPs and psychiatrists
- Renewed adjustment after presentation and discussion of the programme in a group of GPs with long experience in teaching and supervision in primary care

We obtained evidence-based information sufficient to design a programme comprising modules on assessment and treatment of somatisation in general practice, skills in communication and cognitively oriented therapy, and multifaceted implementation strategies. We relied on the experience of other research teams and acknowledged GPs to ensure a programme acceptable to GPs and to optimise implementation. A supplementary explorative study in general practice might have further improved the intervention^{1;2} but could not be made within the time limits of this study.

It was important to enable replication and evaluation of the educational programme. For this purpose the programme and accompanying educational materials were described in detail during the process of development, and have been published in full (Chapter 3 and www.auh.dk/cl_psych/uk/).

Conclusion on methodological aspects of the development of the educational programme

A comprehensive approach based on cross-disciplinary and intersectorial cooperation ensured a theoretically sound basis for the educational programme, a treatment model acceptable to GPs, applicability in routine care, and practicability of implementation strategies.

7.3. Evaluation of the educational programme

This section will address questions of the internal validity of the evaluation study (design, intervention, sampling of participants, and information sources), essential statistical issues and the generalisability of results (external validity).

7.3.1. Setting

The setting for this project was Danish general practice. In Denmark, practices are small, independent units, and they are not geared to research as their resources are scarce and meant for treating the patients. Ideally, research projects in general practice would require the presence of designated research staff in the practices, but their presence would inevitably influence daily routines. Our aim was to investigate effects during routine care (effectiveness); and we accordingly had to design a trial that was feasible under the given circumstances.

7.3.2. Design

We focused our evaluation on quantitative assessments to answer the research questions put forward in this thesis [Chapter 1, Aim, page 14]. For this purpose a randomised controlled trial provides a very robust design³⁻⁵. This design serves to secure comparable groups, and has a high internal validity provided that the groups are large. It also has the unique advantage that unpredictable, immeasurable confounders are randomly allocated, and that selection bias is eliminated. The classic (explanatory) randomised controlled trial recruits a homogeneous population and may include blinding and placebo⁶⁻⁸.

The pragmatic randomised controlled trial

Our aim was to measure effect in routine care and we had to take a pragmatic approach⁷⁻⁹. This generated several problems, which are addressed below.

- GPs' participation in randomised controlled trials is barred by several factors¹⁰ and every step of the trial has to be adapted to routine practice. In our study, this was achieved through discussion meetings with GPs and pilot testing of patient inclusion prior to implementation.
- Patients had to be randomised in clusters in order to avoid the contamination of control patients that would result if randomisation performed at patient level was matched by intervention at GP level^{8;11-13}. Practices were chosen as randomisation units to prevent contamination of control GPs. The clustering of patients reduced the number of units for randomisation and affected the statistical analyses.
- The small number of units induced by clustering weakened the design as the random assignment could no longer secure similar distributions of baseline characteristics among groups^{3;6}. To counteract this problem, stratified block randomisation of GPs was performed and analyses were adjusted for patient factors that could influence outcome.

However, we cannot exclude that immeasurable parameters linked with the GPs may have confounded the study. The small but statistically insignificant differences in GPs' previous education may imply that control GPs were slightly better trained [Chapter 4, Table 1, page 89]. Confounding may thus have reduced the measured differences between the groups.

- Blinding is not practicable in educational interventions. 'Placebo education', such as brief didactic teaching, might have been considered. This would, however, have increased expenditures without ensuring blinding, as GPs might easily have found out which education was the more intensive. Without blinding, behavioural changes may be caused by a Hawthorne effect⁶. Merely taking part in the project would, however, have increased attention towards somatisation in both groups and have reduced the differences measured.
- The design intended to blind patients. They knew that they were part of an investigation but they were not informed about the grouping of their GP. Whether some patients were informed by mistake about the GP grouping was not checked.
- For interventions delivered at practice level, implementation would need to generate a substantial change for measurable effects to be seen at patient level¹⁴. We aimed at detecting a 20% difference between groups, but, in retrospect, this value was set too high. The detection of smaller effects on patient outcome would have been valuable considering the nature of the intervention and the applied design.
- In order to recruit a maximum number of GPs and to keep 'control GPs' motivated for participation, it was necessary from the time of inclusion to guarantee 'control GPs' an invitation to join the training programme in a not too distant future. This time aspect arising from the design confined the time period for follow-up to one year.
- The evaluation trial followed immediately after the first part of the training programme, and the workload may have impaired the implementation of new skills in daily practice. A longer qualification period before patient inclusion might have increased the GPs' opportunities to try out the new skills, but would also have impaired the evaluation of immediate effects of training.

Conclusion on the pragmatic randomised controlled trial

The conduction of a large randomised controlled trial in general practice during routine care proved feasible [Chapter 5, Results, page 105]. Despite random allocation and a large number of participating patients, we must, however, face a possibility of residual confounding due to the small number of practices for allocation. Information about GPs' previous education suggested a possible reduction in differences between groups by confounding. A Hawthorne effect may also have served to reduce differences between groups. Finally, the detection of effects at patient level may have been hampered by the nature of the intervention and the limited observation period.

The longitudinal evaluation

Embedded in the randomised controlled design was a cross-sectional evaluation of GPs' diagnoses [Chapter 5, page 102] and a longitudinal observation of GPs' attitudes [Chapter 4, page 87] and patient outcome [Chapter 6, page 117].

The cross-sectional part benefited from the inclusion of a large patient sample, whereas the longitudinal study only included somatising patients (i.e., patients with a high score on the screening questionnaire for somatisation). This sample reduction held the disadvantage that alternative patient groups could not be formed during the analytic phase, but resources were insufficient to perform follow-up on all patients.

The follow-up was limited to one year and the process of change may not have produced measurable changes in patient outcome within this time frame. The study may therefore have profited from a longer observation time.

Follow-up was conducted for all patients included in the longitudinal part of the study, irrespective of possible changes in GP listings or addresses. It was not possible to register how many of the included patients actually changed their GPs, but in general a change of GP listing occurs in 1% of the population¹⁵ and 3% of the population in Vejle County moved out of the county in year 2000¹⁶. Thus, a replacement of trained GPs by untrained GPs would probably have occurred in a small number of cases and would tend to reduce the effects on patients in the intervention group.

We achieved an almost complete follow-up of patients, but a number of participants chose not to respond to the questionnaires. These non-responders could only be analysed with respect to baseline values [Chapter 6, Results, page 125] and did not differ significantly between groups. More information might have been obtained, for instance by telephone interviewing, but contact to non-responders would meet ethical dilemmas.

Conclusion on the longitudinal part of the study

An observation time of twelve months strengthened the study, though more time may be necessary for substantial behavioural changes to occur. The follow-up implied minor changes in GP listings, which may have reduced measurable effects on patient outcome. Attrition bias seemed to be minimal.

General considerations

Randomised controlled trials deal with assessment in a rigorous way, whereas the evaluation of an educational programme is complex, encompassing evaluation of a process. Ideally, the process evaluation also involves capturing the routine practice in its entirety and the nature of outcome. Restricted measures of separate elements such as attitudes, diagnoses and physical health may not describe the outcome sufficiently, and alternative designs might have been considered.

Non-randomised designs would allow for longer follow-up periods¹⁷, but they would include the same outcome parameters and involve a greater risk of confounding and bias. Qualitative studies may give insight into the process answering questions like, ‘what was implemented and how did it work in routine care?’ or ‘how were patients affected differently after intervention compared with before?’ The qualitative methods are excellent and necessary supplements in the evaluation of training programmes, but they answer different questions and cannot replace the quantitative methods. This study may accordingly have benefited from a concurrent qualitative evaluation, but the shortage of resources cut out this option.

*‘An appreciation of both quantitative and qualitative approaches can enhance a researcher’s ability to answer complex questions in a manner which is efficient, internally valid, and generalizable’*¹⁸ (Stange et al, 1989)

Conclusion on design

In spite of all the limitations and problems described, we chose a design that was fairly robust, matched available resources and was clearly relevant to the research questions put forward in this thesis.

7.3.3. Intervention

The intervention had two steps: GP training, and GPs’ implementation of the TERM-model in routine care. Only the aggregate effect of the intervention could be evaluated and it was not

possible to identify which components of the multifaceted educational programme were effective and which were not.

The TERM-model did not provide a standard treatment for somatisation, but had to be tailored to each patient, and it is unknown to which extent GPs adhered to the model. Furthermore, usual care is inhomogeneous, and some of the GPs in the control group might already have had the qualifications addressed in the training programme. We did not assess the specific treatments provided by GPs in either group and it is possible that poor implementation in intervention practices or the application of TERM-model elements by control GPs reduced measurable effects.

Some information about the implementation of the TERM-model was obtained through GP interviews¹⁹. More valid information about implementation and usual care might have been collected by the use of video recordings of consultations. This approach has, however, proven difficult in previous studies^{20 21} and would demand considerable resources.

The motivation to *implement* the TERM-model may have varied within participating practices, as 1) GPs may have been motivated for participation by different factors (learn a new treatment model, take part in research, reimbursement), 2) some GPs in partnership practices may have felt pressured into participating, and 3) non-participating colleagues in some of the included practices may have influenced participants negatively. These differences in motivation for behavioural change reflect the reality of general practice, but tend to reduce the effects of intervention.

Conclusion on intervention

The evaluation of the educational programme only applied to the aggregate effect of the intervention, and the design did not allow for analysis of whether low efficacy of the TERM-model or poor implementation in routine care could explain the lack in measurable effect on patient outcome. Neither implementation of the TERM-model nor usual care was monitored and the differences in the effect on patient outcome may have been reduced by poor implementation in the intervention group or by skilled GPs in the control group.

7.3.4. Sampling

Sampling of general practitioners

GPs registered with the Vejle County Health Insurance were invited, and replies from all GPs were ensured by telephone contact to non-responders. GPs could be described in terms of parameters from the county health insurance registry. Additional information was obtained on previous professional education using questionnaires (67% response rate) [Chapter 4, Results, page 90] [Appendix D, GP-CME].

A large proportion of the county's GPs (19%) accepted participation, and only a few GPs dropped out after randomisation. The GP sample may, however, still have been atypical because interventions requiring the active participation of health professionals are likely to require a high degree of motivation. The GPs volunteering for a new intervention are often the so-called 'early adopters'. These GPs would be more ready to change than non-participants, which would result in an overestimation of the absolute effect size likely to occur in the majority of GPs and 'late adopters'¹. Furthermore, doctors with the greatest need for educational support may not have volunteered²². However, participating GPs only differed from non-participants with regard to practice geography and, in the analysis of patient data, also seniority. This finding speaks against a selection of particular GPs.

Conclusion on the sampling of general practitioners

The study succeeded in including a large proportion of GPs in a geographical area (Vejle County). Participating GPs may have been specially motivated, but only differed from non-participants with regard to practice geography (and seniority in the analysis of patient data).

Sampling of patients for the cross-sectional analysis

Most secretaries attended information meetings before trial initiation, and they felt well prepared for managing the patient inclusion. The project head was in charge of protocol adherence, which was nurtured by means of practice visits, telephone contacts and ad hoc information letters. Misinformation of patients may, however, have occurred and was not checked. Poor information may have led to refusal and information bias in questionnaires if, for instance, patients were afraid that answers were revealed to their GPs. Precautions were taken by communicating important details in the mandatory patient information letter accompanying the patient questionnaires [Appendix D, PQ1].

