

## Symptom Research

More than half of all outpatient visits are triggered by physical symptoms which, in turn, are not adequately explained by medical disorders at least half of the time. Further, the presence and severity of somatic symptoms often correlate more strongly with psychological, cognitive and behavioral factors than with physiological or biological findings. Finally, our understanding of the etiology, evaluation, and management of somatic symptoms and functional syndromes is less advanced than our knowledge of many defined medical and psychiatric disorders. This special section, edited by Kurt Kroenke, M.D., will highlight original studies that advance the science and clinical care of somatic symptoms.

# A randomized controlled trial of brief training in the assessment and treatment of somatization in primary care: effects on patient outcome

Marianne Rosendal, Ph.D., M.D.<sup>a,\*</sup>, Frede Olesen, M.D., Dr.Med.Sci.<sup>b</sup>,  
Per Fink, M.D., Dr.Med.Sci., Ph.D.<sup>c</sup>, Tomas Toft, M.D., Ph.D.<sup>c</sup>,  
Ineta Sokolowski, M.Sc.<sup>b</sup>, Flemming Bro, M.D., Dr.Med.Sci., Ph.D.<sup>b</sup>

<sup>a</sup>The Research Unit for General Practice, University of Aarhus, DK-8000 Aarhus, Denmark

<sup>b</sup>Research Unit for General Practice, Aarhus University, DK-8000 Aarhus, Denmark

<sup>c</sup>Research Clinic for Functional Disorders, Aarhus University Hospital, DK-8000 Aarhus, Denmark

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## Abstract

**Objective:** Our aim was to evaluate the effect of an educational program designed to improve care for somatizing patients in primary care.

**Method:** Evaluation was performed during routine clinical care in a cluster randomized controlled trial. Patients were included consecutively, and those with a high score on rating scales for somatization were selected for follow-up ( $n=911$ ). Follow-up was conducted 3 months (response rate=0.74) and 12 months (response rate=0.69) after inclusion using questionnaires measuring quality of life (Medical Outcomes Study 36-Item Short Form), disability days (WHO's Disability Assessment Schedule), somatization (Whiteley-7 and Symptom Checklist Somatic Symptom Scale) and patient satisfaction (European Project on Patient Evaluation of General Practice Care). We analyzed differences from baseline to follow-up and compared these for intervention and control groups.

**Results:** Self-reported health improved in both intervention and control groups during follow-up for patients with a high score for somatization, but changes were small. We could not demonstrate any difference between the control group and the intervention group with regard to our primary outcome 'physical functioning.' Patients in the intervention group tended to be more satisfied at 12-month follow-up than those in the control group, but this difference fell short of statistical significance.

**Conclusion:** Training of primary care physicians showed no statistically significant effect on clinical outcome and showed nonsignificant improvement in patient satisfaction with care for patients with a high score for somatization.

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## 1. Introduction

Patients who present with physical symptoms for which there is no specific diagnosis and for which medicine does not provide a cure are extremely common in primary care. Several names, concepts and definitions of such conditions exist. In order to encompass the broad spectrum of disorders that are encountered in primary care, we use the name

'medically unexplained symptoms' or 'somatization' and apply the definition of Lipowski [1]: "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."

Somatization is highly prevalent in primary care where 20–30% of patients fulfill criteria for somatoform disorders [2–4] and even more patients may present medically unexplained symptoms of shorter duration [5]. Despite its high prevalence, somatization often goes unrecognized [3,6], and the default use of biomedical

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\* Corresponding author. Tel.: +45 2041 1619; fax: +45 8612 4788.

E-mail address: [m.rosendal@dadlnet.dk](mailto:m.rosendal@dadlnet.dk) (M. Rosendal).

approaches may cause iatrogenic harm and disablement to somatizing patients [7,8]. Previous studies have demonstrated significant health problems and disability in somatizing patients in general [9], and poorer physical and mental health for chronic somatizing patients compared to patients with physical disorders or to the general population [8].

Primary care physicians must be capable of assessing and treating most somatizing patient within primary care [4] and also express a wish to do so [10,11], but they feel that effective management strategies are lacking and often ask for greater support and training in this field [10,11].

The treatment of somatizing patients has been evaluated in a number of studies, but few have focused on care undertaken by primary care physicians. A review of primary care interventions aimed at improving the treatment of mental disorders reported a positive effect on clinical outcome in 8 of 16 studies, of which only three specifically targeted somatization [12]. Another review found a consistent effect of cognitive-behavioral therapy (71% of 31 controlled trials) on physical health in somatizing patients. However, in these studies, treatment was provided by mental health specialists [13].

Primary care treatment for somatization has taken two main directions [14]. One approach has been shared care, where mental health specialists have offered patient assessment and treatment guidelines [15]. Another approach has been the education of primary care physicians to improve their management of somatization within their own setting. Such a program (the reattribution model) has been tested in a 3-month before–after study and has shown a positive effect on patients' physical functioning, psychiatric disorders [16], illness attribution and patient satisfaction [17]. Two related programs have been tested in randomized controlled trials and have shown slightly conflicting results. A study from The Netherlands demonstrated a significant effect on subjective health and sick leave after 2 years [14], whereas a German study only found marginal effects at the patient level [18]. In both studies, doctors were told which patients they were supposed to apply the model to — an approach that is difficult to implement in routine care.

'The Extended Reattribution and Management Model' was developed to address the whole spectrum of patients with medically unexplained symptoms seen in general practice [19]. Our aim was to evaluate the effect of the routine application of this educational program on patients' physical health, mental health and satisfaction with care.

