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Somatoform disorders in general practice.

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Chapter 9



Medically unexplained physical symptoms in primary care: a controlled study on the effectiveness of cognitive-behavioural treatment by the general practitioner.

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Abstract

Objective To assess the effectiveness of a primary care cognitive-behavioural treatment for somatoform disorders. Our main hypothesis was that a cognitive-behavioural intervention provided by the GP would be more effective in reducing somatic symptoms and functional impairment than care as usual.

Design Controlled study. Care as usual was compared with care as usual supplemented by a cognitive-behavioural intervention by a specially trained GP.

Setting 16 general practices in the Western part of The Netherlands.

Participants 1,830 attendees and 4,579 enlisted patients underwent a two-step screening by means of a mailed questionnaire and a psychiatric diagnostic interview (WHO-SCAN 2.1). After 6 months participants with a DSM-IV somatoform disorder were assessed on eligibility for cognitive-behavioural treatment. Exclusion criteria were a serious psychiatric or somatic disease or current psychological treatment. 100 participants were eligible, and 65 agreed to participate, 31 in the intervention and 34 in the control condition.

Interventions Intervention patients were offered five 45-minute sessions of cognitive-behavioural treatment by their GP in addition to care as usual. In the control condition participants received care as usual.

Main outcome measures The severity of the main physical symptom as indicated on a visual analogue scale (VAS) and the self-reported recovery of the symptoms (better/same/worse) at 6 and 12 months after baseline.

Results The average severity score of the main physical symptom on a VAS decreased from 7.6 at baseline to 6.0 (CI 5.2-6.8) for controls and 6.0 (CI 5.1-6.8) for intervention participants after 12 months. According to their self-reported recovery, 12 out of 34 controls (35%) and 13 out of 31 intervention patients (42%) indicated improvement of symptoms, which was not significantly different. Secondary outcome measures did not show significant differences either. The prescription of psychotropic drugs was associated with a better recovery.

Conclusions We found that 5 sessions of cognitive-behavioural therapy on top of care as usual did not effectuate significantly better results. A possible explanation for the lack of effectiveness is that the treatment was brief and carried out by a general practitioner. Furthermore, the participants in this study were older than in secondary care studies and had relatively more severe symptoms.

Introduction

Medically unexplained physical symptoms are common in general practice. At least one out of 6 participants in primary care has medically unexplained physical symptoms (MUPS) that lead to significant limitations in daily life.^{1,2} Often MUPS are complicated by co-morbid psychiatric disorders such as depression and anxiety.¹ Several authors have reported on successful treatments with cognitive-behavioural therapy (CBT) covering a range of MUPS in secondary care.^{3-5,6} In a meta-analysis, Raine et al. found that interventions for common mental disorders that are effective in secondary care might not have the same results in primary care.⁷ These findings are consistent with recent studies reporting on the limited feasibility and effectiveness of cognitive-behavioural therapy for medically unexplained physical symptoms in general practice.^{8,9} Although the burden of MUPS in primary care is considerable, evidence as to the most appropriate treatment is limited.

The SOUL-project was designed to study the feasibility and effectiveness of cognitive-behavioural treatment for medically unexplained symptoms in an integrated epidemiological and treatment study in primary care, providing detailed information on the selection of participants. Medically unexplained physical symptoms were classified as somatoform disorders according to the DSM-IV psychiatric criteria.¹⁰ Our main hypothesis was that a cognitive-behavioural intervention provided by the general practitioner (GP) in addition to care as usual, would be more effective in reducing somatic symptoms and functional impairment than care as usual.

Methods

The SOMatisation study of the University of Leiden (SOUL-study) was designed as a prospective cohort study with an intervention study to investigate the epidemiology and treatment of somatoform disorders in general practice. Results on the epidemiological part of the study - dealing with questions on prevalence and overlap with anxiety and depression - have been published elsewhere.¹ To assess the effectiveness of cognitive-behavioural treatment we conducted a controlled study. Care as usual was compared with care as usual supplemented by a cognitive-behavioural intervention. The ethics committee of the Leiden University Medical Centre approved of the study.