Information about inclusion and refusal

Complete registration of patients eligible for inclusion was ensured by simultaneous patient registration by secretaries and GPs. This baseline registration was verified by comparison with the county health insurance registry in Vejle. In most practices more patients were actually registered in the project than reimbursed for, indicating complete registration. Only three practices failed to include a large number of patients and they were therefore excluded.

Besides the strength of comprehensive registration, the study also enjoyed the strength that data were retrieved from GP registration forms for all patients, including refusers. Refusers more often received the diagnosis 'somatisation' than participants, indicating that we failed to include some of the targeted patients. The analysis did not allow us to identify whether participation was refused by specific groups of somatisers. However, the consecutive inclusion and the high number of patients accepting participation secured a relevant patient sample.

Bias

Included patients differed slightly between groups in spite of the randomised nature of the design, [Chapter 5, Results, page 106][Chapter 6, Table 2, page 124]. This could have happened by chance, because GPs, as opposed to patients, were randomly allocated (cluster randomisation) and because the number of randomised units was low. Furthermore, the lack of blinding could have raised the level of enthusiasm in the intervention practices. Final inclusion rates were satisfactory in the intervention group (81%), but were slightly lower in the control group (72%). Hypothetically, refusers may have been more chronic and difficult patients and a higher number of chronic somatisers may have been included in the intervention group than in the control group. This is substantiated by the difference observed in the SF-36 at baseline [Chapter 6, Table 2, page 124]. Inclusion bias may have been present at patient level as a result of:

- Skewed inclusion numbers (inclusion rate in the intervention group > control)
- More somatisers among refusers than among participants (number of participating somatisers in the intervention group > control)
- A possible difference in chronicity between participants and refusers (general health scores for participants in the intervention group < control)

This bias may explain some of the difference observed in diagnostic rates [Chapter 5] and may also have reduced the measurable effects on patient outcome because chronic patients are more difficult to treat [Chapter 6].

The period of patient inclusion had to be short out of consideration for participating practices. The period happened to coincide with the first summer days that year, and practices were packed with hay fever patients. Whether and how this may have influenced the number of somatising patients visiting practices is unknown. It should not have affected results on training effect, but it may have influenced prevalence rates [Chapter 5, Results, page 106].

Conclusion on the sampling of patients for the cross-sectional evaluation

A comprehensive patient registration ensured a complete description of the patient sample, and a large number of patients was sampled for the cross-sectional evaluation at baseline. Despite the randomised design, inclusion bias occurred at patient level. This could only explain part of the difference observed in GP diagnoses [Chapter 5, Discussion, page 109] but may have been so serious as to produce the negative trend noticed on patient health [Chapter 6, Figure 3, page 129].

Sampling of patients for follow-up

We included only patients with a new health problem in order to confine analysis to incident cases. It is, however, difficult to distinguish incident cases of somatisation from prevalent cases as symptom patterns vary with time. The probable inclusion of prevalent cases would also comprise chronically somatising patients and thus tend to reduce the effect of intervention on patient outcome.

Patients were selected for follow-up by means of questionnaires in order to obtain a large sample. The questionnaires were filled in before consultation with the GP to make sure that intervention would not affect baseline values or patient selection. The selection of somatising patients depended on the sensitivity and specificity of the applied questionnaires (see patient questionnaires below). We may therefore have obtained a heterogeneous patient sample that included both non-somatising patients as well as chronic somatisers. Since the treatment model was targeted at somatising patients, it may have been difficult to demonstrate its effect on the selected patients.

Subgroups

A specific effect might have been better measured in subgroups of somatising patients. Relevant subgroups for analyses would be: 1) somatising patients who were ill enough to benefit from treatment but not yet chronic cases, and 2) somatisers who were diagnosed by their GP, as recognition is a precondition for the application of appropriate treatment. The questionnaires used were not able to generate such subgroups. GP-diagnosed patients were subjected to explorative analyses [Chapter 6, Figure 2, page 127], but this subgroup may still have been related to severity of disorder as chronic disorders are more easily recognised²³.

Conclusion on sampling of patients for longitudinal evaluation

The method chosen for the selection of patients for follow-up ensured a large sample, but the sample was heterogeneous and was affected by the performance of the applied questionnaires. Relevant subgroups for exploratory analyses were not easily identified.

7.3.5. Questionnaires

The questionnaires used were based on previously validated measuring instruments. They were self-administered, and the procedure of transferring data from questionnaires to databases was blinded by the use of serial numbers to prevent observer bias.

General practitioner questionnaires*General practitioners' attitude*

The questionnaire used for assessment was based on two questionnaires previously used in primary care [Chapter 4, Methods, page 89] [Appendix D, GP-AT0, GP-AT12]. One questionnaire originally targeted somatoform disorders, the other depression, and questions were adjusted to somatisation. The attitude questionnaire might have been improved by a *de novo* development, but this would have required additional validation studies and went beyond the scope of the present study.

General practitioners' classification of patients

The questionnaire was minimized to allow for the large number of patient registrations GPs had to make [Appendix D, GP-REG]. This ensured high response rates from GPs with less than 10% missing values.

Validated scales for GP classifications were not available, but most questions were taken from previous primary care studies²⁴⁻²⁶. In the Nordic study referred to, GPs occasionally reported problems with categorisation of patients with unclarified diagnoses (personal communication, January 2000). Hence, we chose to include the item 'probable physical disease' allowing for the uncertainty that often prevails when GPs are required to diagnose states of illnesses. We received only few comments on our questionnaire, which we take as an indication of the relevance of the categories chosen.

Answers were dichotomised into 'physical disease' or 'somatisation' during the analysis. The axis for this dichotomisation was placed between 'probably physical' and 'medically unexplained' according to protocol. Different axes could have been applied but would not have been consistent with our conception of somatisation [Chapter 5, Discussion, page 110].

The validity of the registration form could have been improved by qualitative interviews with GPs. Such validation was not possible within the framework of this study, even if it may have been relevant in the face of the absence of an agreed case definition in primary care [Chapter 1, The concept of somatisation, page 6].

Patient questionnaires

Assessment of somatisation

SCL-SOM and Whiteley-7 were used to identify somatising patients [Appendix D, PQ1-3]. These scales have been validated internationally and in Denmark^{27,28}. Our dichotomisation of item scores was based on the previous Danish studies²⁹, which however, used a 4-point Lickert scale, whereas we used the original 5-point scale³⁰. Unfortunately, this change in response categories invalidated direct comparisons between the studies. Furthermore, a recent external validation of the questionnaires applied in our study indicates that the chosen dichotomisation of the 5-point scale is not optimal. The questionnaires would have performed slightly better and displayed increased sensitivity if the dichotomisation had been changed downward to divide between 'not at all' and 'a little bit'³¹.

The two scales, SCL-SOM and Whiteley-7, measure different aspects of somatisation (symptom count and illness worry). As there is no golden standard for somatisation, we could not tell which would be the better and, consequently, chose to apply both.

Assessment of health

Clinically relevant changes in patient health may not be sufficiently reflected by changes in the specific measures for somatisation. Overall effect evaluation also requires application of other instruments³². For this purpose we chose the SF-36 [Appendix D, PQ1-3]. International and Danish validation studies have consistently shown that the SF-36 is a reliable and valid quality of life measure³³⁻³⁶. Furthermore, a number of international studies have demonstrated responsiveness in various populations, including populations of patients with disorders related to somatisation^{37,38}. Finally, the SF-36 allows for comparisons with existing literature and with a Danish norm material³⁶.

The SF-36 was supplemented by questions about disability days. Unfortunately, these questions were poorly phrased in Danish and only one item was analysed. The issue of disability days may have been better explored, but it was given low priority in order to limit the size of the questionnaire.

Assessment of satisfaction with care

The instrument chosen (EUROPEP) was based on explorative studies of patient satisfaction with primary care throughout Europe³⁹ and was validated also in Denmark^{40;41}. This instrument provided an overall impression of patients' satisfaction with care [Appendix D, PQ2-3]. An evaluation of satisfaction with more specific elements related to the application of the TERM-model might have shown greater responsiveness, but was not performed in this study as it would have complicated trial logistics.

Other questions

Questions about sociodemography were taken from earlier surveys where they had proven effective²⁴ [Appendix D, PQ1].

The patients were asked about their attributions regarding the problem they were seeing their GP for [Appendix D, PQ1-2]. This question worked well during the first pilot testing. However, after adjusting the questionnaire, the attribution question followed upon questions about alcohol problems, which led to misinterpretations. Despite a second pilot testing, this problem was not realised until the final trial. The question was omitted during analyses due to this construct error.

Pilot testing

All questionnaires were evaluated by GPs and lay people at the Research Unit and Department of General Practice, Aarhus University and/or at the Research Unit for Functional Disorders, Aarhus University Hospital. They were revised several times before a regular pilot testing was conducted. Five practicing GPs were asked to fill in the GP questionnaires, and subsequently every item and all problems encountered were discussed. In the development of patient questionnaires, a research assistant interviewed waiting room patients in a large partnership practice after they had answered patient questionnaire 1. The questionnaire was adjusted and a final pilot testing was performed in another large practice together with the pilot testing of the trial logistics.

The extensive pilot testing of all questionnaires ensured feasibility and increased the validity of the applied questionnaires. Nevertheless, one construct error passed through the pilot testings unnoticed as mentioned above.

Processing questionnaire data

All questionnaires were designed and processed in the computer programme TELEform⁴². This programme prepares questionnaires for automated forms processing, i.e. optical scanning of the answers captures data into a database. A previous study analysed the accuracy of this processing⁴³. Error rates were found to be 4-10 per 10,000 entries, which compared with double manual data entry. In the present study, a random sample (20%) of patient questionnaire 1 was manually entered into SPSS and compared with the TELEform entry. Errors in the TELEform database were found in 6 of 10,000 entries.

Data were automatically transferred to the Statistical Programme for Social Sciences (SPSS) version 10.0 for windows⁴⁴ and checked for errors. If errors were encountered, the original questionnaire was inspected and the database entry corrected.

Conclusion on questionnaires

The application of previously validated instruments guaranteed the validity of the questionnaires, and their brevity ensured high response rates. Processing was accurate and eliminated observer bias. Problems were encountered with the external validation of GPs' classifications and with patient questionnaires on somatisation, as we did not have a golden standard for somatisation in general practice. This made assessment of GPs' diagnostic

accuracy difficult and hampered the inclusion of somatising patients. Well-validated instruments were available for the measuring of patient outcome.

7.3.6. Statistical issues

The intervention was implemented at GP level rather than at the level of the individual patients which required the allocation of clusters of individuals to different intervention groups¹¹. Hence, the patients could no longer be regarded as independent individuals and the analyses had to be performed at GP level. If the variability between clusters (due to properties attributable to the individual GPs and their practices) was ignored as in standard statistical methods, the standard error would be underestimated resulting in too narrow confidence intervals and spurious statistical significance^{11:45:46}. The problems of cluster allocation are that numerous clusters are needed to achieve a balanced comparison and that statistical power is reduced.