## 2. Method

### 2.1. Setting

The study was performed in Vejle County, Denmark, which is a mixed rural–metropolitan area with 350,000 inhabitants served by 121 practices [227 family physicians

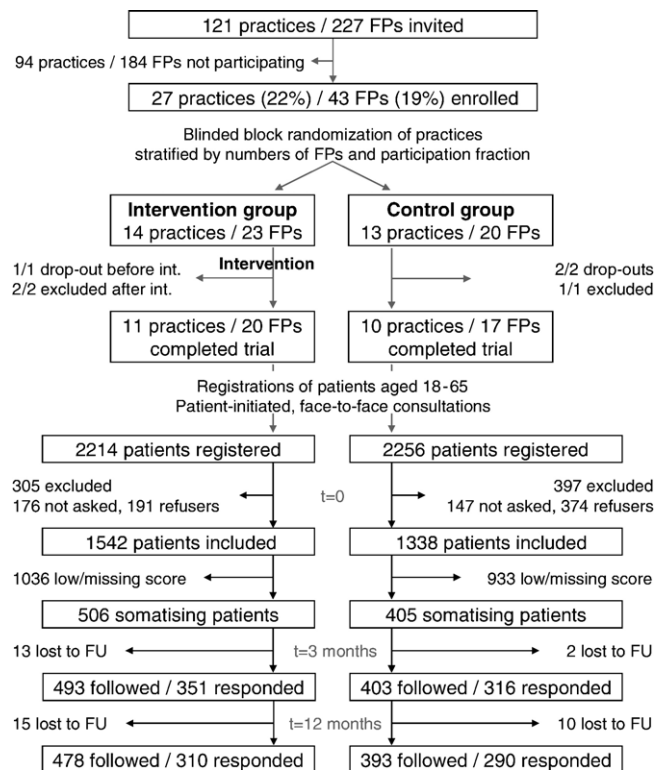
(FPs)]. The Danish health care system is tax financed, and 98% of Danes are listed with one general practice.

### 2.2. FPs and randomization

FPs registered with the Vejle County Health Insurance were invited to participate in November 1999. Inclusion criteria were as follows: participation of at least 50% of FPs from practice and minimum working hours of 2.5 days/week. Enrolled practices were stratified by the number of FPs per practice (1–4) and the proportion of participating FPs in relation to the total number of FPs in practice (0.5–1.0). After inclusion was completed, practices in each stratum were allocated to intervention or control (Fig. 1). A person not involved in the study performed randomization by drawing nontransparent lots containing code numbers. Participating FPs could not be blinded but were asked not to inform patients about their grouping. All FPs received reimbursement for participation.

### 2.3. Patients

Practice secretaries enrolled patients consecutively for 13 working days (May 2000). Inclusion criteria were age from 18 to 65 years and consulting for a new health problem. Exclusion criteria were as follows: severe acute disease requiring immediate treatment, mental handicap, non-Scan-



Excluded were patients with acute severe disease (19) or mental handicap (38), patients of non-Scandinavian descent (311), patients not listed with included family physicians (FPs) (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).

Fig. 1. Randomization of practices, patient registration and follow-up of patients with high scores on a patient screening questionnaire.

dinavian descent, not listed with participating FPs, previously enrolled and participation not possible for other reasons (error in registration number, forgotten glasses, etc.) (Fig. 1).

Follow-up was conducted for somatizing patients, defined as patients with a positive score on one of two rating scales for somatization [Symptom Checklist Somatic Symptom Scale (SCL-Som) [20] and Whiteley-7 [21]]. Items in the two rating scales were dichotomized between *a little bit* and *moderately*. Scales were scored using cut points 3/4 for SCL-Som and 1/2 for Whiteley-7. Somatizing patients received a questionnaire 3 and 12 months after inclusion. This also included patients who left Vejle County (approximately 3%) or who changed their listing with practices (approximately 1%) during follow-up. If patients did not respond to questionnaires, one reminder was sent after 3 weeks.

#### 2.4. Sample size

Power analyses were performed for the entire study, producing a desired sample size of 22 FPs in each arm (Type 1 error=0.05; Type 2 error=0.20) [22]. Power analyses for the primary outcome ‘physical functioning’ based on estimates from previous studies (mean=44, S.D.=20) required 78 somatizing patients in each arm to show a 20% difference. These analyses did not allow for clustering of patients within FPs. Subsequent analysis taking FP

clusters into account yielded an intraclass correlation coefficient for differences close to zero.

#### 2.5. Intervention

Intervention comprised a multifaceted educational program on the assessment, treatment and management of medically unexplained physical symptoms (the TERM model) [19] (Table 1). The program included positive criteria for somatization, skills training in biopsychosocial history taking, a general treatment model for somatization and advice on the management of chronic cases. FPs in the intervention group were trained on April 2000.

Control FPs were only informed about the definitions of somatization in writing and during meetings with the project leader. They were offered the training after completion of the trial.

#### 2.6. Outcome measures

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

Included patients completed a self-administered screening questionnaire in the waiting room prior to their consultation. Follow-up was performed by postal questionnaires sent 3 and 12 months after inclusion.

