General Practitioners and Somatising Patients

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

PhD thesis
Marianne Rosendal

The Committee for Quality Improvement in General Practice, Vejle County Health Insurance and The Research Unit and Department of General Practice Faculty of Health Sciences University of Aarhus Denmark 2003
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

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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 Frostholm, and Mette Bech Riser 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 Túborgh, 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.

My research colleagues at the Research Unit and Department for General Practice are thanked for constructive discussions, a stimulating atmosphere and good fellowship. In particular, I should like to thank Jette Møller Nielsen, Carsten Krogh Jørgensen, Julie Damgaard Nielsen, Janus Laust Thomsen, Peter Vedsted and Jens Søndergaard.

I appreciate the help that I received from the secretaries Eva Højmark Pedersen, Birthe Brauneiser and Solveig Nielsen at the Research Unit for General Practice, Anni Michelsen at the Department of General Practice, Elsebeth Schreiber at The Specific Training for General Practice and Ann Smedegaard at Vejle Hospital, and I am thankful for the assistance provided by Lars Olesen and Bjarne Benner Svendsen, when my computer was tricky. I acknowledge Søren Skadhede for his help with data processing and associate professor Morten Pilegaard for linguistic revision of the text.

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
Aarhus, August 2003
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’.

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 Fink and Dalsgaard 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 symptoms. 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’.

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 only. 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 Engel. 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 disorders.

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 1983 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’.

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.

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), 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.

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 systems.

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-SOM for somatisation and the Whiteley index 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 care.

The restricted diagnostic criteria used in specialist care may have contributed to the disagreements in diagnoses between GPs and psychiatrists observed in previous studies [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).

**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

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 treatment.1

**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 somatisation.15

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 somatisation;23. The symptoms counted in these definitions are not specific to somatisation and other factors may be important for the concept of somatisation;24.

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**’\(^4\)

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 al\(^28\). This classification has been slightly revised to include items ‘a’-‘d’ below\(^27\), 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 group\(^17\).
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 implications. 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’.

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. 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 unknown. 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 symptom.

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%. 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 cultures.
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\textsuperscript{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 cases\textsuperscript{37}.

Similar levels of psychiatric diagnoses, GP diagnoses and agreement between the diagnoses have been found for mental disorders in general\textsuperscript{35} and co-morbidity between somatisation and other psychiatric disorders is common\textsuperscript{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 disorder\textsuperscript{39}.

**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’\textsuperscript{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 patients\textsuperscript{41}.

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 chronicity\textsuperscript{42-44}.

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\textsuperscript{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 themselves. 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. This may entail endless unnecessary tests, medications, hospitalisations and surgeries exposing somatising patients to iatrogenic harm and withholding them from treatment of the underlying illness. Such a course may also contribute to an iatrogenic somatic fixation and the development of chronic illness behaviour.

‘...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)

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 population. Significant health problems and disability is also found in more broadly defined groups of somatising patients.

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 rejected.

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 domains. 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. Such shifts in power balance influence
the doctor-patient relationship and may cause doctors to become frustrated\textsuperscript{56} [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 somatisation\textsuperscript{57}.

### 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\textsuperscript{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’\textsuperscript{29}

Biomedical approaches are used intensively but they are ineffective in the treatment of somatisation\textsuperscript{48} 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 years\textsuperscript{60-62}. Among these therapies, psychodynamic/interpersonal psychotherapy\textsuperscript{63} and cognitive behavioural therapy\textsuperscript{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\textsuperscript{66,57}. 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)\textsuperscript{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\textsuperscript{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 practice\(^71\). GPs were taught in small groups and were able to acquire skills important for recognition of psychological problems\(^72\)-\(^74\). 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 skills\(^77\).

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 model\(^81\) was tested in two to three month prospective before-and-after studies demonstrating that GPs acquired the necessary interviewing skills\(^82\), overall health care cost were reduced for somatising patients\(^83\), and patients’ health beliefs changed\(^84\). Patients’ mental and physical health improved, but merely for somatisers who believed that their symptoms were only partly physically caused\(^85\). There was no effect on the overall patient satisfaction\(^85\), 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 practice\(^86\). 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 beforehand\(^68\) [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 should. 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 factors. 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 A. 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 sessions. This also applies to general practice where multifaceted approaches have been superior to single strategies. 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 time.

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 years. In one study skills even improved over time, but another study showed a decline in patient outcomes over three years.