We performed power analyses for primary outcome measures, but the impact of clustering was unknown at the time of planning of the study, and for some of the assessments the intra-class correlation coefficient, and thus the cluster effect, proved larger than expected [Chapter 5, page 102 and 106]. Furthermore, the size of important effects at patient level was overestimated [Chapter 6, Table 3, page 126]. As a result, the study turned out to be underpowered with regard to analyses of the GPs' diagnoses and the small effects at patient level. It would, however, have been difficult to implement a larger study as costs in terms of financial expenditures, training courses, and human resources involved in the trial would have been immense.

Our choice of analytic unit may be questioned. Randomisation was performed at practice level in order to limit contamination of control GPs. Yet intervention was targeting the individual GP and for this reason GPs were made the units of analysis¹³. Anyhow, the analysis produced the same overall results irrespective of whether the analytic units were GPs or practices.

Conclusion on statistical issues

Cluster analyses had to be performed and involved advanced statistical methods. The clustering of patients reduced the number of analytic units and severely reduced the statistical power in the analyses of the GPs' diagnoses. Low power also affected the analysis of small, but important differences in patient outcome.

7.3.6. Generalisability

In this study, effectiveness was subject to analysis, and few limitations were applied to the inclusion of GPs in order to ensure external validity. Participation in a project does, however, put an extra workload on participants, and they must be particularly motivated to spend time on training and patient inclusion. Thus, selection of a special group of GPs could not be avoided. Nevertheless, the GP sample included a large number of GPs in the county who only differed slightly from non-participants [Chapter 4, Results, page 90, Chapter 5, Results, page 105].

Exclusion criteria were applied to patients, 7% of whom were excluded because they were immigrants. This reduces the generalisability of the results at patient level as immigrants constitute an increasing part of the population in primary care. So far the TERM-model and applied questionnaires have been developed and tested in western societies only, and we do not know about effects on patients from other cultures.

Only a few patients declined the invitation to participate, but a significant proportion of refusers may have been somatisers. We do not know if this group of somatisers differed from

participating somatisers. Furthermore, follow-up rates decreased at twelve months. Some differences were observed between responders and non-responders, and attrition may also limit the external validity of the study [Chapter 6, Results, page 123].

Conclusion on generalisability

The results of this study can be generalised to GPs in similar settings. The effects on patient outcome can only be generalised to primary care patients with a high score on the described screening instrument for somatisation and to patients with a western cultural background.

Summary of the methodological aspects of the evaluation trial

Design

- The conduction of a large randomised controlled trial in routine general practice proved feasible and enabled evaluation of the educational programme in relation to the research questions put forward in this thesis.
- A pragmatic approach had to be taken in order to evaluate effectiveness, but this approach affected the robustness of the randomised controlled trial as described below.
- Residual confounding not captured by random allocation may have been present due to low numbers of units (clusters), and may possibly have reduced the differences between groups.
- Blinding of GPs was not possible and a Hawthorne effect may have been present both within the applied intervention and among all participating GPs because of the project design. The latter would tend to reduce differences between the groups.
- The effects of intervention may have been difficult to measure because 1) educational interventions may only produce small effects, especially, at patient level, 2) small effects may be difficult to evaluate in a pragmatic design, 3) the observation period was limited though behavioural change may take a while for GPs and patients, and 4) some patients may have changed their listing from trained to untrained GPs during the follow-up.

Intervention

- The evaluation of the educational programme only applies to the aggregate effect of the intervention.
- Usual care was not monitored, and we only know little about the actual implementation of the TERM-model. Differences in effect on patient outcome may have been reduced by poor implementation in the intervention group or skilled GPs in the control group.

Sampling

- A large proportion of GPs in a geographically well-defined area completed the trial.
- Participating GPs may have been specially motivated but only differed from non-participants with regard to practice geography (and seniority in the analysis of patient data).
- A comprehensive patient registration ensured a complete description of the patient sample.
- A large number of patients was sampled for the cross-sectional evaluation at baseline
- Despite the randomised design, inclusion bias occurred at patient level complicating the interpretation of the results of the GPs' diagnoses and patient outcome.

- The follow-up sample was heterogeneous and was affected by the performance of the applied screening questionnaires for somatisation.

Questionnaires

- The application of previously validated instruments ensured a high validity of the questionnaires. Furthermore, processing was accurate and eliminated observer bias.
- The assessment of GPs' diagnostic accuracy and the inclusion of somatising patients were affected by a poor external validation of the questionnaires. The external validation was, however, complicated by the lack of a golden standard for somatisation.
- Well-validated instruments were available for the measuring of patient outcome. Evaluation might have benefited from more specific instruments for the measuring of somatisation, patient satisfaction and illness attribution.

Statistics

- Cluster analyses were performed and involved advanced statistical methods. Clustering of patients caused a reduction in the number of analytic units and a severe reduction in statistical power in the analyses of GPs' diagnoses.
- Low power also affected the analysis of small, but important differences in patient outcome.

Generalisation

- The results from this study can be generalised to GPs in similar settings.
- The effects on patient outcome can only be generalised to primary care patients with a high score on the described screening instrument for somatisation and a western cultural background.

Research in somatisation is a challenge and many methodological problems may be encountered, as pointed out by Peveler et al:

*'Research in this area is hampered by lack of agreed case definitions, well-validated assessment measures and appropriate experimental designs'*⁴⁷

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Chapter 8

General discussion of results

8.1. Introduction

The analysis has focussed on answering the aims stated in the General introduction [Chapter 1, page 14], and the results have been discussed in detail in the Chapters 2-6. In this chapter the results will be brought up for an overall discussion and will be related to existing literature. The results presented in this thesis do not represent an exhaustive analysis of all the data collected, for instance cost analyses were included in the study design but this issue still awaits final analysis.

8.2. Development and implementation of the educational programme

8.2.1. Background and approach

The background for the development of the TERM-model has been presented and discussed in Chapter 2. Available educational programmes specifically focusing on somatisation are few, and only a limited number have been scientifically evaluated.

Various approaches have been tried out targeting the organisational level at the interface between psychiatry and primary care^{1;2}. Most of these approaches required considerable resources in terms of mental health care specialists. Such resources were not available in our setting, and we chose to concentrate intervention on general practice. In this way the training of many GPs could meet the aim of giving a large number of somatising patients access to good health care within available resource confines.

Working at the interface of psychiatry and general practice implied cooperation between different specialities in order to develop a theoretically and clinically optimal treatment model and educational programme. This cooperation proceeded in a steady dialogue between participants, but with preservation of autonomy and continuous respect for the individual specialities. This approach differed from some of the previous liaison psychiatric initiatives, where specialists often have been more directly involved in patient care^{1;3;4}.

8.2.2. The TERM-model

For reasons stated in the General introduction [Chapter 1, Treatment, page 10], the original model ('The Reattribution Model') was changed as described in Chapter 3 [Introduction, page 30]. Because of the introduced modifications it may be questioned to which extent we can count on the presence of effects demonstrated in previous studies of 'The Reattribution Model'⁵⁻⁸. We did, however, integrate previously applied skills training, and the training of supervisors by L. Gask ensured consistency [Chapter 3, Introduction, page 34]. Both models were based on a cognitively oriented approach, and the TERM-model was an expansion of 'The Reattribution Model' more than a complete change [Appendix A].

8.2.3. The educational programme

The TERM-model was integrated in an educational programme. An important issue was how comprehensive this programme should be as implementation strategies had to strike a balance between resource restraints and the minimum intervention required for a behavioural change to occur. On one hand, teaching resources were scarce and so was the time the GPs would allot for training. On the other hand, a change in professional behaviour was more likely to be successful if the educational intervention was multifaceted⁹ and accompanied by other approaches^{10;11} [Chapter 1, Changing professional behaviour, page 11]. Addressing all the

aspects listed in Table A [Chapter 1, page 12] would undoubtedly have increased the chances of behavioural change and implementation of the TERM-model in clinical practice, but would also have required more resources than available. We instead decided that intervention should target the GPs' internal processes in the form of GP education. Other important factors were taken into consideration but were not intervened upon. The final selection of implementation strategies was based on a high likelihood of successful implementation with low time expenditure for supervisors and GPs. The chosen strategies proved acceptable both to GPs in this study¹² and to GPs in general (evidenced by the subsequent high demand for the educational programme in Denmark).

Adult learning is a lifelong process that does not end with a brief training programme [Chapter 1, Changing professional behaviour, page 11]. Intervention may start a process and support it for a while, but maintenance is necessary to sustain the process of change¹⁰. An important aspect of maintenance is the continuous monitoring and evaluation of personal progress^{10;13}. Such evaluation was provided through supervision [Chapter 3, Introduction, page 33], but participants were not given tools for continued self-evaluation. GPs may not be accustomed to evaluating the effectiveness of psychosocial treatment¹⁴, and failure to evaluate progress may lead to premature stopping of treatment and feelings of incompetence. Even though GPs actually showed increased confidence and less frustration after training [Chapter 4, Implications, page 95], it is possible that extended training support and self-evaluation tools would have led to better implementation at patient level.

8.2.4. Preconditions for effect at patient level

The effects of intervention depend on the *efficacy* and the *implementation* of the model in clinical care. The efficacy of the TERM-model and 'The Reattribution Model' has not been established. Both models were, however, based on cognitive behavioural therapy, which has proven efficient under ideal circumstances¹⁵⁻¹⁷ [Chapter 1, Treatment of somatisation, page 9].

We cannot establish to which extent the TERM-model was implemented as no assessment was made of its application. Implementation was probably heterogeneous as: 1) we dealt with a complex process of change, 2) GPs had differing starting points and we merely aimed at a modification of their behaviour rather than a complete change, and 3) a number of barriers potentially obstructing implementation were present [Chapter 3, The interaction between the physician and the somatizing patient, page 42]. Nevertheless, participating GPs reported that parts of the model were implemented in routine care¹². Furthermore, the feasibility of reattribution in general practice was supported by results from a Dutch study¹⁸, and before-and-after studies applying similar learning strategies (micro skills training) have demonstrated that key communication skills were acquired after training^{5;6} (Table B). Based on these studies we have reason to believe that parts of the TERM-model were learned and applied in routine care. It is, however, unknown whether the applied skills actually changed the doctor-patient interaction as a number of other factors may also influence this process^{10;11;19-21} [Chapter 1, changing professional behaviour, page 11].

Like 'The Reattribution Model', The TERM-model could be tailored to each patient by the application of relevant elements, and it was assumed that GPs and patients would gain from even small improvements in GPs' performance. Even if full implementation of the model would improve outcome, this would, however, not ensure that a partial implementation would too. Hypothetically, the application of selected parts of the treatment model could also worsen the outcome, depending on which parts were used and how they were implemented.

Conclusion on the development and implementation of the educational programme

- Cooperation between psychiatrists and GPs was necessary for the development of a well-founded and feasible treatment model and educational programme. Cooperation was based on autonomy and continuous respect for the specialities involved and proved a success [Chapter 3].
- Knowledge about assessment and treatment of somatisation could be obtained from the literature and from experts, and it allowed the development of a theoretically sound and evidence-based model [Chapter 2, 3].
- It was possible to incorporate the model together with essential interviewing skills into a short-term training programme applying multifaceted strategies for implementation [Chapter 3]
- The TERM-model and the educational programme was generally accepted by participating GPs¹²

8.3. Evaluation of the educational programme

*'It is striking how little is known about the effectiveness and cost effectiveness of interventions that aim to change the practice or delivery of health care'*²² (Bero et al, 1998)

Referring to the aims stated in Chapter 1 [page 14], training of GPs affected their attitudes towards somatisation [Chapter 4] and their awareness of medically unexplained physical symptoms [Chapter 5]. GP training had no significant effect on patient outcome [Chapter 6]. These results have been discussed in detail in Chapters 4-6.