All patient questionnaires included the following measures:

- Medical Outcomes Study 36-Item Short Form (SF-36) [23]: This brief measure of quality of life comprises eight dimensions for which high scores indicate better quality of life. Scales were scored according to guidelines [23]. The primary outcome measure was physical health.
- WHO’s Disability Assessment Schedule (WHO-DAS): We used only one question from the WHO questionnaire: “In the past 4 weeks, for how many days were you totally unable to carry out your usual activities or work because of any health condition?”
- Whiteley-7 [21]: This short version of the Whiteley index measures illness worry and conviction.
- SCL-Som (Hopkins Symptom Checklist) [20]: This is a 12-item subscale measuring somatization by symptom score.
- SCL-8 (Hopkins Symptom Checklist) [20]: This eight-item subscale measures mental illness in general.

In the scales Whiteley-7, SCL-Som and SCL-8, patients were asked about symptoms during the past 4 weeks, and answers were given on 5-point Likert scales. High scores indicate poor mental health. When used as outcome measures, mean values were calculated for each scale by summarizing item scores (1–5) and dividing them by the number of answered items. If more than half of the items within a scale were missing, all items were set missing.

The follow-up questionnaires also included European Project on Patient Evaluation of General Practice Care

Table 1

Educational intervention: Different parts of the training program and its content

Residential course (2×8 h)
Didactic sessions
Theory and evidence of somatization
Stepwise presentation of the treatment model
Introduction to exercises
Video clips of a trained FP applying skills during consultation
Groups of eight with two supervisors
Three rounds of group discussions
Eight modules of micro skills training in pairs and with amateur actors
Eight video supervisions of consultations performed with an actor
Follow-up meetings (3×2 h, the weeks following the residential course)
Weekly meetings in groups of 8 with 2 supervisors
Video supervision of consultations from practices
Booster meeting (2 h, 3 months after the residential course)
Small group discussions
Outreach visit (30 min, 6 months after the residential course)
A facilitator paid visits to practices aiming at the reinforcement of the learning process
The dialogue with FPs focused on incentives, barriers, strengths, weaknesses, opportunities and threats concerning the “TERM model” applied in routine clinical practice [21]
Facilitators were supervisors from the course
Posted information (9 months after the residential course)
A letter describing the overall experiences from the outreach visits
Total time spent on the course by each participating physician: 25 h

(EUROPEP) [24]. This instrument measures patient satisfaction with primary health care. EUROPEP consists of 23 items grouped as doctor–patient relationship, medical–technical care, information and support, and organization of service. The first three groups were related to our intervention and analyzed. Items were also analyzed separately. Analyses of categories were based on dichotomization of single items [24] and subsequent dichotomization of groups between ‘all items answered positively’ and ‘at least one item answered negatively,’ corresponding to the 75th percentile.

FPs answered questionnaires on eligible patients immediately after index consultations. They were asked to classify the main problem presented by the patient into one of five categories, which were later dichotomized into ‘physical disease’ or ‘somatization’ [22].

Applied questionnaires were pilot tested in nonparticipating practices before the trial.

### 2.7. Statistics and software

Questionnaire data were processed using TELEform 6.1. ‘Intention-to-treat’ analyses at FP level could not be performed, as lost FPs did not provide any patient information. At patient level, information was missing for nonrespondents. Consequently, analyses were performed using complete data only. However, analyses did include respondents who left the county or who were listed with another FP during follow-up.

Chi-square test or Mann–Whitney *U* test was applied to data concerning FPs. Analyses at patient level were performed using linear regression or logistic regression. At this level, 95% confidence intervals (95% CIs) and tests of longitudinal changes within groups were adjusted for FP clusters. Tests of differences between randomized groups were adjusted for patient gender, patient age and FP clusters according to protocol. Intracluster variation was assessed by one-way analysis of variance for random-effects model. Statistical analyses were performed with SPSS 10.0 and STATA SE 8.0 for windows.

### 2.8. Ethics and approval

This study was approved by the Ethics Committee for Funen and Vejle County, the Data Surveillance Authority and the Scientific Research Evaluation Committee of the Danish College of General Practitioners. All eligible patients were informed about the project by the practice secretary and in writing. If they agreed to participate, they provided consent by answering baseline questionnaires.

## 3. Results

### 3.1. FPs

Enrolment comprised 27 practices (43 FPs) randomized to the intervention group or to the control group (Fig. 1). Three practices dropped out before intervention, and another

three were excluded because of low rates of patient inclusion. Participants completing the study had practiced family medicine for fewer years than nonparticipants (10.0 vs. 12.8;  $P=.038$ ) and were from urban areas (97.3% vs. 56.0%;  $P<.001$ ) but did not otherwise differ from nonparticipants on parameters listed in Table 2.

Randomized groups did not differ significantly on selected parameters (Table 2). The FPs in the intervention group accomplished training by participation in the residential course and in at least two follow-up meetings. Nineteen of 20 FPs accepted the outreach visit.

### 3.2. Patients at baseline

Participation was refused by 15% of eligible patients, and 9% of patients were not asked by mistake (Fig. 1). Refusers were older than participants (mean of 45.3 vs. 39.8 years;  $P<.001$ ), and more were diagnosed with somatization (19.5% vs. 12.6%;  $P<.001$ ) by FPs.

The intervention group saw an inclusion rate (81%) higher than that of the control group (72%). Scores on the screening questionnaire for somatization were positive for 33% in the intervention group and for 30% in the control group. Patients included for follow-up scored lower on SF-36 subscales at baseline than the Danish normal population [23], except for ‘role — emotional’ (Table 2).

Ceiling and floor effects were analyzed for SF-36 and WHO-DAS. They were generally low and were all below 50% [i.e., the ratio of patients with the highest (100) or lowest (0) outcome was below 0.5]. Randomized groups differed on two of the listed parameters (Table 2). Somatizing patients in the intervention group were more often unskilled and had poorer ratings for ‘general health’ than patients in the control group.