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)*\(^8\)

<table>
<thead>
<tr>
<th>Approach</th>
<th>Theories</th>
<th>Focus</th>
<th>Interventions, strategy</th>
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<tr>
<td>Focus on internal processes</td>
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<tr>
<td>Educational</td>
<td>Adult learning theories</td>
<td>Intrinsic motivation of professionals</td>
<td>• Bottom up, local consensus development</td>
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<td>• Small group interactive learning</td>
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<td>• Problem based learning</td>
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<td>Epidemiological</td>
<td>Cognitive theories</td>
<td>Rational information seeking and decision making</td>
<td>• Evidence based guideline development</td>
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<td></td>
<td></td>
<td>• Disseminating research findings through courses, mailing, journals</td>
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<tr>
<td>Marketing</td>
<td>Health promotion, innovation and social marketing theories</td>
<td>Attractive product adapted to needs of target audience</td>
<td>• Needs assessment, adapting change proposals to local needs</td>
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<td></td>
<td></td>
<td></td>
<td>• Stepwise approach</td>
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<td></td>
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<td>• Various channels for dissemination (mass media and personal)</td>
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<td>Focus on external processes</td>
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<tr>
<td>Behavioural</td>
<td>Learning theory</td>
<td>Controlling performance by external stimuli</td>
<td>• Audit and feedback</td>
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<td>• Reminder systems, monitoring</td>
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<td>• Economic incentives, sanctions</td>
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<tr>
<td>Social interaction</td>
<td>Social learning and innovation theories, social influence/power theories</td>
<td>Social influence of significant peers/role models</td>
<td>• Peer review in local networks</td>
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<td>• Outreach visits, individual instruction</td>
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<td>• Opinion leaders</td>
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<td>• Influencing key people in social networks</td>
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<td>• Patient mediated interventions</td>
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<td>Organisational</td>
<td>Management theories, system theories</td>
<td>Creating structural and organisational conditions to</td>
<td>• Re-engineering care process</td>
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<td>improve care</td>
<td>• Total quality management/continuous quality improvement</td>
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<td>• Enhancing leadership</td>
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<td>• Changing structures, tasks</td>
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<td>Coercive</td>
<td>Economic, power, and learning theories</td>
<td>Control and pressure, external motivation</td>
<td>• Regulations, laws</td>
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<td>• Budgeting, contracting</td>
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<td>• Licensing, accreditation</td>
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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?
References


70. Smith GR, Jr., Rost K, Kashner TM. A trial of the effect of a standardized psychiatric consultation on health outcomes and costs in somatizing patients. Arch Gen Psychiatry 1995;52:238-43.


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.’

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 detailed during the process of development, and have been published in full (Chapter 3 and www.auh.dk/cl_psych/uk/).
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 design\(^3\text{-}^5\). 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 placebo\(^6\text{-}^8\).

The pragmatic randomised controlled trial

Our aim was to measure effect in routine care and we had to take a pragmatic approach\(^7\text{-}^9\). This generated several problems, which are addressed below.

- GPs’ participation in randomised controlled trials is barred by several factors\(^10\) 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\(^8\text{-}^11\text{-}^13\). 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\(^3\text{-}^6\). 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 population\textsuperscript{15} and 3% of the population in Vejle County moved out of the county in year 2000\textsuperscript{16}. 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 periods\textsuperscript{17}, 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’\textsuperscript{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 interviews. 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 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’. Furthermore, doctors with the greatest need for educational support may not have volunteered. 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 lead 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 recognised.

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 Denmark27,28. 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 somatisation37,38. 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 Europe\textsuperscript{39} and was validated also in Denmark\textsuperscript{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 effective\textsuperscript{24} [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 TELEform\textsuperscript{42}. 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 processing\textsuperscript{43}. 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 windows\textsuperscript{44} 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 groups\(^1\). 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 intraclass 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 analysis\(^13\). 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
References


42. TELEform version 6.1. 1998. San Marcos, California, USA, Cardiff Software Inc.


44. SPSS 10.0 for Windows. (Standard Version (10.0.5)). 27-11-1999. SPSS inc.


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. 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.

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’. 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 multifaceted and accompanied by other approaches [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 study\textsuperscript{12} 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 change\textsuperscript{10}. An important aspect of maintenance is the continuous monitoring and evaluation of personal progress\textsuperscript{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 treatment\textsuperscript{14}, 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 \textit{efficacy} and the \textit{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 circumstances\textsuperscript{15-17} [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 care\textsuperscript{12}. Furthermore, the feasibility of reattribution in general practice was supported by results from a Dutch study\textsuperscript{18}, and before-and-after studies applying similar learning strategies (micro skills training) have demonstrated that key communication skills were acquired after training\textsuperscript{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\textsuperscript{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.
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 symptoms.