In the general discussion of these results, conclusions should be drawn with reservations for the methodological problems discussed in the previous chapters. It should also be kept in mind that most reviews of educational interventions have identified only modest improvement in performance, and many studies have not taken the problems of patient clustering into account²².

8.3.1. Effects on general practitioners

GPs' attitudes

A few small or uncontrolled studies have indicated an effect of training on GPs' attitude²³⁻²⁵, but a recent randomised controlled study on depression showed no effect on attitudes six months after training²⁶. Our findings of a decrease in negative feelings from baseline to twelve months after training without a corresponding change in the control group indicate a positive effect of training at GP level. This conclusion was supported by the simultaneous qualitative study showing that GPs generally expressed increased ease in containment of difficult patients after training¹². Considering the problems somatising patients may cause at the GP level, this is an important effect of the programme [Chapter 1, Problems arising from present care-giving, The doctor perspective, page 8].

Another important change in attitude, which was aimed at but not assessed, was a possible acknowledgment of somatisation as a medical disorder. Such acknowledgement was a precondition for the GPs' learning process and for their subsequent diagnosis and treatment of somatising patients²⁷.

GPs' diagnoses

Somatisation often goes unrecognised in general practice [Chapter 1, Problems arising from present care-giving, The patient perspective, page 8], and a number of the barriers hampering the diagnosing of somatisation were addressed in Chapter 3 [The interaction between the physician and the somatizing patient, page 42]. Besides these barriers, Quill has noted that:

*'They [trainees] are better trained to rule out the unusual than to rule in the most probable diagnosis'*²⁸

In this study trained GPs showed greater awareness of medically unexplained symptoms when assessing the main problems presented by the patients. Improved recognition after training has previously been demonstrated for mental illness in general²⁹⁻³², but not specifically for somatisation. The increased diagnostic rate was statistically significant despite a considerable cluster effect due to large variation between GPs. The variation in GPs' diagnoses was independent of patients' scores on the screening questionnaire for somatisation and has been demonstrated before^{19:33}.

The present study failed to assess the accuracy of the increased diagnostic rates. A major problem with accuracy of diagnosis was the standard of comparison. As stated in Chapter 1, GPs do not agree with the present psychiatric classification systems³⁴, and the concept of somatisation is confusing, especially in primary care [Chapter 1, The concept of somatisation, page 3]. Accuracy cannot be assessed without an appropriate golden standard, and the significance of unchanged agreement between GPs and the applied screening questionnaires does not lend itself to straightforward interpretation.

8.3.2. Effects on patients

Patient health

The educational programme primarily aimed at improving patients' health. To achieve this, a change in GP behaviour had to be followed by a change in patient behaviour. Many of the difficulties in changing behaviour also apply to patients, and several factors other than the GP may have influenced patient outcome (e.g. the patients' family, other doctors). Such factors could reduce the effect of GP intervention, even if the TERM-model was fully implemented.

As previously stated, we do not know to which extent the TERM-model was actually implemented. The model was probably often implemented in part rather than in full, which would produce only minor effects within the one-year follow-up. Even if implementation was accomplished and patient outcome truly improved, the registration of this outcome would depend on the measures applied. We applied validated instruments for some aspects of mental health and quality of life, but other aspects may also have been relevant and may have revealed different outcomes. For instance, a pilot study of problem-solving therapy showed that patients' problems decreased more than their symptoms³⁵.

Additional patient outcome

Measures under direct control of the GP could have been chosen for evaluation (e.g. clinical investigations, medication, referral rates, and patient satisfaction)⁷. As discussed previously, assessment of immediate satisfaction was refrained from in order to facilitate trial logistics. We did, however, measure general satisfaction with care. Patients in the intervention group were more satisfied with the doctor-patient relationship, the medical-technical care and information and support than patients in the control group, though these differences did not reach statistical significance. This finding corresponds to the UK study, that observed an immediate effect on one aspect of patient satisfaction⁷ (Table B). Furthermore, data on the actions undertaken by the GPs' were obtained from central registers, but have not been analysed yet.

General aspects

The GP would have to diagnose somatisation in order to apply the TERM-model, but patients for follow-up were sampled according to screening questionnaires, that did not agree with GP diagnoses [Chapter 5, Table 3, page 108]. Effects measured on this sample may consequently have derived from either a specific treatment effect on the few cases of somatisation recognised by the GP or from a general implementation of parts of the TERM-model on all patients. Recognised cases were analysed separately but were few because the GPs' diagnostic rates were low. A general implementation was aimed at but would only produce small changes on the measuring instruments.

Changes in patient health were small compared with previous studies on somatisation^{3;6;8}, and training of GPs did not significantly affect patient outcome [Chapter 6, Table 3, page 126]. This result disagrees with another randomised controlled trial on reattribution⁸ (Table B) but agrees with recent studies on educational interventions addressing depression^{26;36;37}. A number of differences between studies and methodological aspects already addressed may explain the differences in outcome (Table B).

When effectiveness of educational interventions is studied within a limited follow-up period, it may be impossible to trace changes at GP level all the way down to changes in patient health. Small changes in behaviour might be better explored by other outcome measures³⁸ combined with efficacy studies of effects on patient health. Alternatively, large-scale trials or long-term follow-up studies would be necessary to investigate the effects of educational interventions on final outcome at patient level.

8.3.4. Overall effects of reattribution

The features and results of our study are compared with the two previous studies on reattribution in Table B. Overall, the models applying reattribution have demonstrated effects at GP level (attitude, skills, diagnosis of medically unexplained symptoms). Effect on patient outcome has varied in different study designs and remains uncertain. Results concerning health care utilization are conflicting, but the costs may decrease (Table B).

Conclusion on the evaluation of the educational programme

- Training induced a sustained effect on GPs' attitudes towards somatisation, suggesting that general practitioners may become more confident and find it less frustrating to deal with somatising patients [Chapter 4].
- Training increased GP awareness of medically unexplained physical symptoms in relation to classification of the main problems presented by the consulting patients [Chapter 5].
- Training of GPs did not produce a measurable effect on health or disability days in patients with high scores on a screening instrument for somatisation (SCL-SOM, Whiteley-7) [Chapter 6].
- Training of GPs exerted a positive effect on patient satisfaction with care, but the trend did not reach statistical significance [Chapter 6].

Table B. *Results from trials using reattribution models*

	The Reattribution Model ^{6;7;39}	A modified reattribution model ⁸	TERM-model
Location	Manchester, UK	Amsterdam, The Netherlands	Vejle, Denmark
Design	Prospective, before-and-after study	RCT	RCT
Intervention	8-hour interactive training programme (4 x 2 hours: video training material, role play, video feedback supervision and written material)	20-hour interactive training programme + patient diaries (2 x 5 hours: demonstrations, role-play 4 x 2 hours: role-play of problems 2 hours: individual feedback on 3 taped consultations)	25-hour interactive training programme (2 x 8 hours: demonstrations, role-playing, video supervision 3 x 2 hours: small group video supervision 2 hours: discussion meeting ½ hour: outreach visit)
Control	Usual care before training	Usual care in control group	Usual care in control group
Follow-up	3 months	24 months	12 months
GP inclusion	8 of 17 volunteers selected 8 GPs completed the intervention Minimum 5 years seniority	19 GPs invited 15 GPs participated (10 intervention + 5 control) 9 GPs completed the intervention Minimum 5 years seniority	All GPs in the county invited (227) 43 GPs participated (23 intervention + 20 control) 20 GPs completed the intervention
Patient inclusion	Two cohorts (103 and 112 patients): <ul style="list-style-type: none"> • Consecutive attenders • Physical complaint >2 weeks • Illness attribution physical • GHQ-12 score > 3 • GP does not have evidence of pathology explaining all symptoms or disability • Interview after 1 month confirms psychiatric disorder 	75 intervention + 87 control patients: <ul style="list-style-type: none"> • 20-45 years • Minimum 15 visits to their GP during the previous 3 years • Minimum 5 life-time somatisation symptoms on DSM-III-R, somatisation scale • According to the patient, doctors had not explained symptoms by organic disease • Intervention patients were disclosed to the GP 	1542 intervention + 1338 control patients: <ul style="list-style-type: none"> • Consecutive attenders • 18-65 years • New health problem • 506 intervention + 405 control patients of these • SCL-SOM score >3 or Whiteley-7 score >1

Outcome measures	<p>Patient questionnaires</p> <ul style="list-style-type: none"> • GHQ-12 • SF-36 • Physical symptoms • Illness attributions • Satisfaction with care (satisfaction scale) <p>Health care utilization</p> <ul style="list-style-type: none"> • Interview at 1 month (Retro PAS) • Psychiatric disorder • Health care utilization <p>Costs were also based on primary care records</p>	<p>Patient questionnaires</p> <ul style="list-style-type: none"> • Visits to health care workers • Medicines used • Subjective health on VAS • Sick leave • SCL-SOM <p>Practice records</p> <ul style="list-style-type: none"> • Number of visits to GP 	<p>GP questionnaire</p> <ul style="list-style-type: none"> • Attitude towards patients with somatoform disorders or somatisation • Classification of main problem presented by patient <p>Patient questionnaires</p> <ul style="list-style-type: none"> • Whiteley-7 • SCL-SOM • SCL-8 • SF-36 • Disability days (WHO-DAS) • Satisfaction with care (EUROPEP)
Results	<ul style="list-style-type: none"> • Improved interviewing skills • Decreased psychiatric disorders at 1 month and increased functioning at 3 months (partial somatisers only) • Unchanged overall satisfaction with care, but increased satisfaction concerning 'receiving the help they wanted' after 1 month • Decrease in beliefs that symptoms were entirely physical at 3 months • Unchanged incidence of investigations, prescriptions or referrals • Costs of referrals outside the primary care team decreased by 23%. 	<ul style="list-style-type: none"> • Subjective health increased • Sick leave decreased • Number of health care visits decreased • Number of medicines used remained unchanged • Scores on SCL-SOM decreased 	<ul style="list-style-type: none"> • Improved GP attitude towards somatisation • Increased GP awareness of medically unexplained symptoms when diagnosing main problem presented by the patient • Unchanged mental health, quality of life, and disability days • Statistically insignificant increase in patient satisfaction with care

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Chapter 9

Conclusion

9.1. Conclusion

The project succeeded in the interdisciplinary development of an evidence-based educational programme for functional disorders, that was acceptable to GPs. Implementation of this programme induced a sustained, positive change in GPs' attitudes towards somatisation. Furthermore, trained GPs exhibited an increased awareness of medically unexplained physical symptoms when making diagnoses. Whether increased diagnostic rates of medically unexplained symptoms also reflected improved diagnostic accuracy remains, however, undetermined. The educational programme had no discernible impact on patient health at one-year follow-up, but increased patient satisfaction with care.

The previous Chapters 7 and 8 have arrived at conclusions in relation to the methods applied and the results presented. These conclusions are recapitulated below.

