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## Mindfulness therapy for somatization disorder and functional somatic syndromes: Analysis of economic consequences alongside a randomized trial<sup>☆</sup>

Lone Overby Fjorback<sup>\*</sup>, Tina Carstensen, Mikkel Arendt, Eva Ørnbøl, Harald Walach, Emma Rehfeld, Per Fink

The Research Clinic for Functional Disorders and Psychosomatics, Aarhus University Hospital, Nørrebrogade 4, Aarhus, Denmark

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## ABSTRACT

**Objective:** The objective of the present study is to estimate the economic consequences of somatization disorder and functional somatic syndromes such as fibromyalgia and chronic fatigue syndrome, defined as bodily distress syndrome (BDS), when mindfulness therapy is compared with enhanced treatment as usual.

**Methods:** A total of 119 BDS patients were randomized to mindfulness therapy or enhanced treatment as usual and compared with 5950 matched controls. Register data were analyzed from 10 years before their inclusion to 15-month follow-up. The main outcome measures were disability pension at the 15-month follow-up and a reduction in total health care costs. Unemployment and sickness benefit prior to inclusion were tested as possible risk factors.

**Results:** At 15-month follow-up, 25% from the mindfulness therapy group received disability pension compared with 45% from the specialized treatment group ( $p = .025$ ). The total health care utilization was reduced over time in both groups from the year before inclusion (mean \$5325, median \$2971) to the year after inclusion (mean \$3644, median \$1593) ( $p = .0001$ ). This overall decline was seen in spite of elevated costs due to assessment and mindfulness therapy or enhanced treatment as usual. The BDS patients accumulated significantly more weeks of unemployment and sickness benefit 5 and 10 years before inclusion ( $p < .0001$ ) than the population controls.

**Conclusions:** Mindfulness therapy may prevent disability pension and it may have a potential to significantly reduce societal costs and increase the effectiveness of care. Accumulated weeks of unemployment and sickness benefit are possible risk factors for BDS.

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## Introduction

Bodily symptoms that cannot be explained by well-defined physical disease form one of the most expensive categories of health care expenditure and lead to high societal costs [1]. Somatization disorder and functional somatic syndromes such as fibromyalgia, irritable bowel syndrome, and chronic fatigue syndrome are major public health concerns for which effective treatment is rarely delivered [2–4]. Consequently, these patients may have elevated rates of medical care utilization [5] and time missed from work [6].

An estimated minimum of 5% of the Danish population suffers from functional somatic syndromes, and they account for 10–20% of the expenses of the Danish health care system [7]. In the UK, functional somatic syndromes reportedly account for 20–35% of all consultations [8,9]. In the Netherlands, medically unexplained symptoms and somatoform disorders is the fifth most expensive diagnostic category [10,11]. The costs appear to be higher than those incurred by stroke and cancer [1,11].

The high health care costs do not include time lost from work and reduced productivity, but cover medical consultations and expensive investigations, which lead to little or no health gain [1].

Thus, somatization disorder and functional somatic syndromes are common, costly, and highly debilitating conditions [12]. In spite of a clear need to develop cost-effective interventions, research into this domain remains limited and lacks a clear definition. Different medical specialties use different syndrome diagnoses; whereas somatization disorder is used in psychiatry.

Bodily distress syndrome (BDS) is a diagnosis developed from empirical research that may unite different functional somatic syndromes and somatization disorder [13,14]. Multi-organ BDS requires functional somatic symptoms from at least three out of four bodily systems: cardiopulmonary, gastrointestinal, musculoskeletal, or general symptoms and with moderate to severe impairment in daily life [15]. The diagnostic criteria for multi-organ BDS were used in two randomized controlled treatment trials [16]. The present study is based on one of these studies entitled 'Mindfulness therapy for somatization disorder and functional somatic syndromes – Randomized trial with- Randomized trial with one year follow-up' [17], where a total of 119 patients were randomized to *mindfulness therapy* or *enhanced treatment as usual*. The majority had multiple functional somatic syndrome diagnoses; over 70% fulfilled criteria for chronic fatigue syndrome and more than 80% for

<sup>☆</sup> The trial is registered at <http://clinicaltrials.gov/ClinicalTrials.gov>, number NCT00497185.