Procedure

Participants with medically unexplained physical symptoms were recruited among patients registered with sixteen GPs, whose practices were situated in urban areas in

the Western part of The Netherlands. Twelve GPs were university-affiliated; the other four were regular GPs. A total of 1,083 attendees and 4,579 enlisted patients were screened. The study was limited to natives of The Netherlands.

Participants received a questionnaire through the mail and one reminder. All high-risk participants were contacted by telephone to arrange a diagnostic interview. A score of 5 or more on the Physical Symptom Checklist (PSC)¹ or a total score of 15 or more on the Hospital Anxiety and Depression Scale (HADS)¹¹ defined the high-risk sample. In addition, a random selection of participants with a low score was invited for the diagnostic interview. To assess the willingness of enlisted patients to participate, the following questions were asked in the questionnaire as well as on the telephone: 'Are you bothered by physical symptoms' and 'Would you consider joining a study on the effect of treatment by your own general practitioner?' Patients who had answered negatively were not invited for further assessment.

After a follow-up period of 6 months all the participants with a DSM-IV diagnosis of somatoform disorder were evaluated as to eligibility for cognitive-behavioural therapy. Requirements for inclusion in the treatment study were: 1) the presence of a somatoform disorder, 2) a minimum score of 5 of the main unexplained physical symptom on a VAS (range 0-10) and 3) written informed consent. Exclusion criteria were: 1) unable to participate in treatment due to handicaps such as deafness, aphasia or cognitive impairment, 2) ongoing psychological treatment, 3) a serious somatic disease or 4) a serious psychiatric disorder such as psychosis, substance abuse, post-traumatic stress disorder or severe personality disorder. Patients with a comorbid common psychiatric disorder such as a depressive or anxiety disorder were eligible.

Initial assessment

In the questionnaire physical symptoms were reported on the Physical Symptoms Checklist (PSC)¹. The PSC has 51 non-gender specific items and four gender specific items, one for men and three for women. We excluded the gender-specific items from the analyses to rule out bias. The presence of symptoms was rated on a severity scale from 0 to 3 (4-point Likert scale) for the preceding week. A symptom was rated as present for the scores 2 and 3 if it was 'bothersome often or most of the time during last week'; the total score on the PSC ranges from 0 to 51. The HADS¹² consists of 14 questions on mental distress, it contains no questions on physical symptoms. The total score ranges from 0-42 with 7 questions on depression and 7 questions on anxiety.¹¹ Functional impairment was measured with the MOS-SF-36¹³, a widely used generic health status measure. Health anxiety and health behaviour were measured with the Illness Attitude Scales (IAS).^{14 15}

The Schedules for Clinical Assessment in Neuropsychiatry (SCAN 2.1)¹⁶ were used by WHO-certified psychologists for the psychiatric diagnostic interviews. During

the interview, participants were asked about concurrent physical illnesses and the GP-researcher (IA) supervised all interviews for psychiatric and somatic diagnostic data. Whenever necessary, medical diagnostic data concerning symptoms were obtained from the individual general practitioners.

In addition, participants with a somatoform disorder reported the frequency and the severity of the main unexplained symptoms during the interview. Frequency could be expressed in 'never', 'sometimes', 'often' or 'always'. Participants indicated the severity of their symptoms on a visual analogue scale (VAS), where 0 meant 'no symptoms' and 10 meant 'unbearable symptoms'.

Follow-up assessments

At 6 and 12 months after baseline participants received questionnaires for follow-up measurements. In addition to the severity of their main symptom, the self-reported rate of improvement was used to evaluate the patient's overall judgement of improvement. Participants were asked to indicate whether their symptoms had improved, were the same or had become worse, compared to the situation at baseline.

Health care utilization was evaluated from the GPs' and from the participants' perspective. First, the electronic medical records of the GPs provided the number of face-to-face contacts with the participants and the prescription of psychotropic medication. Second, participants were asked about attendance of a mental health professional to assess psychological treatment.