### 3.3. Follow-up of somatizing patients

Twelve-month follow-up questionnaires were sent to 94% of somatizing patients (i.e., patients with high scores for somatization) in the intervention group and to 98% of those in the control group. The response rates were 71% and 78% at 3 months, and 65% and 74% at 12 months. Deaths amounted to four in each group.

Each group was analyzed separately for changes in outcome measures over time. Individual changes varied widely, but overall changes were small at both 3- and 12-month follow-ups (Table 3). Improvement was observed in both groups for most parameters after 12 months. ‘Role — physical,’ ‘bodily pain,’ ‘physical component summary,’ transition question, Whiteley-7, SCL-Som and SCL-8 improved statistically significantly in both groups. ‘General health,’ ‘vitality,’ ‘social functioning’ and disability days only improved significantly in the control group.

Baseline values for patients not responding at 12-month follow-up were analyzed and compared to those for respondents. Nonrespondents were younger (39.4 vs. 43.1 years;  $P<.001$ ), more of them were men (42.3% vs. 31.8%;  $P=.001$ ) and unskilled (39.0% vs. 30.0%;  $P=.001$ ), and

Table 2  
Baseline characteristics for participating FPs and patients included for follow-up

	Control	Intervention	P
Characteristics for FPs			
Participants (n)	17	20	
Men [n (%)]	11 (64.7)	15 (75.0)	.50 <sup>a</sup>
Age in years (mean [95% CI])	47.9 [45.2, 50.6]	48.1 [44.5, 51.7]	.73 <sup>b</sup>
Seniority as FP (mean [95% CI])	7.6 [4.0, 11.2]	12.0 [7.4, 16.6]	.22 <sup>b</sup>
Partnership practices [n (%)]	12 (70.6)	14 (70.0)	.97 <sup>a</sup>
Urban practices [n (%)]	17 (100.0)	19 (95.0)	1.00 <sup>a</sup>
Number of FPs per practice [median (25th–75th percentiles)]	2 (1–3)	3 (1–4)	.13 <sup>b</sup>
Number of listed patients per FP (mean [95% CI])	1645 [1550, 1740]	1526 [1390, 1662]	.14 <sup>b</sup>
FPs who have attended previous longer courses <sup>c</sup> [n (%)]	8 (50.0) <sup>d</sup>	6 (30.0)	.22 <sup>a</sup>
FPs who have attended previous supervision <sup>c</sup> [n (%)]	8 (50.0) <sup>d</sup>	9 (47.4) <sup>d</sup>	.88 <sup>a</sup>
Patient characteristics			
With a high score on SCL-Som or Whiteley-7 (n)	405	506	
Men [n (%)]	127 (31.4)	192 (37.9)	.10 <sup>e</sup>
Age in years (mean [95% CI])	42.2 [40.9, 43.4]	41.6 [39.6, 43.6]	.60 <sup>e</sup>
With symptom duration of <6 months [n (%)]	283 (76.1)	355 (76.5)	.92 <sup>e</sup>
Diagnosed as somatizers by GP [n (%)]	66 (17.7)	98 (21.0)	.33 <sup>e</sup>
Sociodemographic characteristics [n (%)]			
Living with partner or spouse (vs. living alone or with parents)	279 (69.4)	337 (67.8)	.66 <sup>e</sup>
Accomplished primary school only (vs. further school)	231 (57.8)	295 (60.7)	.45 <sup>e</sup>
Unskilled (vs. accomplished formal education)	111 (28.9)	175 (36.8)	.02 <sup>e</sup>
Employed (vs. students, unemployed, pensioners, etc.)	240 (61.5)	273 (57.6)	.30 <sup>e</sup>
SF-36 subscales (0–100)			
Physical functioning [median (25th–75th percentiles)]	84.2 (65.0–95.0)	80.0 (61.1–95.0)	.61 <sup>e</sup>
Role — physical (mean [95% CI])	50.3 [44.3, 56.3]	49.9 [45.3, 54.6]	.93 <sup>e</sup>
Bodily pain (mean [95% CI])	48.0 [44.8, 51.1]	49.6 [46.8, 52.4]	.41 <sup>e</sup>
General health (mean [95% CI])	58.8 [56.1, 61.6]	54.3 [52.1, 56.5]	.01 <sup>e</sup>
Vitality (mean [95% CI])	50.0 [47.3, 52.7]	48.3 [46.2, 50.3]	.26 <sup>e</sup>
Social functioning [median (25th–75th percentiles)]	75.0 (62.5–100)	75.0 (62.5–100)	.64 <sup>e</sup>
Role — emotional [median (25th–75th percentiles)]	100 (33.3–100)	100 (33.3–100)	.67 <sup>e</sup>
Mental health (mean [95% CI])	67.0 [64.4, 69.5]	65.6 [63.4, 67.8]	.38 <sup>e</sup>
SF-36 component summaries and transition question (mean [95% CI])			
Physical component summary	41.6 [40.2, 43.0] <sup>f</sup>	41.6 [40.1, 43.0] <sup>d</sup>	.98 <sup>e</sup>
Mental component summary	47.4 [45.8, 49.0] <sup>f</sup>	41.4 [44.9, 47.9] <sup>d</sup>	.34 <sup>e</sup>
Health compared to 1 year ago	3.2 [3.1, 3.3]	3.2 [3.1, 3.3]	.68 <sup>e</sup>
Disability days [median (25th–75th percentiles)]			
Number of disability days (0–28)	1 [0, 8]	0 [0, 7] <sup>d</sup>	.56 <sup>e</sup>
Psychological screening [median (25th–75th percentiles)]			
SCL-Som score (1–12)	2.3 (2.0–2.6)	2.3 (1.9–2.6)	.57 <sup>e</sup>
Whiteley-7 score (1–7)	2.0 (1.6–2.5)	2.1 (1.7–2.6)	.44 <sup>e</sup>
SCL-8 score (1–8)	1.9 (1.5–2.6)	2.0 (1.5–2.8)	.64 <sup>e</sup>

Information was missing in <10% of patients, except when stated otherwise.