<sup>\*</sup> Corresponding author. Tel.: +45 22385426; fax: +45 78464340.  
E-mail address: [lonefjor@rm.dk](mailto:lonefjor@rm.dk) (L.O. Fjorback).

fibromyalgia, 100% fulfilled diagnostic criteria for somatization disorder and had symptom duration of at least two years. The primary outcome measure was change in physical health (SF-36 Physical Component Summary) from baseline to 15-month follow-up. The primary result was negative; both groups registered clinically significant improvement over time. The aim of the present study was to estimate the economic consequences of BDS. We hypothesized that patients suffering from BDS received more disability pension at baseline and at 15-month follow-up compared with the background population. We also hypothesized that the two active treatment modalities *mindfulness therapy* and *enhanced treatment as usual* were equally effective in maintaining the patient's connection to the labor market and reducing health care utilization and health care cost.

## Methods

### Study design and population

The social and economic follow-up data were obtained alongside a randomized controlled trial comparing *mindfulness therapy* with *enhanced treatment as usual* in patients suffering from multi-organ BDS. The present study included two different populations: 1) a cohort of 119 referred BDS patients included in the randomized controlled trial; and 2) a cohort of 5950 population controls, alive at baseline and matched on gender, age, and ethnicity. The central registry Statistics Denmark randomly sampled the population controls in a proportion of 50 to 1 to obtain high statistical power. The details on the randomized controlled trial are given elsewhere [17].

### Resource use

Denmark runs a nationwide centralized register of personal information, the Civil Registration System, where every citizen is given a unique personal identification number. Virtually every government agency and all central registries in Denmark receive information about a person from the database in which data are continuously updated with all relevant health-related and other information. This unique data pool allows every citizen to be followed closely from birth to death. In the present study, we extracted relevant person-specific information from these centralized Danish registries.

### Transfer payments

DREAM is a database administered by the Danish Labor Market Authority. The DREAM database can be used for follow-up of social and economic consequences of disorders [18]. It may be used for public health research, and may be useful for socioeconomic analyses of selection bias and dropout from other studies [18]. DREAM contains weekly information on transfer payments for all citizens in Denmark since 1991. Transfer payments include sickness benefit, disability pension, unemployment benefit, flexible work (jobs created for persons with limited working capacity), etc. A transfer payment is registered in DREAM for a week if the person has received a transfer benefit for at least one day during a week. Regarding sick leave, the first two weeks are paid by the employer, so there is a threshold of two weeks for registration, but the full period is registered if a sick leave period continues for more than two weeks. Information on students' grants, maternity leave, retirement pension, etc. is also registered in DREAM.

### Health care costs

Any public health care-related cost, whether incurred in the primary or secondary health care sector, is registered by the Danish Ministry of Health, which calculated the aggregated health care costs from 2006 to 2009 for the 119 included patients. Every Danish citizen is entitled to publicly funded health care and most examinations and treatments

are free of charge, e.g. visits to family physicians, specialist doctors, emergency rooms, and hospitalization, including tests, treatment, follow-up care, and some drugs. Health care users pay for non-essential cosmetic surgery, dental care, and a portion of prescription medication. The aggregated health care costs are divided into four variables: total health care costs; costs related to general hospital (in- and out-patients); costs related to primary care; and costs related to psychiatric services (in- and out-patients). Health care visits in private clinics are not registered. Most of the population uses the public health care system, and the optional private health care sector is limited.