9.2. Development and implementation of the educational programme

9.2.1. Methodological aspects

- A comprehensive approach based on cross-disciplinary and intersectorial cooperation ensured a theoretically sound basis for the educational programme, a treatment model acceptable to GPs, applicability in routine care, and practicability of implementation strategies.

9.2.2. Results

- Cooperation between psychiatrists and GPs was necessary for the development of a well-founded and feasible treatment model and educational programme. Cooperation was based on autonomy and continuous respect for the specialities involved and proved a success [Chapter 3].
- Knowledge about assessment and treatment of somatisation could be obtained from the literature and from experts, and it allowed the development of a theoretically sound and evidence-based model [Chapter 2, 3].
- It was possible to incorporate the model together with essential interviewing skills into a short-term training programme applying multifaceted strategies for implementation [Chapter 3]
- The TERM-model and the educational programme was generally accepted by participating GPs

9.3. Evaluation of the educational programme

9.3.1. Methodological aspects

Design

- The conduction of a large randomised controlled trial in routine general practice proved feasible and enabled evaluation of the educational programme in relation to the research questions put forward in this thesis.
- A pragmatic approach had to be taken in order to evaluate effectiveness, but this approach affected the robustness of the randomised controlled trial as described below.

- Residual confounding not captured by random allocation may have been present due to low numbers of units (clusters), and may possibly have reduced the differences between groups.
- Blinding of GPs was not possible and a Hawthorne effect may have been present both within the applied intervention and among all participating GPs because of the project design. The latter would tend to reduce differences between the groups.
- The effects of intervention may have been difficult to measure because 1) educational interventions may only produce small effects, especially, at patient level, 2) small effects may be difficult to evaluate in a pragmatic design, 3) the observation period was limited though behavioural change may take a while for GPs and patients, and 4) some patients may have changed their listing from trained to untrained GPs during the follow-up.

Intervention

- The evaluation of the educational programme only applies to the aggregate effect of the intervention.
- Usual care was not monitored, and we only know little about the actual implementation of the TERM-model. Differences in effect on patient outcome may have been reduced by poor implementation in the intervention group or skilled GPs in the control group.

Sampling

- A large proportion of GPs in a geographically well-defined area completed the trial.
- Participating GPs may have been specially motivated but only differed from non-participants with regard to practice geography (and seniority in the analysis of patient data).
- A comprehensive patient registration ensured a complete description of the patient sample.
- A large number of patients was sampled for the cross-sectional evaluation at baseline
- Despite the randomised design, inclusion bias occurred at patient level complicating the interpretation of the results of the GPs' diagnoses and patient outcome.
- The follow-up sample was heterogeneous and was affected by the poor performance of screening questionnaires for somatisation.

Questionnaires

- The application of previously validated instruments ensured a high validity of the questionnaires. Furthermore, processing was accurate and eliminated observer bias.
- The assessment of GPs' diagnostic accuracy and the inclusion of somatising patients were affected by a poor external validation of the questionnaires. The external validation was, however, complicated by the lack of a golden standard for somatisation.
- Well-validated instruments were available for the measuring of patient outcome. Evaluation might have benefited from more specific instruments for the measuring of somatisation, patient satisfaction and illness attribution.

Statistics

- Cluster analyses were performed and involved advanced statistical methods. Clustering of patients caused a reduction in the number of analytic units and a severe reduction in statistical power in the analyses of GPs' diagnoses.
- Low power also affected the analysis of small, but important differences in patient outcome.

Generalisation

- The results from this study can be generalised to GPs in similar settings.
- The effects on patient outcome can only be generalised to primary care patients with a high score on the described screening instrument for somatisation and a western cultural background.

9.3.2. Results

- Training induced a sustained effect on GPs' attitudes towards somatisation, suggesting that general practitioners may become more confident and find it less frustrating to deal with somatising patients [Chapter 4].
- Training increased GP awareness of medically unexplained physical symptoms in relation to classification of the main problems presented by the consulting patients [Chapter 5].
- Training of GPs did not produce a measurable effect on health or disability days in patients with high scores on a screening instrument for somatisation (SCL-SOM, Whiteley-7) [Chapter 6].
- Training of GPs exerted a positive effect on patient satisfaction with care, but the trend did not reach statistical significance [Chapter 6].

Chapter 10

Perspective and future research

The concept of somatisation and the confusion of its definitions have been brought up several times throughout this thesis. The terms ‘somatisation’, ‘medically unexplained symptoms’ and ‘functional disorders’ are not unambiguously defined and have been used synonymously. For instance, ‘medically unexplained symptoms’ may only *exclude* cases with *certain* pathophysiological findings yielding a rather high prevalence, whereas a narrower conception may *exclude* all patients with a *probable* physical disease and provide a much lower prevalence. It was our impression that the latter description was more in accordance with the clinicians’ interpretations of the term ‘somatisation’. Some GPs even reserved the term for patients with obvious psychosocial problems or chronic conditions. The results in Chapter 5 indicated large variations in GPs’ diagnosis of somatisation, which could be a reflection of variations in the GPs’ conception of somatisation – in spite of the uniform definitions provided in this study.

A clear conception of somatisation in general practice is important when developing and applying a treatment model and is vital when GP’s diagnostic accuracy is assessed or well-defined patients need to be included in evaluation studies. A clarified concept would also benefit research and teaching in this field in general. Future research should make an effort to explore the existing concepts of somatisation and clarify those relevant to primary care. The challenge of seeking agreement on one definition may border on the impossible, but attempts should be made to establish operational criteria including factors predicting treatment and outcome. The development of diagnostic criteria applicable in general practice and the research in somatisation would profit from cooperation between GPs and psychiatrists.

If new agreed criteria could be generated, prevalence rates and diagnostic accuracy in general practice may need reconsideration.

The successful development of the TERM-model and educational programme was dependent on interdisciplinary cooperation. This cooperation primarily took place between GPs and psychiatrist, but it also involved anthropologists and psychologists. Furthermore, the supervisors/teachers who carried out the training were engaged in the process. This ensured an acceptable and theoretically sound educational programme for GPs and an improved treatment model for somatisation that did not require specialist resources in patient care. The success of this intersectorial and multidisciplinary approach may have been attributable to the continuous dialogue between the implicated individuals combined with the preservation of autonomy for the specialities involved. Future research working at the interface of general practice and specialist care may benefit from similar approaches.

The educational programme was appreciated and readily accepted by GPs, but other problems remain. An important issue is how to support the continuing process of behavioural change within the limits of supervisor and GP resources. We have suggested improved self-evaluation and assisted small group activities. Reinforcement of the process may also be achieved by the application of different implementation strategies, including organisational changes. It is an ongoing challenge to find ways of supporting initiated behavioural changes with minimum use of supervision resources.

Much CME related to somatisation has not incorporated evidence for somatisation and implementation. We found sufficient evidence to develop a programme specifically aimed at somatisation and applicable in general practice. The results of this thesis and the parallel FIP-study indicate a positive effect of the programme. The structured programme development has been described in detail and the approach may find expedient use in relation to other attempts at improving CME in general practice. Furthermore, it would seem natural also to incorporate

the TERM-model in pre- and postgraduate medical training, considering the problems arising from present care-giving.

The evaluation of the TERM-model showed a positive change in attitudes. Little is known about the impact of this change on doctor-patient interaction and patient care during routine clinical work.

Training induced an increase in GPs' diagnosis of medically unexplained symptoms. The significance of this observation cannot be explored until agreement on diagnostic criteria is achieved, but the issue clearly needs further study. Future research should also consider employing longitudinal diagnoses instead of cross sectional classifications and should emphasise the reason for encounter.

GPs vary widely with regard to their diagnoses of somatisation. Previous studies on mental disorders have provided some insight into this variation, but our understanding remains deficient.

It is important to evaluate patient outcome when changes in routine care are induced. However, in this study changes at patient level proved difficult to assess. A number of methodological problems may have served to diminish measurable effects and future research should carefully consider the methodological approach to educational intervention evaluation at patient level.

Evaluation of interventions also involves organisational and economic aspects. The present study included data on health care utilisation and future analysis of these may add important information about the effects of intervention on the health care system.

This study was designed to evaluate effectiveness, and the results give no insight into the 'black box' of training and implementation. We know only little about what succeeded and what did not. In order to improve training and increase chances for improved outcome, it is necessary to open this 'black box'. The inclusion of intermediary outcome measures and/or the application of qualitative methods may improve our understanding and may also provide more information about the nature of effects on GPs and patients.

The classic (explanatory) randomised controlled trial provides a robust study design. Future research should, however, pay more attention to the problems arising from pragmatic approaches. Patient clustering, in particular, may severely affect trials. If the variation between clusters is large, the cluster effect may implicate a considerable enlargement of the study.

Furthermore, trials of professional education only produce small changes at patient level. Though small, these changes are, however, important. The registration of small differences also requires many participants. In the light of the challenges posed by clustering and the need to detect even small changes, it is clear that a randomised trial must, indeed, include a huge number of participating units.

The change of behaviour is a process that takes time for both doctors and patients. It may therefore be worthwhile to include longer follow-up periods than the usual 3 to 24 months. Longer follow-up would require well-defined groups of patients and may involve different study designs because GPs are unlikely to accept randomisation to a poorly trained group running for several years.

Approaches allowing for highly selected patient groups and/or assurance of GP diagnoses may be considered as alternatives or supplements to the studies in routine care. Studies of the

TERM-model under ideal circumstances (efficacy studies) would also provide more knowledge about whether the treatment model or the implementation at patient level would need improvement.

Finally, future trials would gain from the development of improved measuring instruments for the sampling of somatising patients and for the assessment of patient outcome.

Chapter 11

English summary

This PhD thesis is based on the project ‘Somatising patients in general practice, an intervention study’ conducted in Vejle County, Denmark. The project was developed and implemented in close cooperation between ‘The Committee for Quality Improvement in General Practice, Vejle County Health Insurance’, ‘The Research Unit and Department for General Practice, Aarhus University’ and ‘The Research Unit for Functional Disorders, Aarhus University Hospital’. The PhD study was initiated in 1999, and the thesis was submitted in August 2003.

General introduction

The thesis consists of a general introduction, five articles, an overall discussion of methods and results, and a conclusion. Finally, the results are put into perspective, and directions for future research are proposed.

Chapter 1 introduces the concept of somatisation in relation to general practice for which there is a profusion of names, and definitions and the concept remains somewhat confusing. This study conceptualised somatisation according to Lipowski’s definition as, ‘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’. This definition was operationalised into four subgroups (acute and subacute functional symptoms, chronic somatisation, presenting somatisation, and illness worry, illness aggravation and pathological illness behaviour in cases of genuine physical diseases). The name ‘somatisation’ is used synonymously with ‘medically unexplained symptoms’, ‘functional disorder’ and ‘functional somatic symptoms’.

Significant somatisation probably lies at the root of 15-35% of GP consultations. Little is known about its natural course, but present care-giving gives rise to a number of problems: patients do not receive proper treatment and risk iatrogenic somatic fixation and harm, the doctor-patient relationship is negatively affected and GPs become frustrated, and the overall health care system suffers from high expenditures on unnecessary physical investigations and treatments.

Effective treatment is available in the form of cognitive behavioural therapy provided by specialists. Only few treatments administered by GPs have been studied. One is ‘The Reattribution Model’, which has shown promising results in before-and-after studies. Implementation of a new treatment model in general practice implicates a change in professional behaviour. Such a change is a complex process involving numerous factors, and multiple strategies must be applied to guarantee its success.