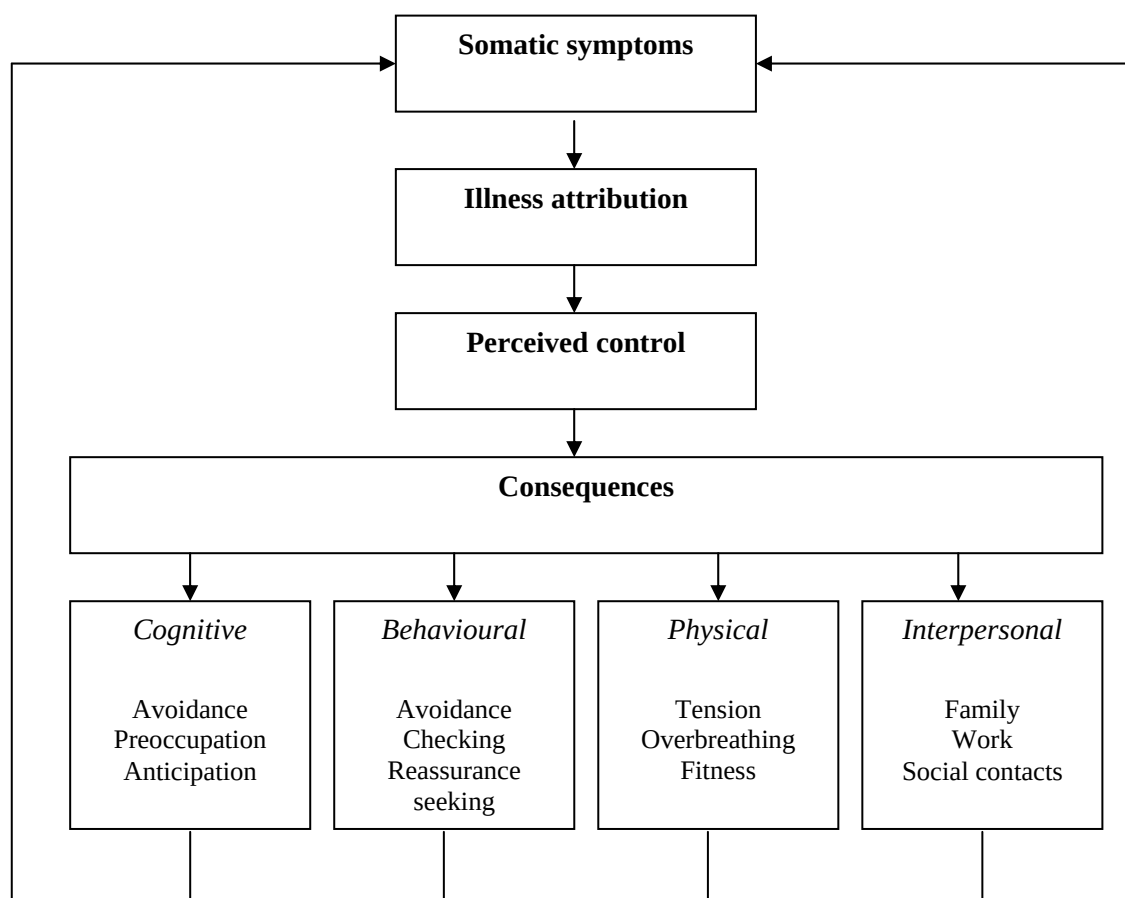
Assignment

Since the training and treatment would be time-consuming, the intervention was carried out by GPs who volunteered to participate in the experimental condition. Control GPs were matched with intervention GPs on practice characteristics such as urbanisation grade, university affiliation, and age and gender of the GP. To avoid contamination of treatment effects, intervention and control practices were kept separate. The GPs had no influence on patient selection since the GP-researcher (IA) selected the participants. Names of the participants were not revealed to the control GPs. All eligible participants received identical information on the trial and were only informed about their allocation after they had signed the informed consent form.