### Medication

All prescribed medications are registered, and we made a summary of prescribed medication of opioids (including derivatives of opiates), benzodiazepines (including anxiolytic and hypnotic benzodiazepines), and antidepressants (including selective serotonin reuptake inhibitors, dual serotonin and norepinephrine reuptake inhibitors, noradrenaline and specific serotonergic agent, tricyclic antidepressant) given to patients and controls. Medications did not differ between the intervention groups at any time. For most patients, benzodiazepines and opioids were not prescribed; antidepressant medication was prescribed for some, but it is unknown whether the indication was depression, anxiety, or pain. At all time points, more patients than population controls were receiving prescribed opioid, benzodiazepine, and antidepressant medication. These data are not presented, but may be collected from the authors.

### Outcome measures

#### Transfer payments

Transfer payments were divided into five categories: 1: disability pension; 2: flexible work (jobs created for persons with limited working capacity); 3: sickness benefit; 4: unemployed; and 5: self-supporting. Which of these five categories each patient fit into was determined at two time points: a 12-week period immediately before baseline and a 12-week period 15 months after baseline. We chose a 12-week period over a one-week period to obtain an estimate as precise as possible of the transfer payments received during the two time periods.

The procedure of categorization is as follows: 1) the person entering the group with the highest number of weeks registered; 2) a hierarchy of the groups overruling other groups, i.e. if a person within the 12 weeks period had had one week on flexible work, the person entered this group even if the person had more weeks on other benefits, and disability pension overruled flexible work. Presently, DREAM includes 110 transfer codes; a table displaying the exact categorization of each code can be collected from the authors.

We used the transfer payment categories proposed by Hjollund et al. [18] and Carstensen [19]. Carstensen [19] grouped sickness benefit and vocational rehabilitation as temporary health-related benefits, whereas flexible work and disability pension were grouped as permanent health-related benefits. Some BDS patients had already dropped out of the labor market at baseline, and to be able to distinguish between possible levels of marginalization, we divided the permanent health-related benefits group into two separate categories: flexible work and disability pension.

The self-supporting group includes the working population, students receiving Danish students' grants, and parents receiving maternity benefits. If a person had no entry in DREAM or had emigrated, we assumed that that person was self-supporting. Furthermore, those who received vocational rehabilitation benefits were allocated to the self-supporting group, because eligibility for such benefits requires that the person will be able to fully support him- or herself.

The unemployment category consists of all unemployed citizens receiving unemployment benefit together with citizens on social benefit. Social benefit is a transfer income administered by the municipal social service department and is allocated to citizens who have no income and

where the absence of such assistance would make them unable to support themselves.

### Health care costs

We measured the total amount of money spent on health care over two time periods: 1) a one-year period that begins from one year prior to baseline and ends at baseline, and 2) a one-year period that begins at and includes baseline and ends one year later.

Changes in the randomized BDS patients' health care costs between the two time periods were measured as total health care costs, costs related to general hospital, costs related to primary care, and costs related to psychiatric services. Also included in the analysis of health care expenditure one year after baseline were costs incurred due to assessment, *mindfulness therapy*, and *enhanced treatment as usual*. The costs were calculated in 2007 Danish kroner (at their 2007 value), and we used the average exchange rate for 2007 given by the National Bank of Denmark to exchange into 2007 U.S. \$ (100/544,5551) for the calculation into U.S. dollars.

### Main outcomes

Disability pension at the 15-month follow-up and reduction in total health care costs are used as main outcomes.

### Risk factors

In order to detect possible risk factors for BDS and to describe social and economic consequences over time, we compared the BDS patients with the background population in terms of three pre-treatment variables: 1) self-support; 2) sickness benefit; and 3) unemployment benefit. We counted the number of weeks on transfer payment of the specific types registered in the DREAM database five years (i.e. 0–260 weeks) and ten years (i.e. 0–520 weeks) before baseline. The distributions were highly skewed, and we chose to group the observations on each variable in three groups: 1) fully self-supporting or no transfer benefits; 2) between one week and to 90th percentile; and 3) the uppermost 10%.

### Self-supporting

Self-support during the previous five years (total 0–260 weeks) was categorized as: 1) full self-support (260 weeks); 2) 57–259 weeks; and 3) <57 weeks. Self-support during the previous ten years (total 0–520 weeks) was categorized as: 1) full self-support (520 weeks); 2) 181–519 weeks; and 3) <181 weeks.