<sup>a</sup> Chi-square test.

<sup>b</sup> Mann–Whitney *U* test.

<sup>c</sup> Supervision and courses of at least 3 days' duration concerning communication skills and psychiatric training.

<sup>d</sup> Missing information on one FP.

<sup>e</sup> Logistic regression adjusting for GP clusters.

<sup>f</sup> Missing information in 10–15% of patients.

fewer were living with a partner (63.0% vs. 71.7%;  $P=.039$ ). They did not differ from respondents with regard to the other parameters listed in Table 2. When these nonrespondents were analyzed according to their randomization, their baseline values did not differ between randomized groups, except for their larger number in the intervention group.

### 3.4. Effect of intervention on physical and mental health

A large number of items were analyzed to examine the possible effect of intervention (Table 3). After 3 months, no

statistically significant differences or definite patterns in the differences between groups were observed. At 12 months, the overall pattern of differences between randomized groups appeared to favor the control group, although most differences were small (Fig. 2). Two patients in the intervention group having extreme negative differences (–73 and –85) could explain the larger improvement in the control group. Removing those patients from the analyses changed outcome on physical functioning to favor the intervention group (adjusted difference=0.4; 95% CI=[–2.4, 3.1]). Most differences between the

Table 3  
Differences in scores on patient questionnaires on follow-up versus baseline for somatizing patients

	Control		Intervention		Adjusted difference <sup>a</sup>	
	<i>n</i>	Mean [95% CI <sup>b</sup> ]	<i>n</i>	Mean [95% CI <sup>b</sup> ]	ΔMean [95% CI <sup>b</sup> ]	<i>P</i> <sup>c</sup>
3-Month follow-up±baseline						
SF-36: eight subscales (0–100)						
Physical functioning	311	−0.3 [−2.2, 1.6]	328	−0.1 [−2.3, 2.2]	0.3 [−2.6, 3.1]	.85
Role — physical	300	5.8 [2.6, 9.1]	326	3.4 [−0.6, 7.5]	−2.5 [−7.4, 2.4]	.31
Bodily pain	311	8.2 [4.6, 11.8]	339	5.0 [2.9, 7.0]	−3.5 [−7.4, 0.5]	.09
General health	310	−0.7 [−3.1, 1.7]	317	1.0 [−0.6, 2.6]	1.6 [−1.2, 4.3]	.25
Vitality	309	−0.6 [−2.5, 1.3]	336	−0.9 [−2.8, 1.0]	−0.2 [−2.9, 2.5]	.85
Social functioning	317	1.0 [−1.0, 2.9]	342	−1.1 [−3.7, 1.5]	−2.3 [−5.4, 0.8]	.14
Role — emotional	298	0.4 [−5.9, 6.7]	321	0.5 [−4.1, 5.2]	0.1 [−7.5, 7.6]	.99
Mental health	311	0.8 [−1.4, 3.1]	336	−0.7 [−2.4, 1.0]	−1.5 [−4.3, 1.2]	.25
SF-36 component summaries and transition question						
Physical component summary (0–100)	272	1.5 [0.4, 2.6]	280	1.1 [0.3, 1.9]	−0.4 [−1.7, 0.9]	.48
Mental component summary (0–100)	272	−0.1 [−1.4, 1.2]	280	−0.6 [−1.7, 0.5]	−0.5 [−2.1, 1.1]	.55
Health status compared with that 1 year ago (1–5)	316	−0.1 [−0.3, 0.0]	338	−0.1 [−0.2, 0.0]	0.1 [−0.1, 0.2]	.42
Disability days						
WHO-DAS (0–28)	294	−0.7 [−1.6, 0.1]	302	−0.3 [−1.4, 0.8]	0.5 [−0.8, 1.8]	.46
Psychological screening						
Whiteley-7 (1–7)	314	−0.3 [−0.4, −0.2]	348	−0.3 [−0.4, −0.2]	0.0 [−0.1, 0.1]	.98
SCL-Som (1–12)	315	−0.2 [−0.3, −0.2]	351	−0.2 [−0.2, −0.1]	0.1 [0.0, 0.1]	.21
SCL-8 (1–8)	314	−0.2 [−0.3, −0.1]	348	−0.1 [−0.2, −0.0]	0.1 [0.0, 0.2]	.19
Response rate [ <i>n</i> (%)]	317 (78)		352 (71)			
12-Month follow-up±baseline						
SF-36: eight subscales (0–100)						
Physical functioning	284	0.8 [−0.9, 2.6]	288	0.5 [−1.7, 2.8]	−0.1 [−2.9, 2.7]	.89
Role — physical	271	9.3 [5.1, 13.4]	289	4.6 [0.7, 8.5]	−4.6 [−9.9, 0.7]	.09
Bodily pain	287	10.5 [8.5, 12.5]	293	6.5 [3.8, 9.3]	−4.1 [−7.4, −0.8]	.02
General health	277	1.9 [−0.3, 4.1]	286	0.5 [−1.1, 2.2]	−1.3 [−3.9, 1.4]	.34
Vitality	282	1.9 [−0.5, 4.4]	300	−0.4 [−2.4, 1.6]	−2.3 [−5.3, 0.7]	.12
Social functioning	290	2.6 [−0.2, 5.4]	303	−1.5 [−4.0, 1.0]	−4.2 [−7.8, −0.6]	.02
Role — emotional	271	1.9 [−3.4, 7.2]	286	−2.4 [−7.8, 2.9]	−4.2 [−11.3, 3.0]	.24
Mental health	283	1.0 [−1.9, 3.8]	299	0.4 [−1.9, 2.6]	−0.5 [−4.1, 3.0]	.76
SF-36 component summaries and transition question						
Physical component summary (0–100)	247	2.7 [1.8, 3.5]	245	2.0 [1.0, 2.9]	−0.7 [−1.9, 0.5]	.25
Mental component summary (0–100)	247	0.2 [−1.4, 1.8]	245	−0.6 [−1.8, 0.6]	−0.8 [−2.7, 1.1]	.42
Health status compared with that 1 year ago (1–5)	287	−0.5 [−0.6, −0.3]	299	−0.4 [−0.5, −0.3]	0.1 [−0.1, 0.2]	.21
Disability days						
WHO-DAS (0–28)	272	−1.1 [−2.1, −0.2]	270	−0.9 [−2.0, 0.2]	0.3 [−1.1, 0.2]	.71
Psychological screening						
Whiteley-7 (1–7)	285	−0.4 [−0.4, −0.3]	307	−0.3 [−0.4, −0.2]	0.1 [−0.1, 0.2]	.37
SCL-Som (1–12)	284	−0.2 [−0.3, −0.2]	304	−0.2 [−0.2, −0.1]	0.1 [0.0, 0.2]	.23
SCL-8 (1–8)	285	−0.2 [−0.3, −0.1]	306	−0.1 [−0.2, 0.0]	0.1 [−0.1, 0.2]	.32
Response rate [ <i>n</i> (%)]	290 (74)		311 (65)			