Chapter 1 concludes with a presentation of the **aim** of the thesis. Two main objectives were pursued: one was to develop and implement an educational programme for GPs on assessment and treatment of functional disorders, another was to evaluate the effect of this programme during routine care in general practice. The specific research questions addressed in this study were:

- Can a theoretically sound educational programme on assessment and treatment of somatisation be developed for and be accepted in general practice?
- Does this training programme produce a change in GPs’ attitude towards somatising patients?
- Do trained and untrained GPs differ in their patterns of diagnosis and in their diagnostic agreement with rating scales for somatisation?
- Is patient health and satisfaction with care affected by GP training?

Development and implementation of the educational programme

[Models for continuing education in general practice focusing on functional disorders] Efteruddannelsesmodeller med fokus på funktionelle lidelser i almen praksis (Article 1)

Chapter 2 provides an overview of programmes for continuing medical education (CME) addressing functional disorders and targeting GPs. The Danish CME related to functional disorders has mainly been based on general knowledge about psychiatric disorders or on general communication and treatment skills. Many programmes lack scientific and theoretical knowledge for functional disorders and do not link evidence about these disorders to skills training. Internationally, ‘The Reattribution Model’ has demonstrated effect on GP skills, patient outcome and health care costs in before-and-after studies. Other treatment models and detailed guidelines exist but only few have been scientifically evaluated. In the light of this, the development of a new Danish treatment model for functional disorders (The Extended Reattribution and Management Model) is described briefly.

Assessment and Treatment of Functional Disorders in General Practice: The Extended Reattribution and Management Model (Article 2)

Chapter 3 introduces the contents of the educational programme on assessment and treatment of functional disorders. This article also formed a part of the educational material for GPs participating in the programme and contains an extensive general description of somatisation targeting clinicians. The educational program was based on the Reattribution Model, developed by D. Goldberg and L. Gask in the UK, which was modified, and new elements were added. Accordingly, the name was altered to the ‘TERM-model’. The entire research article has been contained within this chapter, but *only the Introduction and Sections 4 and 5 contain my main contributions*. Sections 5 to 7 describe the TERM-model in detail.

Evaluation of the educational programme

The educational programme was evaluated in a cluster randomised controlled trial with practices as randomisation unit. The GPs in Vejle County were invited in 1999 and 27 accepting practices (43 GPs) were allocated to intervention or control group. Intervention GPs were trained according to the described educational programme. Following the training all participating practices enrolled patients consulting for a new health problem. The outcome was assessed by the use of questionnaires for GPs and patients. Follow-up was conducted at three and twelve months for patients with high scores on a screening questionnaire for somatisation and at twelve months for GPs.

Effect of short-time training on general practitioners’ attitude towards somatisation (Article 3)

Chapter 4 seeks to answer the second research question and evaluates the effect of the TERM-model on GPs’ attitude towards somatisation. The GPs’ attitude was measured before intervention and at the twelve-month follow-up. Baseline values confirmed the previous findings that general practitioners find it difficult to deal with somatising patients. Compared with the control doctors, the intervention doctors’ attitude towards patients with somatoform disorders had changed significantly after training with regard to parameters related to the GPs’ feelings. Doctors now felt more comfortable in dealing with somatising patients. Attitudes to other parameters related to aetiology and course of somatisation changed in the expected direction, but these changes were not statistically significant.

General practitioners' diagnosis of somatisation - effect of an educational intervention in a cluster randomised controlled trial (*Article 4*)

Chapter 5 examines the effect of training on the GPs' diagnosis of somatisation in routine clinical practice. The primary outcome was the GPs' diagnostic rate of somatisation and the agreement of their diagnoses with a patient screening questionnaire for somatisation. GPs diagnosed somatisation less frequently than previously observed, but with much variation between GPs. The intervention GPs had a higher diagnostic rate of somatisation than the control GPs (14.2% vs. 10.8%), but the difference fell short of significance at a 5% level ($p=0.094$). However, the subclass 'medically unexplained physical symptoms' was diagnosed twice as often in the intervention group as in the control group (7.7% vs. 3.9%). Analysis of the agreement between the GPs' diagnoses and the results of the screening questionnaire revealed no significant difference between the groups.

Does general practitioner training targeting somatisation affect patient outcome? A cluster randomised controlled trial (*Article 5*)

Chapter 6 addresses the final research question. The assessment of patient outcome was considered highly important, as the overall aim of the educational programme was to improve the health of somatising patients. Resource constraints allowed us to follow up on somatising patients only. Somatisers were selected by the use of screening questionnaires (SCL-SOM and Whiteley-7) before GP consultation. Patient outcome was assessed at baseline and follow-up with regard to: quality of life (SF-36), disability days (WHO-DAS), somatisation (Whiteley-7 and SCL-SOM) and patient satisfaction (EUROPEP). Differences from baseline to follow-up between intervention and control groups were analysed.

The somatisers' self-reported health had improved in both intervention and control groups at the twelve-month follow-up, but changes were small. Statistically significant differences between randomised groups were only observed for 'bodily pain' and 'social functioning', and the changes were most pronounced in the control group (not corrected for mass significance). Other differences between groups fell short of statistical significance, including our primary outcome 'physical functioning'. Patients in the intervention group tended to be more satisfied at follow-up than those in the control group, but the difference was statistically insignificant. A number of methodological problems encountered are discussed in Chapters 6 and 7.

General discussion, conclusion and perspective**Discussion of methods**

Chapter 7 discusses the applied methods across chapters, and it serves as a supplement to the detailed discussions in the Chapters 2-6. The discussion focuses on the two main aspects of the study: the development of the educational programme and its evaluation. The methodological approach to the evaluation of the training programme was in many ways robust, but limitations were encountered in relation to design, intervention, sampling of participants, information sources, statistics and generalisability. For an outline, please see page 144.

Discussion of results and Conclusion

Chapter 8 discusses the results of the study in relation to existing literature and concludes on the project. The project succeeded in the interdisciplinary development of an evidence-based educational programme for functional disorders that was acceptable to GPs. Implementation of this programme induced a sustained, positive change in GPs' attitudes towards somatisation. Furthermore, trained GPs exhibited an increased awareness of medically

unexplained physical symptoms when making diagnoses. Whether increased diagnostic rates of medically unexplained symptoms also reflected improved diagnostic accuracy remains undetermined. The educational programme had no discernible impact on patient health at one-year follow-up, but may have increased patient satisfaction with care. **Chapter 9** presents a summary of the conclusions drawn.

Perspective and future research

Chapter 10 puts the study results into perspective and points to essential implications of the study. Reviewing the literature and considering the large variation in GPs' diagnoses, we clearly lack an agreed definition for somatisation in general practice both clinically and in research. Present pregraduate, postgraduate and continuing medical education in assessment and treatment of somatisation leaves much to be desired and the TERM-model has been welcomed. However, we still lack knowledge about the process of implementation at GP level and about the efficacy of the model at patient level. This study demonstrated an effect at GP level; yet we do not know how this influences doctor-patient interactions. We know little about the accuracy of the GPs' increased diagnostic rates of 'medically unexplained symptoms' and it remains unclear why GPs display large variations in their diagnoses. Finally, methodological difficulties impede research into the effects on patient outcome when intervention is administered at the GP level, and future research should carefully consider their methodological approaches.

Chapter 12

Dansk resumé

Ph.d.-afhandlingen bygger på projektet 'Somatiserende patienter i almen praksis – et interventionsstudie', der blev gennemført i Vejle Amt i perioden 1999 til 2003. Dette projekt blev udviklet og iværksat i et tæt samarbejde mellem Kvalitetsudviklingsudvalget for Almen Praksis, Vejle Amt, Forskningsenheden og Institut for Almen Medicin, Aarhus Universitet og Forskningsenheden for Funktionelle Lidelser, Århus Universitetshospital.

Generel introduktion

Afhandlingen består af en generel introduktion, fem artikler og en generel diskussion af metoder og resultater samt en konklusion. I sidste kapitel perspektiveres resultaterne, og nye forskningsspørgsmål stilles.

I **kapitel 1** introduceres begrebet somatisering i relation til almen praksis. Der findes adskillige navne og definitioner, hvilket giver anledning til en del forvirring på området. I dette studie blev somatisering defineret rent deskriptivt, ifølge Lipowski, som: 'en tendens til at være plaget af legemligt besvær og fysiske symptomer, som ikke kan forklares ved patologiske fund, at tilskrive disse en legemlig lidelse og søge medicinsk hjælp herfor'. Denne definition blev operationaliseret ved en inddeling i fire grupper (akutte og subakutte funktionelle symptomer, kronisk somatisering, præsenterende somatisering og sygdomsbekymring og sygdomsaggraving samt patologisk sygdomsadfærd ved somatisk lidelse). Begrebet 'somatisering' anvendes synonymt med 'medicinsk uforklarlige symptomer', 'funktionel lidelse' og 'funktionelle symptomer'.

Somatisering er årsag til 15-35% af alle henvendelser i almen praksis. Det spontane forløb er dårligt beskrevet, men undersøgelser har vist en række problemer i relation til behandling af disse lidelser: 1) Patienterne får ikke en tilstrækkelig behandling og risikerer at blive fastholdt i somatiske sygdomsaspekter samt at pådrage sig iatrogene skader, 2) læge-patient forholdet bliver påvirket i negativ retning og praktiserende læger oplever frustration, og 3) sundhedsvæsenet bruger mange ressourcer på unødvendige fysiske undersøgelser og behandlinger.

Kognitiv adfærdsterapi har vist sig at være en effektiv behandling, når den udføres af specialister. Der findes kun få undersøgelser af behandlinger udført af praktiserende læger; men en af dem 'The Reattribution Model' har vist lovende resultater i før-efter-studier. Implementering af en sådan ny behandling i almen praksis kræver en ændring af lægens adfærd. Det er en kompleks proces at ændre adfærd. Man må tage højde for mange forskellige faktorer, og det er nødvendigt at anvende en flerdimensional tilgang for at øge chancen for succes.

Sidst i kapitel 1 præsenteres **formålet** med afhandlingen. Projektet havde to overordnede mål: det ene var at udvikle og implementere et efteruddannelsesprogram for praktiserende læger om udredning og behandling af funktionelle lidelser, det andet var at evaluere effekten af dette program i almen praksis. Studiets specifikke forskningsspørgsmål var:

- Er det muligt at udvikle et teoretisk sundt efteruddannelsesprogram i udredning og behandling af somatisering, der kan accepteres af alment praktiserende læger?
- Giver den beskrevne efteruddannelse anledning til ændringer i praktiserende lægers holdning til somatiserende patienter?
- Er der forskel på uddannede og ikke-uddannede praktiserende lægers diagnostik af somatisering og på deres diagnostiske overensstemmelse med et screeningsinstrument for somatisering?
- Påvirker efteruddannelsen af lægerne de somatiserende patienters helbred og tilfredshed?