Treatment conditions

Intervention consisted of care as usual combined with five sessions of cognitive-behavioural therapy provided by their own general practitioner. A broad cognitive-behavioural treatment approach based on the consequences model was used in view of the heterogeneous nature of the participants' problems (figure 1).¹⁷

Figure 1. General treatment model based on the physical symptoms and their various consequences by Speckens (1995).



The same treatment model was used in a study we performed in secondary care and we tailored it for use by the GP.⁴ The central idea of this approach was to focus on the consequences rather than on the causes of the symptoms, providing an opportunity to treat physical symptoms without fruitless discussions on causes. Cognitive and behavioural techniques in the consequences model aim at changing the consequences of the symptoms. Frequently occurring consequences of unexplained symptoms such as chronic fatigue or pain are dysfunctional cognitions, inactivity or increased muscle tension. Changing dysfunctional cognitions may relieve anxiety and improve adequate coping. Other patients may benefit from explicit advice about the planning of activities or the use of relaxation methods. All eight GPs who carried out the intervention followed a training of 20 hours in cognitive-behavioural therapy. Techniques used were scheduling activities, relaxation therapy and challenging dysfunctional cognitions. Fixed components of the treatment consisted of a problem analysis according to the consequences model and a treatment plan with a graded increase in activities. If indicated, the GP could apply relaxation therapy or cognitive interventions. The first four sessions with the patient were scheduled every fortnight;

the last session was planned three months later. Each session lasted 45 minutes and was structured according to a treatment protocol with instructions for the GP. In addition to the initial training, all GPs in the intervention group received 3 two-hour sessions of supervision by a highly qualified cognitive-behavioural therapist (PS). Adherence to the therapy was further optimised with a detailed manual for the GP and a self-help book and leaflets for the participants.

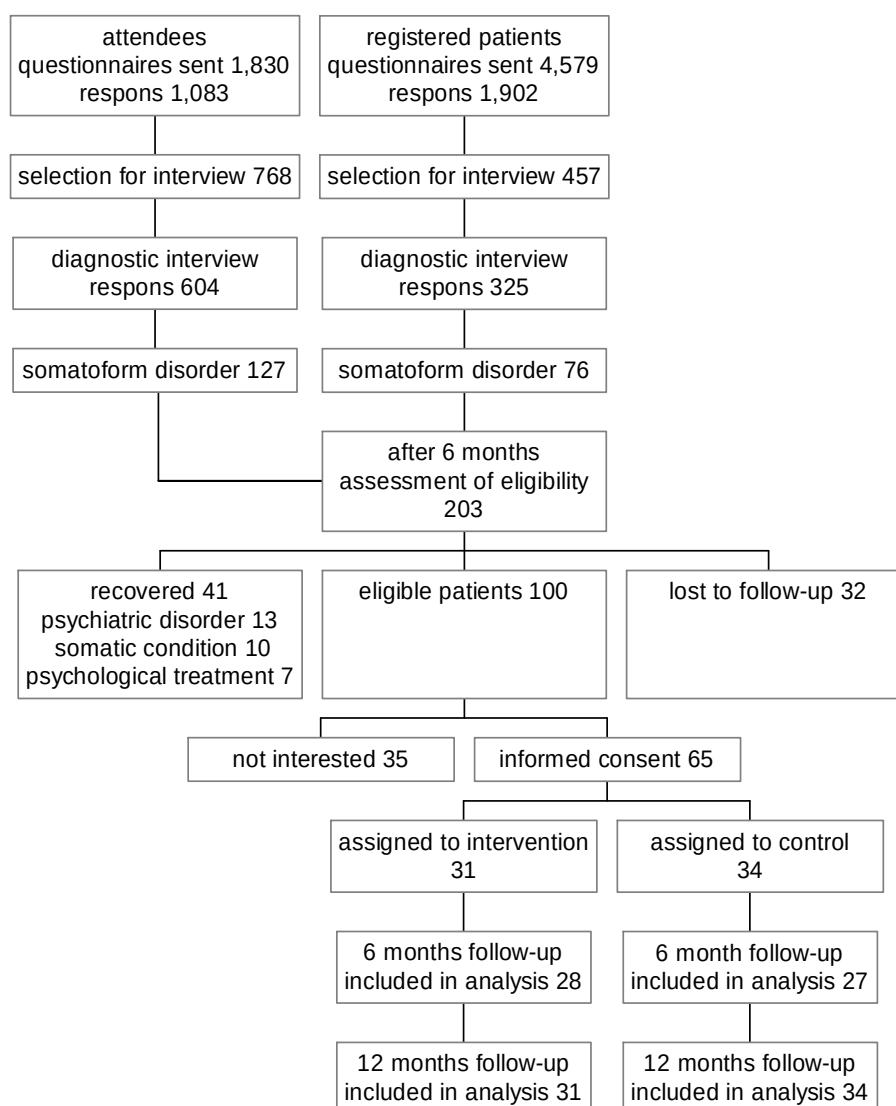
Control participants received care as usual from their GP, which implied any treatment or referral that was indicated. Official treatment guidelines are available to the GP for some functional somatic syndromes such as headache, irritable bowel syndrome and low back pain. Still, guidelines that explicitly address medically unexplained physical symptoms or somatoform disorders are lacking. As a result the diagnosis and treatment of somatoform disorders may vary.