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

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

'Mean' specifies the mean of differences for patients' scores on follow-up minus scores at baseline.

For SF-36 items, the threshold for statistical significance should be corrected for multiple testing (i.e.,  $P < .006$ ;  $\alpha = .05/\text{number of tests} = 8$ ).

<sup>a</sup> Differences are calculated by subtracting the mean value in the control group from that in the intervention group. They have been adjusted for patient gender, patient age and GP clusters.

<sup>b</sup> Confidence intervals are adjusted for GP clusters.

<sup>c</sup> Linear regression adjusting for patient gender, patient age and GP clusters.

intervention group and the control group, including our primary outcomes 'physical functioning' and 'physical component summary,' fell short of significance. Statistical significance was only observed for 'bodily pain' and 'social functioning,' and the significance disappeared when correction for multiple comparisons was performed. Supplemen-

tary analyses adjusting for SF-36 general health baseline values did not affect the overall results.

The proportion of patients having no disability days during the past 28 days increased from 50.2 at baseline to 55.3 after 12 months in the intervention group, compared with 47.8 and 55.3 in the control group.

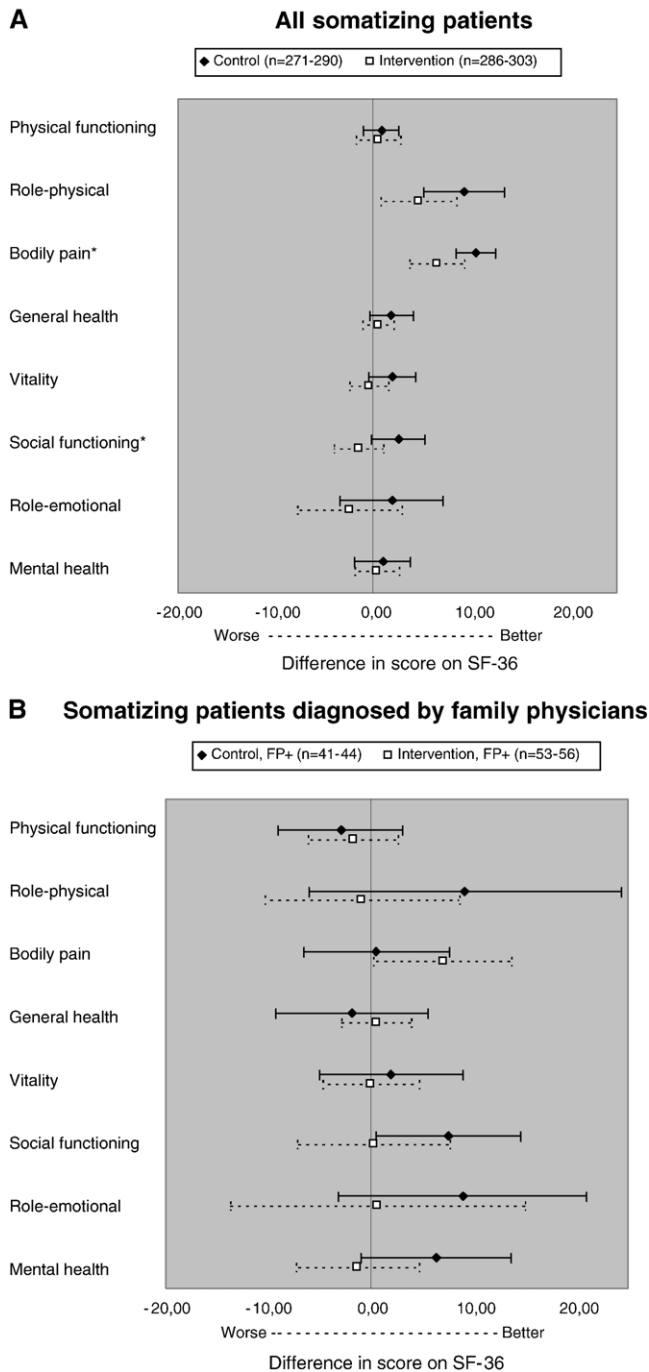


Fig. 2. Mean differences in scores on the eight subscales of SF-36 for somatizing patients according to randomization group. Scores at baseline were subtracted from scores at 12-month follow-up (possible values for differences are  $-100$  to  $100$ ). (A) includes all patients with a high score for somatization whereas (B) only includes the patients with high scores who were also diagnosed with somatization by their family physician. \* $P < .05$ .

Supplementary analyses were performed at 12-month follow-up on the subgroup of somatizing patients who were also diagnosed by their FPs (Fig. 2). The FPs' diagnostic rate was lower than expected, and the numbers produced for analysis were small (41–58). Differences between random-

ized groups on the subscales of SF-36 varied from 1.4 (95% CI=[ $-5.9$ ,  $8.2$ ]) for 'physical functioning' to  $-10.5$  (95% CI=[ $-27.5$ ,  $6.6$ ]) for 'role — physical.' The physical component summary improved by 2.2 units (95% CI=[ $-1.8$ ,  $6.2$ ]) more in the intervention group than in the control group ( $P = .271$ ). There was no specific pattern in the differences between randomized groups (Fig. 2), and none of them was statistically significant. Disability days decreased by 1.7 days in the control group (95% CI=[ $-4.3$ ,  $1.0$ ]) and increased by 1.0 day in the intervention group (95% CI=[ $-2.4$ ,  $4.4$ ]), an insignificant difference ( $P = .212$ ).