Udvikling og implementering af efteruddannelsesprogrammet

Efteruddannelsesmodeller med fokus på funktionelle lidelser i almen praksis (artikel 1)

Kapitel 2 giver en oversigt over efteruddannelsesprogrammer for praktiserende læger i relation til funktionelle lidelser. Den danske efteruddannelse på dette område har primært baseret sig på generel viden om psykiske lidelser og generelle færdigheder i kommunikation og terapimetoder. Mange programmer mangler et videnskabeligt og teoretisk afsæt i behandlingen af funktionelle lidelser og forbinder ikke evidens om disse lidelser til færdighedstræning. Internationalt har 'The Reattribution Model' i før-efter-studer vist effekt på praktiserende lægers færdigheder og en bedring af somatiserende patienters helbred samt lavere udgifter for sundhedsvæsenet. Der findes også andre behandlingsmodeller og retningslinier, men kun få er blevet videnskabeligt testet. I lyset heraf præsenteres udviklingen af en ny dansk behandlingsmodel for funktionelle lidelser (The Extended Reattribution and Management Model).

Udredning og behandling af funktionelle lidelser i almen praksis: The Extended Reattribution and Management Model (artikel 2)

Kapitel 3 beskriver indholdet af efteruddannelsesprogrammet om udredning og behandling af funktionelle lidelser. Denne artikel indgik også i det kursusmateriale, praktiserende læger modtog i forbindelse med efteruddannelsen. Artiklen indeholder derfor en omfattende generel beskrivelse af somatisering stilet til de praktiserende læger. Efteruddannelsesprogrammet tog udgangspunkt i 'The Reattribution Model' udviklet af D. Goldberg and L. Gask i England. Modellen blev ændret, og nye elementer blev tilføjet. Navnet blev derfor ændret til 'TERM modellen'. Hele artiklen er gengivet i dette kapitel, men kun introduktionen og sektion 4 og 5 indeholder mine væsentligste bidrag. Sektion 5 til 7 indeholder en detaljeret beskrivelse af TERM-modellen.

Evaluering af efteruddannelsesprogrammet

Efteruddannelsesprogrammet blev evalueret i et cluster randomiseret kontrolleret studie med lægepraksis som randomiseringsenhed. Alle praktiserende læger i Vejle Amt blev inviteret til at deltage i 1999 og 27 praksis (43 læger) tilmeldte sig. Deltagende praksis blev allokeret til interventions og kontrolgruppe, hvorefter læger fra interventionspraksis gennemgik den beskrevne efteruddannelse. Herefter inkluderede alle deltagende praksis de patienter, der henvendte sig i praksis med et nyt helbredsproblem. Effekten blev vurderet ved brug af spørgeskemaer til praktiserende læger og patienter. Der blev lavet followup på patienter med en høj score på et screeningsinstrument for somatisering efter tre og tolv måneder samt på deltagende læger efter tolv måneder.

Effekten af en kortvarig efteruddannelse på praktiserende lægers holdning til somatisering (Artikel 3)

Kapitel 4 belyser forskningsspørgsmål 2 og evaluerer effekten af TERM-modellen på praktiserende lægers holdning til somatisering. Praktiserende lægers holdning blev målt før interventionen og tolv måneder efter. Værdierne før intervention viste, som i tidligere studier, at praktiserende læger finder det svært at håndtere somatiserende patienter. Tolv måneder efter havde interventionslægenes ændret deres holdning betydeligt til patienter med somatiserende lidelse. Der fandtes en signifikant ændring på de parametre, der relaterede sig til lægens følelser således, at interventionslægerne havde det bedre og følte sig mere trygge, når de havde med somatiserende patienter at gøre, mens kontrollægenes holdninger var uændrede. Lægenes holdning til andre forhold, så som ætiologiske faktorer og forløb af

somatisering, ændrede sig i en positiv retning, men disse ændringer var ikke statistisk signifikante.

Praktiserende lægers diagnostik af somatisering – effekten af efteruddannelse i et cluster randomiseret studie (artikel 4)

I **kapitel 5** belyses effekten af efteruddannelse på praktiserende lægers diagnostik af somatisering i daglig klinisk praksis. Det primære effektmål var lægernes diagnostiske rate af somatisering og overensstemmelsen mellem deres diagnoser og et screeningsinstrument for somatisering. Lægerne stillede ikke diagnosen somatisering så hyppigt, som tidligere rapporteret, men variationen mellem de enkelte læger var meget stor. Efteruddannede læger havde en højere diagnostisk rate af somatisering end kontrollægerne (14.2% vs. 10.8%), men denne forskel var ikke statistisk signifikant på et 5% niveau ($p=0.094$). Interventionslægerne klassificerede imidlertid patienternes henvendelse i kategorien ‘medicinsk uforklarlige symptomer’ mere end dobbelt så hyppigt som kontrollægerne (7.7% vs. 3.9%, $p=0,007$). Analyser af overensstemmelsen mellem lægernes diagnoser og screeningsinstrumentet for somatisering viste ingen signifikant forskel mellem grupperne.

Har efteruddannelse af praktiserende læger med fokus på somatisering en effekt på patientniveau? Et cluster randomiseret kontrolleret studie (artikel 5)

Det sidste forskningsspørgsmål belyses i **kapitel 6**. Det blev anset for at være væsentligt at måle effekten på patientniveau, idet efteruddannelsens overordnede mål var at forbedre somatiserende patienters helbred. Der blev kun lavet followup på gruppen af somatiserende patienter på grund af ressourcebegrænsninger. De somatiserende patienter blev udvalgt ved brug af spørgeskemaer (SCL-SOM og Whiteley-7), som blev udfyldt inden lægekonsultationen. Patienterne blev vurderet ved inklusion og followup på følgende parametre: generel helbredsstatus (SF-36), uarbejdsdygtighed (WHO-DAS), somatisering (Whiteley-7 and SCL-SOM) og patienttilfredshed (EUROPEP). Forskellen mellem interventions og kontrolgruppe i ændringer fra inklusion til followup blev analyseret.

Somatiserende patienters selvrapporterede helbred var bedre efter tolv måneder end ved inklusionen i både interventions og kontrolgruppen; men ændringerne var små. Der var signifikant forskel mellem interventions- og kontrolgruppen for ændringer i ‘fysisk smerte’ og ‘social funktion’, dog således at ændringerne var mest udtalte i kontrolgruppen (ikke korrigeret for massesignifikans). De øvrige forskelle mellem grupperne, inklusive vores primære effektmål ‘fysisk funktion’, var ikke statistisk signifikante. Patienterne i interventions gruppen viste tendens til at være mere tilfredse ved followup end patienterne i kontrolgruppen, men forskellen var ikke statistisk signifikant. En række metodologiske problemer forbundet med denne del af studiet diskuteres i kapitel 6 og 7.

Generel diskussion, konklusion og perspektivering

Diskussion af metoder

Som et supplement til den detaljerede diskussion af resultater i de enkelte kapitler, bliver de anvendte metoder diskuteret på tværs af afhandlingen i kapitel 7. Diskussionen fokuserer på de to hovedområder: Udvikling af efteruddannelsesprogrammet og evaluering af dette program. Metodetilgangen til evalueringsprojektet var på mange måder robust, men rummede også begrænsninger i relation til design, intervention, sampling af deltagere, informationskilder, statistik og generaliserbarhed. En oversigt er vist på side 144.

Diskussion af resultater og konklusion

I **kapitel 8** diskuteres projektets resultater i relation til litteraturen og de endelige konklusioner drages. Det lykkedes at udvikle et evidensbaseret efteruddannelsesprogram om funktionelle lidelser i et tværfagligt samarbejde, og dette program blev godt modtaget af de praktiserende læger. Implementeringen af programmet medførte en vedvarende, positiv ændring af praktiserende lægers holdning til somatisering. Efteruddannede læger udviste større opmærksomhed på medicinsk uforklarlige symptomer i deres diagnostik. Det er dog fortsat uvist om den højere diagnostiske frekvens af medicinsk uforklarlige symptomer også er udtryk for en bedre diagnostisk præcision. Efteruddannelsen havde ingen indvirkning af betydning på patienters helbred efter et års followup, men patienternes tilfredshed med behandlingen blev forbedret. I **kapitel 9** findes konklusionerne i en sammenfattende oversigt.

Perspektivering og fremtidig forskning

I **kapitel 10** perspektiveres projektets resultater, og der gives forslag til fremtidig forskning. Set i forhold til litteraturen og den store variation i praktiserende lægers diagnostik, mangler vi en entydig definition for somatisering i almen praksis både i kliniske og i forskningsmæssige sammenhænge. Den aktuelle prægraduate uddannelse, videreuddannelse og efteruddannelse i udredning og behandling af somatisering er utilstrækkelig, og TERM-modellen er blevet positivt modtaget. Vi mangler imidlertid fortsat viden om implementeringsprocessen på lægeniveau og om modellens effekt på patientniveau. Dette projekt har vist effekt på lægeniveau; men vi ved ikke, hvad effekten heraf er på interaktionen mellem læge og patient. Vi fandt en øget diagnostisk rate af 'medicinsk uforklarlige symptomer', men vi ved kun lidt om, hvad det betyder for praktiserende lægers diagnostiske præcision. Ligesom det fortsat er uklart, hvorfor praktiserende læger udviser så stor variation i deres diagnostik. Endelig vanskeliggøres udforskning af effekter på patientniveau, når der intervenseres på lægeniveau, af metodologiske problemer. Disse bør nøje overvejes ved fremtidig forskning.

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Appendices

Appendix A. The TERM-model compared to The Reattribution Model

New items incorporated into the TERM-model have been marked in *italic*.

The TERM-model ¹	The Reattribution Model ^{2;3}
<p>Understanding</p> <ol style="list-style-type: none"> 1. Take a full symptom history (seek clarification, identify accompanying symptoms, describe a typical symptom day) 2. Explore emotional clues 3. Inquire directly about symptoms of anxiety and depression 4. Explore life events, stress and other external factors (social, work-related and family) 5. <i>Explore functional level (physical, social and family)</i> 6. Explore the patient's health beliefs 7. <i>Explore the patient's expectations to treatment and examinations</i> 8. Make a brief, focused physical examination and, if indicated, para-clinical examinations <p><i>Interviewing techniques</i></p> <ul style="list-style-type: none"> • <i>Socratic questioning:</i> • <i>Be neutral and genuinely curious</i> • <i>Use open questions</i> • <i>Use encouragement (facilitation)</i> • <i>Keep the focus</i> • <i>Make frequent summaries</i> 	<p>Feeling understood</p> <ul style="list-style-type: none"> • History of the present complaint <ul style="list-style-type: none"> - Associated symptoms - "Typical day" - Specific example • Respond to emotional cues <ul style="list-style-type: none"> - Assess mood • Explore social and family factors • Explore health beliefs/ patient's view of problem • Brief focused physical examination
<p>The physician's expertise and acknowledgement of illness</p> <ol style="list-style-type: none"> 9. Feedback the results of the physical examination 10. Acknowledge the reality of the symptoms 11. <i>Make clear that there is no (or that there is indeed) indication for further examination or non-psychiatric treatment</i> <p><i>Interviewing techniques</i></p> <ul style="list-style-type: none"> • <i>Empathy / emotional feedback</i> 	<p>Broadening the agenda</p> <ul style="list-style-type: none"> • Feedback results of examination or investigations • Acknowledge reality of pain or other symptoms

The TERM-model¹**The Reattribution Model^{2;3}****Negotiating a New Model of Understanding (Reframing)****Broadening the agenda – CONTINUED**