Enrolment and follow-up statistics

Between April 2000 and December 2001 the recruitment took place in two random samples of patients aged 25-79 (figure 2).

The first sample consisted of all 1,083 consulting patients who had participated in the prevalence study preceding this treatment study. To recruit additional patients a second sample of 4,579 patients registered with a GP was screened. Out of the 5,662 screening questionnaires, a total of 2,985 was returned (52%). For the initial assessment 1,225 patients were invited and 929 patients were interviewed (76%). A somatoform disorder was established in 203 patients, who all received a second questionnaire 6 months after the initial assessment. The questionnaires of 171 patients were returned and suitable for analysis (84%). Out of 171 patients, 41 reported a severity of their main physical symptoms of less than 5 on a VAS and were considered 'recovered'. Of all 130 patients reporting persisting physical symptoms, 30 had to be excluded. The exclusion criteria were ongoing psychological treatment (n=7), a serious psychiatric disorder (n=13) or a concurrent serious somatic condition (n=10). Thus, a 100 patients were offered the intervention. Thirty-five were not interested in treatment, the majority indicating that they were not motivated to undergo treatment because they had accepted their symptoms as a part of their life. Thus, a total of 65 participants met the inclusion criteria and signed informed consent, 31 in the intervention group and 34 in the control group. All participants had visited their GP in the year prior to the screening procedure. At 6 months 55 questionnaires (85%) were returned and at 12 months 60 (92%). For the 5 non-responding participants at 12 months follow-up, the missing information on the severity scores on the VAS, self-rated improvement and health care utilisation was obtained by telephone (IAA).

Figure 2. Flow-chart of patient selection.



Analyses

Main outcome measures were the severity of the main physical symptom as indicated on a VAS and the self-rated improvement of symptoms at 6 and 12 months follow-up. Recovery was defined as a decrease in severity of the main physical symptom of at least 30% on the VAS. Power calculations were based on a previous LUMC treatment study.⁴ We estimated that 70% of the intervention patients and 40% of the controls would report recovery. With a two-sided significance of 5% and a power of 80% the following formula calculated a sample size of 36 participants per treatment arm: $n = (70 \cdot 30 + 40 \cdot 60) / (70 - 40)^2 \cdot 7.9 = 35.5$.¹⁸

Secondary outcome measures were self-reported physical symptoms (PSC), anxiety and depressive symptoms (HADS), functional limitations (SF-36), health anxiety and behaviour (IAS) and health care utilisation. All analyses were conducted

on an intention-to-treat basis. Chi squared tests were used for categorical data and t-tests for numerical data. With logistic regression models, additional analyses tested the contribution to recovery of the individual GP, the number of sessions, psychotropic medication and treatment by a mental health professional. Analyses were conducted using SPSS for Windows 12.0.