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). 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 satisfaction (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 reattribution\(^8\) (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 measures\(^38\) 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

<table>
<thead>
<tr>
<th>The Reattribution Model&lt;sup&gt;6,7,39&lt;/sup&gt;</th>
<th>A modified reattribution model&lt;sup&gt;8&lt;/sup&gt;</th>
<th>TERM-model</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Location</strong></td>
<td>Manchester, UK</td>
<td>Amsterdam, The Netherlands</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>Prospective, before-and-after study</td>
<td>RCT</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>8-hour interactive training programme (4 x 2 hours: video training material, role play, video feedback supervision and written material)</td>
<td>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)</td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>Usual care before training</td>
<td>Usual care in control group</td>
</tr>
<tr>
<td><strong>Follow-up</strong></td>
<td>3 months</td>
<td>24 months</td>
</tr>
<tr>
<td><strong>GP inclusion</strong></td>
<td>8 of 17 volunteers selected 8 GPs completed the intervention Minimum 5 years seniority</td>
<td>19 GPs invited 15 GPs participated (10 intervention + 5 control) 9 GPs completed the intervention Minimum 5 years seniority</td>
</tr>
<tr>
<td><strong>Patient inclusion</strong></td>
<td>Two cohorts (103 and 112 patients): • Consecutive attenders • Physical complaint&gt;2 weeks • Illness attribution physical • GHQ-12 score &gt; 3 • GP does not have evidence of pathology explaining all symptoms or disability • Interview after 1 month confirms psychiatric disorder</td>
<td>75 intervention + 87 control patients: • 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</td>
</tr>
</tbody>
</table>
### Chapter 8. General discussion of results

#### Outcome measures

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<tr>
<th>Patient questionnaires</th>
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<tr>
<td>GHQ-12</td>
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<td>SF-36</td>
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<tr>
<td>Physical symptoms</td>
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<td>Illness attributions</td>
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<td>Satisfaction with care (satisfaction scale)</td>
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<td>Health care utilization</td>
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<td>Interview at 1 month (Retro PAS)</td>
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<td>Psychiatric disorder</td>
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<td>Health care utilization</td>
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<td>Costs were also based on primary care records</td>
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<th>Patient questionnaires</th>
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<tr>
<td>Visits to health care workers</td>
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<tr>
<td>Medicines used</td>
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<td>Subjective health on VAS</td>
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<td>Sick leave</td>
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<td>SCL-SOM</td>
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<tr>
<td>Practice records</td>
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<td>Number of visits to GP</td>
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<th>GP questionnaire</th>
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<tr>
<td>Attitude towards patients with somatoform disorders or somatisation</td>
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<tr>
<td>Classification of main problem presented by patient</td>
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<td>Patient questionnaires</td>
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<tr>
<td>Whiteley-7</td>
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<td>SCL-SOM</td>
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<td>SCL-8</td>
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<td>SF-36</td>
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<td>Disability days (WHO-DAS)</td>
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<td>Satisfaction with care (EUROPEP)</td>
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#### Results

- 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%

- Subjective health increased
- Sick leave decreased
- Number of health care visits decreased
- Number of medicines used remained unchanged
- Scores on SCL-SOM decreased

- 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
References


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 my 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 somatizing 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

**Generel introduktion**


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 sygdomsbekyrning og sygdomsaggravering 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) sundhedsvesenet bruger mange ressourcer på unødvendige fysiske undersøgelser og behandlinger.


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 efteruddannelsen 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 læerne de somatiserende patienters helbred og tilfredshed?
Udvikling og implementering af efteruddannelsesprogrammet

Efteruddannelsesmodeller med fokus på funktionelle lidelser (artikel 1)


Udredning og behandling af funktionelle lidelser i almen praksis: The Extended Reattribution and Management Model (artikel 2)


Evaluering af efteruddannelsesprogrammet


Effekten af en kortvarig efteruddannelse på praktiserende lægers holdning til somatisering (Artikel 3)

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 kontrolægerne (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)


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 begrensninger i relation til design, intervention, sampling af deltagere, informationskilder, statistik og generaliserbarhed. En oversigt er vist på side 144.
Diskussion af resultater og konklusion

Perspektivering og fremtidig forskning
Reference list


Gask L, Morriss R, Goldberg D. Reattribution. Managing Somatic Presentation of Emotional Distress. Video Recording 1999;University of Manchester, School of Behavioural Sciences:


Jorgensen, C. K. Patients with musculoskeletal illness in general practice - An analysis with emphasis on mental health issues. 2000. Research Unit and Department of General Practice, Aarhus University.