### Sickness benefit

Sickness benefit during the previous five years (total 0–260 weeks) was categorized as: 1) no sickness benefit (0 weeks); 2) 1–26 weeks; 3) >26 weeks. Sickness benefit during the previous ten years (total 0–520 weeks) was categorized as: 1) no sickness benefit (0 weeks); 2) 1–51 weeks; and 3) >51 weeks.

### Unemployment

Unemployment during the previous five years (total 0–260 weeks) was categorized as: 1) no unemployment (0 weeks); 2) 1–79 weeks; and 3) >79 weeks. Unemployment during the previous ten years (total 0–520 weeks) was categorized as: 1) no unemployment (0 weeks); 2) 1–157 weeks; and 3) >157 weeks.

### Statistical analysis

Purely descriptive statistics for the social categorization flow from baseline to 15-month follow-up are reported. Concerning the outcome disability pension, a comparison of *mindfulness therapy* and *enhanced treatment as usual* was made by  $\chi^2$  tests.

We described highly skewed health care costs by reporting inter quartile ranges, medians, and means. This was supported by non-parametric Wilcoxon matched pairs test of the paired data of one year before and one year after as well as non-parametric Wilcoxon Mann–Whitney test of equal distribution of the change from one year before to one year after in *enhanced treatment as usual* and *mindfulness therapy*. We calculated a non-parametric Wilcoxon Mann–Whitney test for the non-normally distributed data such as week counts of the various types of transfer payments 5 and 10 years back in time from the assessment. The data were processed in Stata version 11 [20].

### Results

Fig. 1. features the trial profile. 119 BDS patients were included in the trial. The treatment drop-out rate in the *mindfulness therapy* group was 12% compared with 3% in the *enhanced treatment as usual* group, but the register data were obtained for all 119 patients. No significant differences in baseline characteristics were observed between the two treatment groups, neither between subjects who participated or declined participation, nor between drop-outs and completers [17].

Table 1 shows the baseline characteristics of patients included in the randomized trial and the population controls. The BDS patients had a lower yearly income in 2008 than population controls (Wilcoxon Mann–Whitney, difference = \$15,223,  $p < .0001$ ), but there was no difference between the groups in terms of the percentage of individuals with a higher education, defined as having a college or university degree.

### Transfer payment

Table 2 shows that fewer BDS patients in the *mindfulness therapy* group than patients in the *enhanced treatment as usual* group were receiving disability pension at the 15-month follow-up. The difference between the groups remained significant when disability pension at baseline was excluded from the analysis. At baseline there was no significant difference between groups in the prevalence of disability pension  $\chi^2(1) = 0.847$  and  $p = .36$ .

Table 3 shows that more BDS patients than population controls were receiving transfer payments at the 15-month follow-up. Table 3 details the categorization flow between categories from baseline to the 15-month follow-up. The largest shift is observed among patients receiving sickness benefit at baseline. At baseline, 21 (36%) patients in the *mindfulness therapy* group and 23 (38%) patients in the *enhanced treatment as usual* group were receiving sickness benefit and all but one (99%) shifted to a new category. This should be compared with the population control group where 36 (19%) participants receiving sickness benefit at baseline were still receiving sickness benefit at the 15-month follow-up. In the *mindfulness therapy* group, 7 (33%) patients shifted from sickness benefit to the self-support category, 4 (19%) to the unemployed category, 6 (28%) shifted to flexible work, and 4 (19%) were receiving disability pension. In the *enhanced treatment as usual* group, 3 (13%) shifted to the self-support category, 1 (4%) to the unemployed category, 8 (35%) shifted to flexible work, and 10 (43%) were receiving disability pension. Flexible work and disability pension are permanent health-related benefits, and a comparison of the *mindfulness therapy* group and the *enhanced treatment as usual* group showed that significantly more participants from the latter group had shifted to a permanent health-related benefit,  $\chi^2(1) = 5.5321$  and  $p = .019$ .