Results

When comparing the patient characteristics of the intervention group with those of the control group at initial assessment, most differences appeared to be small and not significant (table 1).

Table 1. Patient characteristics at initial assessment in control group and intervention group.

	Control (n=34)		Intervention (n=31)		
	n	%	n	%	
Gender: women	30	88%	27	87%	ns
Married or cohabiting	25	74%	22	71%	ns
Unemployed or sick leave	17	50%	20	65%	ns
Secondary education less than 5 years	14	41%	19	61%	ns
High physical symptom count (PSC-51 15+)	19	56%	18	58%	ns
High distress score (HADS 15+)	19	56%	13	42%	ns
Age in years: mean (95% CI)	48 (45-52)		46 (42-50)		ns
Duration of main symptoms in months: mean (median)	80 (75)		86 (85)		ns

ns: not significant, $p > 0.05$

Both intervention and control group showed similar improvements at 6 and 12 months follow-up (table 2) when looking at the severity of the main physical symptom on a VAS. The mean severity score for both groups decreased from 7.6 at baseline to 6.0 at 12 months follow-up. According to the patients' overall judgement of improvement at 12 months follow-up, 35% of the control group and 42% of the intervention group had improved, which was not significantly different. Recovery at 12 months follow-up as determined by a 30% decrease in the severity score on a VAS or a VAS less than 5 was also similar: 29% for the control group and 32% for the intervention group.

As to the secondary outcomes, most baseline and follow-up measurements were comparable, except for the mean number of physical symptoms at baseline (table 3). Participants in the intervention group reported more physical symptoms than controls

Table 2. Primary outcomes: self-reported severity of main symptoms and overall judgement of recovery. Comparison of control group and treatment group at baseline and after 6 and 12 months follow-up (95% CI).

	Baseline		6 months			12 months		
	Control (n=34)	Intervention (n=31)	Control (n=28)	Intervention (n=28)		Control (n=34)	Intervention (n=31)	
Severity of main symptom					T-test			T-test
Mean VAS	7.6	7.6	6.7	6.6	P=0.68	6.0	6.0	P=0.77
(CI 95%)	(7.2-7.9)	(7.1-8.0)	(6.1-7.3)	(5.8-7.3)		(5.2-6.8)	(5.1-6.8)	
Recovery of main symptom					Chisq			Chisq
% (n) with VAS < 5			15% (4)	18% (5)	p=0.76	29% (10)	32% (10)	p=0.80
% (n) VAS 30% decrease from t0			22% (6)	18% (5)	p=0.69	29% (10)	32% (10)	p=0.80
Patient's overall judgement of improvement from t0					Chisq			Chisq
- no			11% (3)	21% (6)	p=0.35	27% (9)	23% (7)	p=0.85
- same			61% (17)	43% (12)		38% (13)	36% (11)	
- better			29% (8)	36% (10)		35% (12)	42% (13)	

Table 3. Secondary outcomes: self-reported symptoms, functional impairment and illness behaviour. Comparison of control group and treatment group at baseline and after 6 and 12 months follow-up (95% CI).

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Illness attitude scale⁴	10.4
Illness behaviour	(9.1-12.2)
Health anxiety	(7.5-10.8)

¹ Symptoms on Physical Symptom Checklist 'bothersome often or most of the time during last week' (range 0-51)

² Subscales of the Hospital Anxiety and Depression Scale: anxiety (range 0-21) and depression (range 0-21)

³ Scales of SF-36: standardised to range 0-100 (100 means optimal health, 0 worse possible health)

⁴ Subscales of Illness Attitude Scale: illness behaviour (range 0-24) and health anxiety (range 0-44)

* T-test p<0.05

(12.6 versus 9.4, $p = 0.02$). At 6 and 12 months follow-up differences in physical symptoms or other measurements were not significant. In general most symptoms and impairments remained stable or improved slightly during the follow-up period.