Negotiate with the patient a new model of understanding of his/her illness

- Reframe the complaint: summarise all the symptoms and suggest link to life events

Simple explanations

12. Physical symptoms are common reactions to e.g. stress and strain/nervousness
13. Depression lowers the threshold of pain
14. Muscular tension in anxiety and nervousness causes pain

Demonstrations

15. Practical (hyperventilation, muscular tension)
16. Establish the association between physical discomfort, emotional reactions and life events.
17. "Here and now"

Severe cases

18. Known phenomenon with a name; somatization

19. Basically the cause is unknown, but nothing indicates a hidden physical disease.

20. Biological explanation: Some are bodily more sensitive than others

21. Individual symptom coping and reactions determine your future well-being.

Interviewing techniques

- **Roll with resistance (Rope-a-dope)**
- **Support empowerment**

Making the link

- How symptoms might have occurred before during "stress"
- How tension can cause physical pain
- How symptoms can be related to life events
- How depression can lower the pain threshold
- How the symptoms can make you more depressed – "the vicious cycle"
- Linking in the "Here and now"
- Significant others

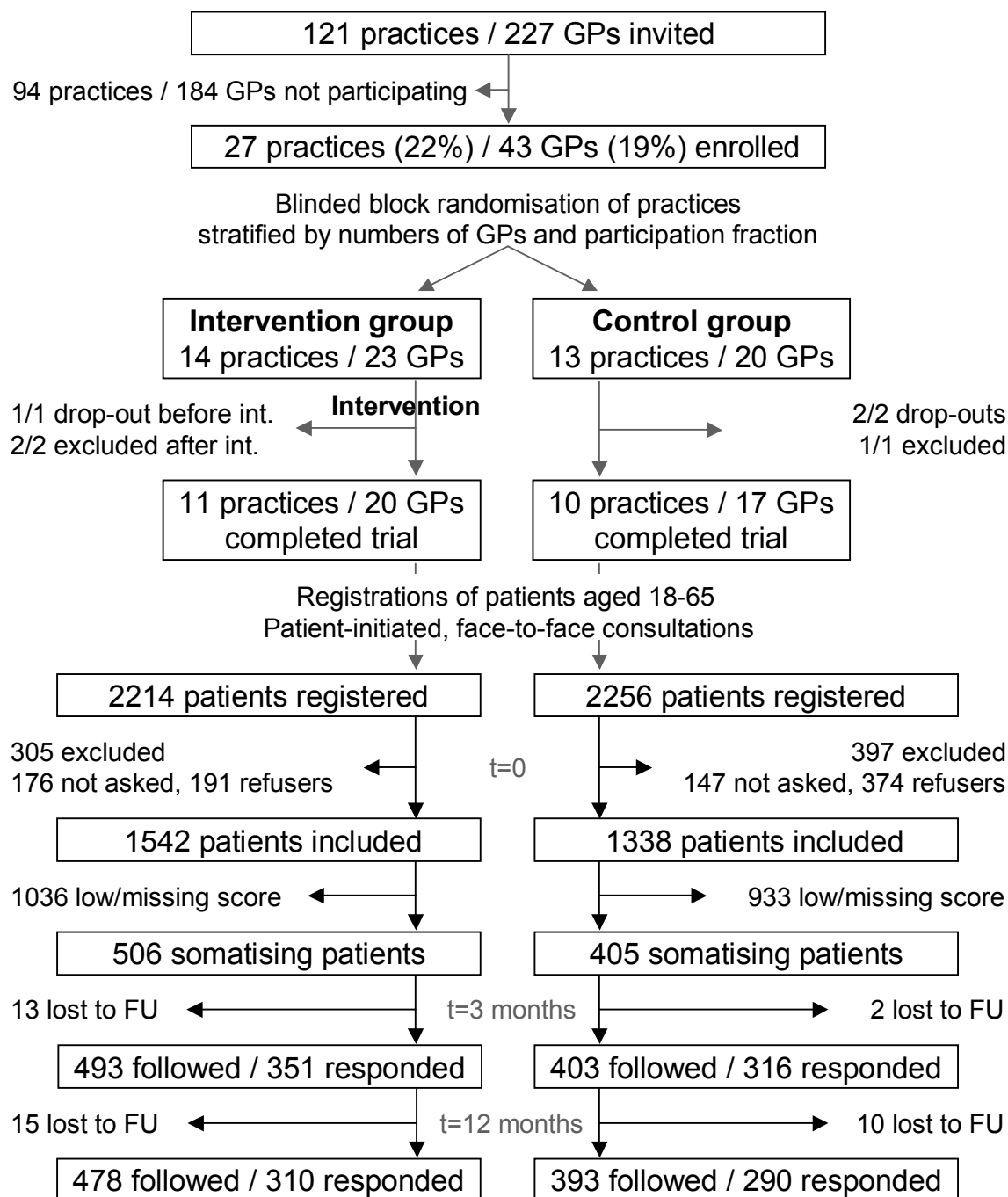
Negotiating further treatment**Negotiating treatment**

22. Sum up agreements made during the consultation
23. Agree upon specific objectives, contents and form of the future course.
24. Acute cases: no further appointments
25. Subacute cases: therapy sessions, regular scheduled appointments.
26. **Chronic: consider status consultation, regular scheduled appointments (see advice on management)**
27. Consider referral to psychiatrist, psychologist or specialist service.

- Explore patient's views
- Acknowledge patient's worries and concerns
- Problem-solving and coping strategies
- Relaxation
- Appropriate treatment of depression
- Specific plans for follow-up

Appendix B. Flowchart for the trial

Randomisation, patient registration and follow-up



Excluded were patients with acute severe disease (19) or mental handicap (38), patients of non-Scandinavian descent (311), patients not listed with included GPs (53) and patients who could not be included for other reasons (error in registration number or procedures, not able to read or write because of forgotten glasses or arm problems, one of the above but not specified etc. (281)).

A small number of visiting patients were not asked to participate by mistake (not asked) and some patients refused to participate when asked (refusers).

Appendix C. Measures

The questionnaires in appendix D include a large number of variables, of which some were not used in the analyses in this thesis. A summary of the variables analysed is given here. Variables have been divided into secretary, GP, and patient measures.

Abbreviations refer to the following questionnaires:

S-REG	=	Secretaries' registration form
GP-CME	=	General practitioners' education in communication and psychiatry
GP-AT0	=	General practitioners' attitude towards somatisation at baseline
GP-AT12	=	General practitioners' attitude towards somatisation after twelve months
GP-REG	=	General practitioners' registration form
PQ1	=	Patient questionnaire 1
PQ2	=	Patient questionnaire 2
PQ3	=	Patient questionnaire 3
Q	=	Item (question) number in questionnaire

Secretaries

Measures	Constructed variables	Questionnaire
Identification	Date for response	S-REG / head
	Serial number for practice	
	Patient identification	S-REG / column 1
Patient registration	Type of consultation (whether inclusion is possible)	S-REG / column 2
	Any exclusion criteria used	S-REG / column 3
	Refusal to participation	S-REG / column 4

General practitioners

Measures	Constructed variables	Questionnaire	Original	
Identification	Date for response	All		
	Serial number for GP and practice	All		
	Patient identification	GP-REG / column 1		
Practice characteristics	Type of practice	Register data		
	Practice geography			
	Number of GPs in practice			
	Number of listed patients per GP			
GP characteristics	Gender	Register data		
	Age			
	Seniority as GP			
	Previous longer courses		GP-CME / Q4	Questionnaire developed at The Research Unit for General Practice, Aarhus University ^{4,5}
	Previous supervision		GP-CME / Q6	
GP attitudes	Attitude towards somatoform disorders	GP-AT0 / Q1-7 GP-AT12 / Q1-7	Based on Hartman ⁶	
	Attitude towards somatisation	GP-AT0 / Q8-24 GP-AT12 / Q8-24	Based on Botega ⁷	
Patient registration	Inclusion/exclusion	GP-REG / column 2		
	New health problem	GP-REG / column 3		
Characterisation of symptoms	Duration of symptoms	GP-REG / column 4		
	Categorisation (dichotomised into physical and non-physical during analyses)	GP-REG / column 5	Based on Munk-Jorgensen ⁸ and Goldberg ⁹	

Patients

Measures	Constructed variables	Questionnaire	Original
Identification	Date for response	PQ1 / head	
	Gender	PQ2 / Q1, head	
	Age	PQ3 / Q1, head	
Sociodemographic characteristics	Habitation	PQ1 / Q41	
	Education	PQ1 / Q43-44	
	Employment	PQ1 / Q45	
Somatisation	Summary score SCL-SOM	PQ1 / Q1-12 PQ2 / Q19_1-12 PQ3 / Q20_1-12	SCL-SOM ¹⁰
	Summary score Whiteley-7	PQ1 / Q15-21 PQ2 / Q19_15-21 PQ3 / Q20_15-21	Whiteley-7 ¹¹
General mental health	Summary score SCL-8	PQ1 / Q23-30 PQ2 / Q19_23-30 PQ3 / Q20_23-30	SCL-8 ¹⁰
	Mental component summary	PQ1 / Q46, 48-58 PQ2 / Q5-Q12a PQ3 / Q5-Q12a	SF-36 ¹²
General physical health	Physical component summary		
General health evaluation	General health	PQ1 / Q46 PQ2 / Q2, 13 PQ3 / Q2, 13	
	Transition question	PQ1 / Q47 PQ2 / Q3 PQ3 / Q3	
Mental health	Vitality	PQ1 / Q54 PQ2 / Q11 PQ3 / Q11	
	Social functioning	PQ1 / Q51, 55 PQ2 / Q8, 12a PQ3 / Q8, 12a	
	Role limitations – emotional	PQ1 / Q50 PQ2 / Q7 PQ3 / Q7	
	Mental health	PQ1 / Q54 PQ2 / Q11 PQ3 / Q11	

Patients - continued

Measures	Constructed variables	Questionnaire	Original
Physical health	Physical functioning	PQ1 /Q48 PQ2 /Q5 PQ3 /Q5	SF-36
	Role limitations – physical	PQ1 /Q49 PQ2 /Q6 PQ3 /Q6	
	Bodily pain	PQ1 /Q52, 53 PQ2 /Q9, 10 PQ3 /Q9, 10	
Disability days		PQ1 / Q59 PQ2 / Q15 PQ3 / Q15	WHO-DAS
Satisfaction with care	‘Doctor-patient relationship’	PQ2 / Q21_1-6 PQ3 / Q22_1-6	EUROPEP ^{13;14}
	‘Medical-technical care’	PQ2 / Q21_7-11 PQ3 / Q22_7-11	
	‘Information and support’	PQ2 / Q21_12-15 PQ3 / Q22_12-15	

Appendix D. Questionnaires

All questionnaires were prepared and distributed in Danish using TELEform. They were pilot tested before the trial in practices not otherwise participating in this study.

This appendix includes the following questionnaires:

- General practitioners' education in communication and psychiatry (GP-CME)
- General practitioners' attitude towards somatisation (GP-AT0, GP-AT12)
- Registration form for the secretaries (S-REG)
- Registration form for the general practitioners (GP-REG)
- Patient questionnaire 1 (PQ1)
- Patient questionnaire 2 (PQ2)
- Patient questionnaire 3 (PQ3)

Covering letters and instructions precede the questionnaires.

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