### Health care costs

Table 4 displays the health care costs. Complete health care costs were obtained for all 119 patients, which is 100% of the patients included in the randomized controlled trial. No differences in the health care costs one year prior to baseline between patients in the two intervention groups were found. Exploratory non-parametric tests were performed on total health care costs, costs related to general hospitals, primary care, and psychiatric services. The tests revealed a larger reduction in total costs, costs related to general hospitals, and primary care. In contrast, the analysis showed an increase in costs related to psychiatric services, which is attributable to the extra costs incurred by the trial: assessment, *mindfulness therapy*, and *enhanced treatment as usual*. No differences were observed between the groups, except for psychiatric costs which were significantly higher in the *mindfulness therapy* group than in the *enhanced treatment as usual* group (Wilcoxon Mann–Whitney  $Z = -8.773$ ,  $p < .0001$ ). *Mindfulness therapy* was about 5–6 times as expensive as *enhanced treatment as usual* (the costs of *mindfulness therapy* and *enhanced treatment as usual* were US \$3102 and US \$564, respectively), even if the time accrued from a group of 12 participants meeting 9 times equals the time seeing 12 participants for individual consultations. The pre-existing categories in the national health care system led to the observed difference in costs between the two treatments, because of reimbursement due to pre-existing categories.

### Risk factors

Table 5 displays possible risk factors for BDS. We found that patients were more inclined to receive sickness benefit, be more unemployed, and less self-supporting 5 and 10 years back in time than the gender-, age- and ethnicity-matched population controls. In the 5-year period preceding the baseline, the patients had only been able to support themselves about half of the time, whereas population controls had been able to support themselves