Regarding the actual treatment that patients received in the year following baseline, 17 out of the 31 participants in the intervention group (55%) did not complete all five sessions of the cognitive-behavioural treatment and 8 of them even withdrew before the start of the intervention (26%) (table 4). There were no significant differences in health care utilisation between the intervention and the control group, although participants of the intervention group tended towards more primary care visits than the control group (7.0 versus 6.5). They used more psychotropic medication (70% versus 48%) and more often received treatment from a mental health professional (42% versus 30%).

When all participants were analysed as one group, ignoring assignment, the prescription of psychotropic medication in the 12 months following informed consent was significantly associated with a better recovery on the VAS (42% versus 15%, $p = 0.05$). Recovery rates for attendees or listed patients did not differ (33% versus 28%), nor did the mean number of primary care visits (7.4 versus 6.0) or receiving psychological treatment from a mental health psychologist (30% versus 31%). Recovery rates in the per-protocol analysis were not different: 33% for those who completed treatment (5 sessions) versus 21% for less than 5 sessions.

Table 4. Treatment received during 12 months following baseline.

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Treatment as part of the intervention		
- 5 sessions (completed intervention)		4
- 2-4 sessions (partly completed intervention)		5
- none (withdrawal before the start of the intervention)		%
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		=
		1
		4
		)
		2
		9
		%
		(
		n
		=
		9
		)
		2
		6
		%
		(
		n
		=
		8
		)
Treatment as part of care as usual		
GP medical records [#]		
	6	7
- Primary care visits, mean (95% CI)	·	·
	5	0
- Psychotropic medication, % (n)	(	(
Patient self-report	4	5
- Psychological treatment from mental health professional, % (n)	·	·
	9	4
	-	-
	8	8

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	0	6
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	4	6
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	3	4
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	%	%
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data missing for 1 control patient and 2 intervention patients

Conclusions

Main findings

In a controlled study on somatoform disorders and the effectiveness of cognitive-behavioural therapy performed by the GP, we found that 5 sessions of cognitive-behavioural therapy on top of care as usual did not effectuate significantly better results. In the cognitive-behavioural therapy group as well as in the care as usual group about 30% of the patients showed an improvement in clinically relevant outcomes. Our findings in primary care are in contrast with those in a previous study, conducted by us in secondary care, where cognitive-behavioural therapy was superior to optimised medical care. Although we aimed at using the same treatment model, tailored to the general practitioner, and applied similar inclusion and exclusion criteria, we could not confirm the beneficial effects of this treatment model in primary care.

Strengths and weaknesses

The treatment study was nested in a population-based cohort, allowing us to evaluate the generalisability towards the entire primary care population. All participants, both attendees and listed patients, were sampled and assessed with a similar procedure, independent from the GP. In addition, we took meticulous care to diagnose somatoform disorders according to the DSM-IV. This is all the more relevant since medically unexplained physical symptoms cover a broad and ill-defined range of symptoms, which may induce diagnostic uncertainty. Several safeguards ensured the quality of the treatment. First, a protocol for cognitive-behavioural therapy that had proven to be successful in secondary care was tailored for use in primary care. Second, a detailed manual for the GP and self-help materials for the participants supported the integrity of the treatment. Finally, training and treatment were supervised by the same experienced cognitive behaviour therapist (PS) as in the secondary care study.

Despite an elongation of the study period we were not able to include the preset number of patients (we included 65 instead of 72). Although we screened 5,662 participants and made a substantial effort to recruit participants, relatively few patients met the inclusion criteria. A quarter of the participants with an initial diagnosis of somatoform disorder recovered in six months. Among the patients with persisting symptoms, serious psychiatric disorders and ongoing psychological interventions were the main reasons for exclusion, indicating that participants with somatoform disorders in primary care were often already receiving care from mental health services. On the other hand, a substantial number of eligible patients were not interested in receiving cognitive-behavioural therapy, as appears from the high withdrawal rate. The main reason eligible patients gave for not being interested in treatment, was the acceptance of their symptoms

as part of their lives. An intervention in the early stages of the disease, offered in a regular consultation with their GP, might have been more acceptable to some patients.