Smith GR, Jr., Rost K, Kashner TM. A trial of the effect of a standardized psychiatric consultation on health outcomes and costs in somatizing patients. Arch Gen Psychiatry 1995;52:238-43.


SPSS 10.0 for Windows. (Standard Version (10.0.5)). 27-11-1999. SPSS inc.


STATA/SE 8.0. 2003. 4905 Lakeway drive college station, Texas 77845, STATA Corporation.


Appendices
## Appendix A. The TERM-model compared to The Reattribution Model

New items incorporated into the TERM-model have been marked in *italic*.

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<thead>
<tr>
<th>The TERM-model</th>
<th>The Reattribution Model</th>
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<td><strong>Understanding</strong></td>
<td><strong>Feeling understood</strong></td>
</tr>
<tr>
<td>1. Take a full symptom history &lt;br&gt;(seek clarification, identify accompanying symptoms, describe a typical symptom day)</td>
<td>● History of the present complaint - Associated symptoms - &quot;Typical day&quot; - Specific example</td>
</tr>
<tr>
<td>2. Explore emotional clues</td>
<td>● Respond to emotional cues - Assess mood</td>
</tr>
<tr>
<td>3. Inquire directly about symptoms of anxiety and depression</td>
<td>● Explore social and family factors</td>
</tr>
<tr>
<td>4. Explore life events, stress and other external factors (social, work-related and family)</td>
<td>● Explore health beliefs/ patient’s view of problem</td>
</tr>
<tr>
<td>5. <em>Explore functional level (physical, social and family)</em></td>
<td>● Brief focused physical examination</td>
</tr>
<tr>
<td>6. Explore the patient’s health beliefs</td>
<td></td>
</tr>
<tr>
<td>7. <em>Explore the patient’s expectations to treatment and examinations</em></td>
<td></td>
</tr>
<tr>
<td>8. Make a brief, focused physical examination and, if indicated, para-clinical examinations</td>
<td></td>
</tr>
</tbody>
</table>

**Interviewing techniques**
- Socratic questioning:
- Be neutral and genuinely curious
- Use open questions
- Use encouragement (facilitation)
- Keep the focus
- Make frequent summaries

**The physician’s expertise and acknowledgement of illness**

| 9. Feedback the results of the physical examination | Broadening the agenda |
| 10. Acknowledge the reality of the symptoms | ● Feedback results of examination or investigations |
| **11. Make clear that there is no (or that there is indeed) indication for further examination or non-psychiatric treatment** | ● Acknowledge reality of pain or other symptoms |

**Interviewing techniques**
- Empathy / emotional feedback
**The TERM-model**

<table>
<thead>
<tr>
<th>Negotiating a New Model of Understanding (Reframing)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negotiate with the patient a new model of understanding of his/her illness</td>
</tr>
</tbody>
</table>

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

Interviewing techniques
- Roll with resistance (Rope-a-dope)
- Support empowerment

**Negotiating further 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.

**Negotiating treatment**

26. Chronic: consider status consultation, regular scheduled appointments (see advice on management)
27. Consider referral to psychiatrist, psychologist or specialist service.

---

**The Reattribution Model**

<table>
<thead>
<tr>
<th>Broadening the agenda — CONTINUED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reframe the complaint: summarise all the symptoms and suggest link to life events</td>
</tr>
</tbody>
</table>

**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
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

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<td>Serial number for practice</td>
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<td>Patient identification</td>
<td>S-REG / column 1</td>
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<tr>
<td>Patient registration</td>
<td>Type of consultation (whether inclusion is possible)</td>
<td>S-REG / column 2</td>
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<td>Any exclusion criteria used</td>
<td>S-REG / column 3</td>
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<td>Refusal to participation</td>
<td>S-REG / column 4</td>
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## General practitioners

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<td></td>
<td>Serial number for GP and practice</td>
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<td>Practice characteristics</td>
<td>Type of practice</td>
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<td>Questionnaire developed at The Research Unit for General Practice, Aarhus University^{4,5}</td>
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<td>Previous longer courses</td>
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<td>Previous supervision</td>
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<td>GP attitudes</td>
<td>Attitude towards somatoform disorders</td>
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<td>Attitude towards somatisation</td>
<td>GP-AT12 / Q8-24</td>
<td>Based on Botega^{7}</td>
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<td>New health problem</td>
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<td>Characterisation of symptoms</td>
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<td>Based on Munk-Jorgensen^{8} and Goldberg^{9}</td>
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<td>(dichotomised into physical and non-physical during analyses)</td>
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## Patients

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### Patients - continued

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<td>PQ3 / Q22_12-15</td>
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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.
References