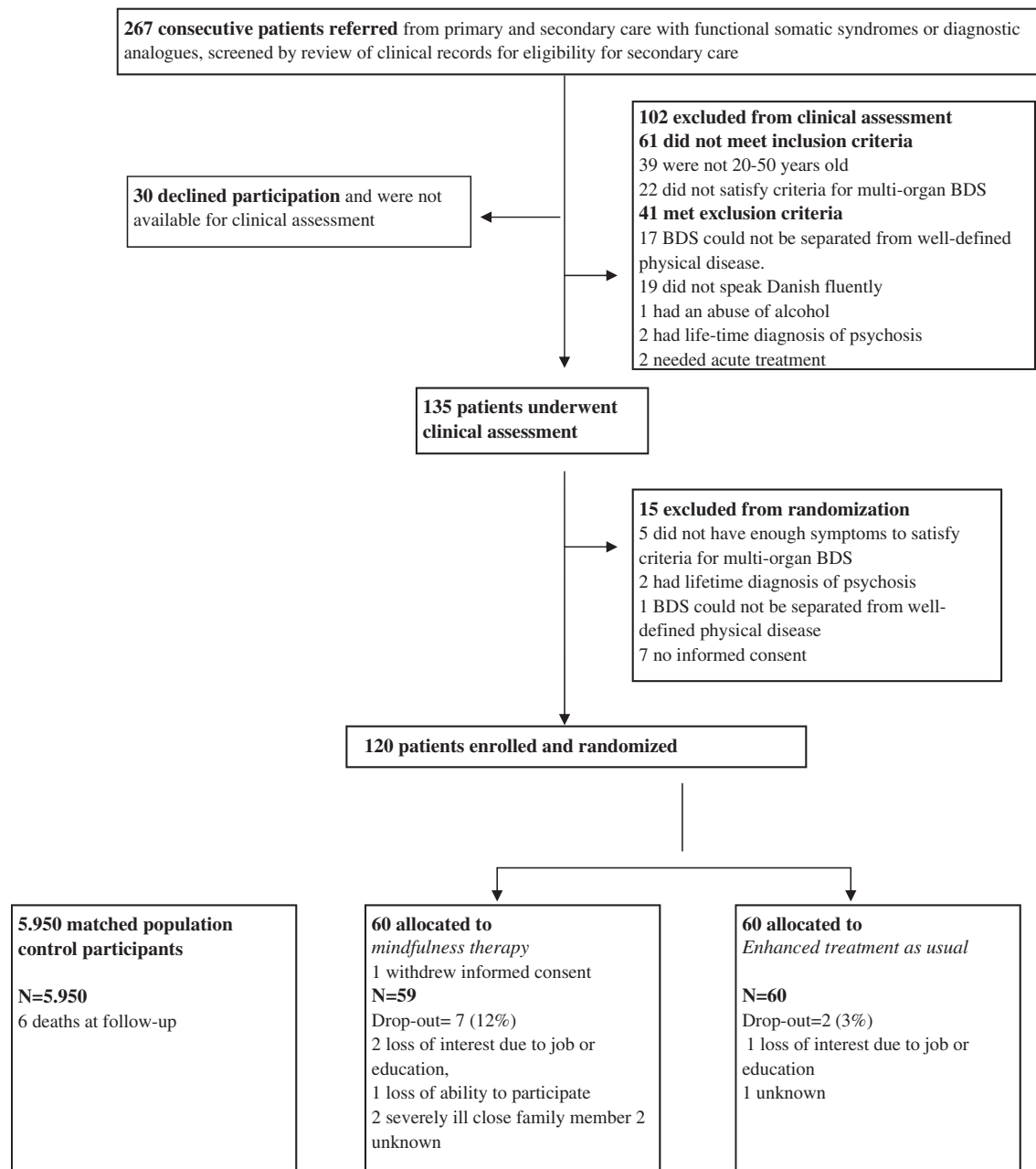


Fig. 1. Trial profile.

almost all the time. The benefit figures may even be underestimated because only adult citizens can receive a transfer payment, and 5 patients and 250 population controls were not adults (>18 years of age) 5 years back in time, and 17 patients and 850 population controls were not adults 10 years back.

## Discussion

*Mindfulness therapy* for patients suffering from multi-organ BDS had substantial socioeconomic benefits compared with *enhanced treatment as usual*. The costs related to permanent health-related benefits in general and disability pension in particular were significantly lower in the *mindfulness therapy* group than in the *enhanced treatment as usual* group over a 15-month follow-up period. The rate of disability pension increased significantly in both groups from baseline to the 15-month follow-up, which substantiates the severity of somatization disorder and functional somatic syndromes. It may raise the question of whether the treatments made people more ill.

However, we do not think that this is likely. A more feasible explanation of the increased disability pension rate may be that when the patients were seen at our clinic, they had already been ill for a long time. In Denmark, it is a natural consequence after years of illness that people are granted disability pension. In any event, going back to work was not part of these novel and brief interventions that aimed at testing the feasibility and the effect on self-reported physical health. In addition, we do not have any information on the rate of disability pension in a similar untreated patient population. The observed social marginalization demonstrates a clear need to develop cost-effective interventions.

Both interventions saved money within the health care system. *Mindfulness therapy* was significantly more expensive than *enhanced treatment as usual*, in spite of these additional costs, *mindfulness therapy* appears to reduce the overall health care costs within the range of *enhanced treatment as usual*. The reduction in costs observed in primary care equals a reduction of four visits per year in both groups. And the reduction of costs observed in general hospitals equals a reduction of nine

**Table 1**  
Baseline characteristics

	Patients: <i>Mindfulness</i> <i>therapy</i> N = 59	Patients: <i>Enhanced</i> <i>treatment</i> N = 60	Population controls N = 5950
Years of age (SD), median	38 (9), 40	40 (8), 40	39 (9), 40
Female gender	47 (80%)	48 (80%)	4750 (80%)
Married	32 (54%)	29 (48%)	2929 (49%)
Children living at home	35 (59%)	35 (58%)	3364 (55%)
Education			
Only primary school or high school	22 (37%)	11 (18%)	1734 (29%)
College or university degree	20 (34%)	23 (38%)	2272 (38%)
Others	17 (29%)	26 (44%)	1944 (33%)
Total income in 2008, mean (SD)	\$38,864 (19,463)	\$43,028 (18,674)	\$56,189 (37,253)