Meaning of the study

We considered several factors in our study that might have contributed to the lack of additional effects of cognitive-behavioural treatment to care as usual.

Several factors concerning treatment aspects might explain why our results differ from previous reviews on the beneficial effects of cognitive-behavioural treatment. In contrast with the studies in secondary care, our intervention was not carried out by a professional psychotherapist but by a trained general practitioner. In this primary care setting the number of sessions was limited to 5 whereas most other interventions reported a total of 8-16 sessions. On top of that, only 45% of all the patients included in the intervention group completed the treatment. This implies that the professional level and the intensity of our interventions are not comparable with secondary care treatment.

A second important explanation relates to differences in characteristics of the study populations. Most studies on referred participants report that the average age was 35-40,^{3 4} whereas the included primary care participants were 10 years older. Compared to our secondary care study⁴ they had more severe symptoms and functional limitations, which might have had a negative effect on the receptivity to a cognitive-behavioural treatment and thus prognosis. Apparently, with our emphasis on severity and persistence of symptoms we mainly selected patients who already received treatment or had reached a chronic stage with no explicit need for treatment. As we hypothesise that chronic symptoms have a negative influence on the effect of treatment response, treatment should be initiated in an early stage of the somatoform disorder.

Thirdly, moderate but clinically relevant effects were also established in one third of the patients who received care as usual. We considered several factors in care as usual which might have been responsible for improvement. Spontaneous recovery or regression to the mean during the follow-up period could explain the shift of the symptoms towards improvement. In addition, recovery might be the result of an effective care as usual provided by the GPs working in a university-affiliated practice. It may well be possible that the control participants also received treatment with cognitive-behavioural techniques. This explanation is supported by the contents of the National Guidelines for GPs for the treatment of low back pain and irritable bowel syndrome. These guidelines recommend various cognitive-behavioural techniques such as the exploration of worrying thoughts and a time-contingent increase in activity.¹⁹ A study among depressed participants also reported that GPs used cognitive-behavioural techniques for depressed participants during regular consultations.²⁰ If this is true, it indicates that low-intensity cognitive-behavioural therapy is as effective as the intensive approach we had in the intervention group. Furthermore, both intervention and control

patients frequently used antidepressants or tranquillisers. Since a better outcome was related to prescription of this psychotropic medication, we assume that care as usual contained effective pharmacological interventions.

The implications of this study focus on the main aspects of somatoform disorders in primary care. The magnitude of the problem is obvious: one in six participants consulting his GP suffers from medically unexplained symptoms with serious impairments. However, evidence on adequate treatment options is not yet readily available in primary care. Considering the differences between primary care patients in terms of the range in severity of the symptoms and motivation for therapy, it is not likely that one single treatment approach will be appropriate for somatoform disorders. Instead, we propose that a stepped-care model for the treatment of somatoform disorders should be developed.^{6 21} The first step could contain implicit cognitive-behavioural interventions carried out by the GP during regular consultations. This would be suitable for patients who are likely to recover within due time or who are not motivated for an intensive treatment. Following steps should offer more intensive treatment by professional therapists for patients with chronic and disabling symptoms. Pharmacological interventions could add to treatment success since psychotropic medication was associated with better treatment outcomes in our treatment study and in the literature.²² Such a treatment model with a stepwise increasing intensity would better allow for the variation in severity and patient characteristics as encountered in primary care.

Conclusions

We could not demonstrate that the extra training of GPs and the cognitive-behavioural intervention that we offered in this study were more effective than the clinical improvements realized by care as usual. Our findings are in contrast with recent reviews that indicate evidence for cognitive-behavioural therapy as the treatment of choice for medically unexplained physical symptoms in referred patients. Moreover, for most patients with somatoform disorder a brief cognitive-behavioural intervention was not a feasible option due to serious somatic and psychiatric comorbidity or motivational problems for explicit treatment. Future research should develop appropriate treatment options for somatoform disorders in a primary care setting. A stepped-care treatment model could provide more efficient care, ranging from simple “upgrading” of the care as usual of GPs to intensive interventions by specialised professionals for chronic patients.

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