### 3.5. Effect of intervention on somatization

Improvements in scores on SCL-Som and Whiteley-7 were very small, and randomized groups did not differ significantly.

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

### 3.6. Effect of intervention on patient satisfaction with care

Patient satisfaction was measured at 3 and 12 months and could not be directly compared as we asked for satisfaction at different time intervals (the past 3 months and the past 12 months, respectively). No statistically significant differences were observed at either time. Analyses of single items showed no specific pattern.

At 12 months, 39.1% of patients in the intervention group compared with 36.5% of patients in the control group were very satisfied with the doctor–patient relationship ( $P = .409$ ); 29.0% of patients in the intervention group compared with 24.7% of patients in the control group were very satisfied with medical–technical care ( $P = .237$ ); and 36.8% of patients in the intervention group versus 30.6% patients in the control group were very satisfied with information and support ( $P = .069$ ) (Fig. 3). None of these individual differences reached statistical significance, but they pointed in the same direction concerning all three issues: more patients were fully satisfied in the intervention group than in the control group.

## 4. Discussion

### 4.1. Summary of main findings

The representative participation of primary care physicians indicates that the results may be generalized to similar

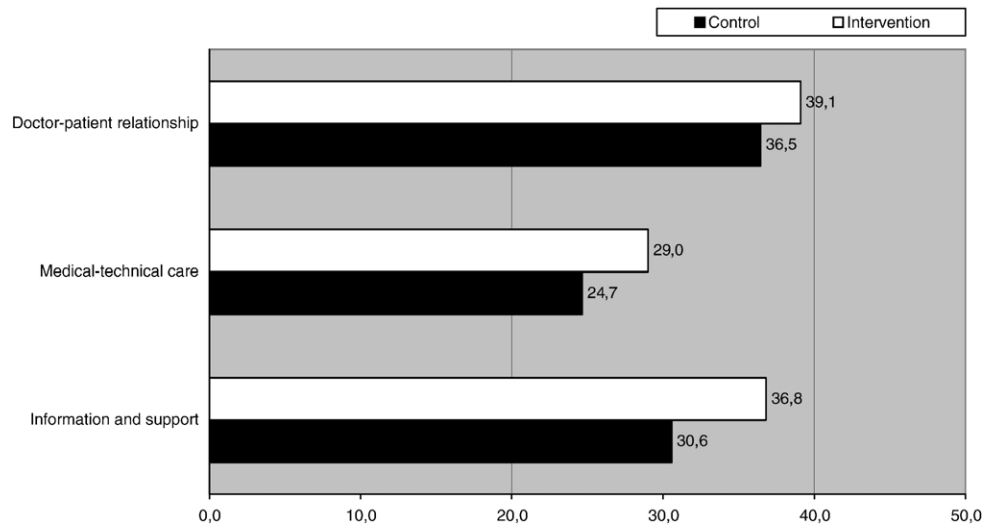


Fig. 3. Patient evaluation of their FP 1 year after intervention. Numbers refer to the proportion of patients with high satisfaction. Satisfaction was measured on three issues using the EUROPEP instrument. Logistic regression adjustment for patient gender, patient age and physician clusters resulted in *P* values of (1) .409, (2) .237 and (3) .069, respectively.

settings. The overall changes in self-reported health were small during 1-year follow-up for patients with high scores on a screening questionnaire for somatization. Training of physicians was associated with nonsignificant improvements in satisfaction with care. No statistically significant effect was found with regard to patients' physical function, quality of life, disability days or somatization after 1-year follow-up.

#### 4.2. Strengths and weaknesses of the study

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

Changes in health measures were small and even tended to be lower in the intervention group than in the control group after 1 year. These findings were unexpected since the physicians' attitudes changed in a positive direction in the present study [25,26] and the intervention was based on principles that had previously shown promising effects at patient level. The surprising nature of these results may be ascribed to: (1) inclusion bias at patient level; (2) the patient sampling method; (3) inadequate instruments for measuring outcome; (4) a minimal effect of training within the first year; and (5) unchanged clinical practice in the intervention group (i.e., no effect of intervention):

1. Inclusion bias may have been present as intervention practices had a higher patient inclusion rate, included a higher proportion of somatizers and had poorer baseline scores on SF-36 for included patients and for respondents at 12-month follow-up compared to control practices. Somatization may, hence, have been more chronic in the intervention group than in the control group. Increased chronicity is correlated with poorer responsiveness to intervention. Bias may have been small, but if we also consider the fact that it took only two patients with extreme values to change the overall patterns, the bias may have been sufficient to produce the observed results.
2. Patients were included by the use of questionnaires, but the applied screening questionnaires are subject to a large degree of uncertainty. Furthermore, the primary care physicians' diagnoses of somatization are only weakly associated with questionnaires based on psychiatric classifications [22,27]. Nevertheless, at present, we do not have a gold standard for diagnosis somatization in the primary care patient population, and these scales are currently our best tools for rating somatization by the use of questionnaires. The included patients presented a wide spectrum of somatization, and changes in outcome may have occurred to different degrees and at different speeds in distinct subgroups of patients. Our choice of inclusion made it difficult to identify relevant subgroups of patients that may have gained most from the intervention.
3. We used previously validated questionnaires to measure outcome, and general health measures were supplemented by specific measures for somatization. The responsiveness of SF-36 has been established



[28], whereas the responsiveness for SCL-Som and Whiteley-7 is poorly described.

4. We know only little about how the TERM model was implemented in clinical practice. Previous studies have demonstrated that taught skills are learned and applied [29], and a qualitative study of the TERM model rendered probable the implementation of parts of the model in routine practice [26]. The time period for implementation may, however, have been too short and reinforcement may have been too weak, as the acquisition of complex skills may not be straightforward for primary care physicians. Finally, doctors must recognize somatization to apply a new treatment, but the physicians' diagnostic rates were low [22] and numbers for analyses were small.

The questionnaires contained a large number of items yielding multiple statistical analyses, and the few statistically significant values found disappeared when corrected for multiple comparisons.

#### 4.3. Comparison with other studies

Some of the scores on SF-36 subscales and on psychological screening improved statistically significantly during follow-up. These results agree with a before–after study by Morriss et al. [16]. Although changes were statistically significant, they were small and not clinically impressive [30]. Changes were also small compared to other interventional studies on somatization. This may be due to the fact that we used different questionnaires for the sampling of patients. In our study, patients generally had better baseline scores on SF-36, and most of them had symptom durations of <6 months, whereas previous studies have been concerned with persistent somatization. Blankenstein [14] and Smith et al. [15] observed significant effects of intervention on clinical parameters in randomized controlled trials. Our results do not support those findings, but there are some important differences between the studies. The study by Smith et al. involved assessment by an acknowledged psychiatrist, and primary care physicians were given diagnosis and treatment instructions for selected patients [15]. In the study of Blankenstein [14], the doctors also knew which patients to treat, and treatment was reinforced by the use of protocols. In contrast, one German study similar to the Dutch study found only marginal effects [18], and another found no effect on psychological outcome [31], which is in line with our results.

The FIP study [2], which is closely related to this study but also includes standardized interviews, performed identical analyses and could not confirm the trend of a negative effect observed in this study (personal communication, January 2007). On the contrary, the FIP study reported improvement in 'physical functioning' for patients diagnosed with somatoform disorders [32] and also demonstrated improved patient satisfaction in the intervention group [33].

Studies on depression have shown similar results. A study in 2002 showed no improvement in patient outcome upon a brief training of primary care physicians and showed the same overall negative trend as our study [34]. Their conclusion that it may be difficult for primary care physicians to learn necessary skills in a short time is in line with a recent review of treatment stating that "treatment seem[s] to be more effective in patients in secondary care than [in patients] in primary care" [35]. The improvement of patient health with regard to patients with somatization and mental disorders, in general, may require system interventions and not only isolated education of primary care physicians [36].

#### 4.4. Meaning of the study and implications for future research

This study addresses two important issues: how to improve care for somatizing patients in the primary care setting and whether educational interventions targeting physicians also affect patient outcome. The health care system should offer the same professional treatment to somatizing patients as it provides for patients with well-defined physical diseases, and there is a need for continuous development and evaluation of treatment strategies for patients with medically unexplained symptoms. However, it may be difficult to measure significant changes at patient level, as small but important effects are watered down when a broadly defined group of patients is to benefit from an educational activity in routine clinical care. For the evaluation of educational interventions such as the TERM model, we may have to consider an approach where well-defined cases of somatization are observed and physicians' recognition of cases is ensured. Such an approach would be methodologically stronger but would suffer from the disadvantage of being less applicable to routine clinical practice.

Future research in the field of medically unexplained symptoms and somatization would gain from the development of improved classification in primary care and specific outcome measures. Finally, we may have to design more comprehensive interventions that also involve organizational changes.

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