**Table 2**  
Disability pension at 15-month follow-up

	<i>Mindfulness therapy</i>	<i>Enhanced treatment as usual</i>	$\chi^2$ (df), p
<i>Disability pension at 15-month follow-up</i>			
Yes	15 (25%)	27 (45%)	5.0 (1), p = .025
No	44 (75%)	33 (55%)	
<i>Disability pension at baseline excluded from the analysis</i>			
Yes	11 (20%)	20 (38%)	4.1 (1), p = .042
No	44 (75%)	33 (55%)	

outpatient visits per year in the *mindfulness therapy* group and six visits per year in the *enhanced treatment as usual* group.

Five and ten years before their inclusion, the BDS patients were less self-supporting than an age-, gender- and ethnicity-matched population control group; the BDS patients accumulated more weeks of sickness benefit and unemployment. Thus, the included BDS patients may have been ill and in high risk for a social decline five and ten years before they received a proper diagnosis and treatment. For the year of inclusion, the BDS patients had a lower yearly income than the population controls, even if the two groups had identical fractions of members with a higher education. These results indicate that the social and economic consequences of BDS are significant and *mindfulness therapy* may have the potential to improve function, prevent social decline, and reduce societal costs.

**Table 3**  
Categorization flow of transfer payments from baseline to 15-month follow-up

		Self-support follow-up	Unemployed follow-up	Sickness benefit follow-up	Flexible work follow-up	Disability pension follow-up	Total
Self-support baseline	<i>Mindfulness</i>	10 (53%)	1 (5%)	2 (11%)	4 (21%)	2 (11%)	19 (100%)
	<i>Enhanced</i>	10 (59%)	0	1 (6%)	1 (6%)	5 (29%)	17 (100%)
	Population	4712 (93%)	213 (4%)	145 (3%)	7 (0.1%)	5 (0.1%)	5086 (100%)
Unemployed baseline	<i>Mindfulness</i>	0	4 (67%)	0	0	2 (33%)	6 (100%)
	<i>Enhanced</i>	0	3 (50%)	0	0	3 (50%)	6 (100%)
	Population	120 (42%)	126 (45%)	17 (6%)	3 (1%)	16 (6%)	283 (100%)
Sickness benefit baseline	<i>Mindfulness</i>	7 (33%)	4 (19%)	0	6 (28%)	4 (19%)	21 (100%)
	<i>Enhanced</i>	3 (13%)	1 (4%)	1 (4%)	8 (35%)	10 (43%)	23 (100%)
	Population	108 (57%)	22 (12%)	36 (19%)	19 (10%)	6 (3%)	191 (100%)
Flexible work baseline	<i>Mindfulness</i>	0	0	0	6 (67%)	3 (33%)	9 (100%)
	<i>Enhanced</i>	0	0	1 (14%)	4 (57%)	2 (29%)	7 (100%)
	Population	2 (2%)	1 (1%)	3 (3%)	101 (86%)	10 (9%)	117 (100%)
Disability pension baseline	<i>Mindfulness</i>	0	0	0	0	4 (100%)	4 (100%)
	<i>Enhanced</i>	0	0	0	0	7 (100%)	7 (100%)
	Population	0	0	0	0	272 (99.6%)	273 (100%)
Total	<i>Mindfulness</i>	17 (29%)	9 (15%)	2 (3%)	16 (27%)	15 (25%)	59 (100%)
	<i>Enhanced</i>	13 (22%)	4 (7%)	3 (5%)	13 (22%)	27 (45%)	60 (100%)
	Population	4942 (83%)	362 (6%)	201 (3%)	130 (2%)	309 (5%)	5944 <sup>a</sup> (100%)

<sup>a</sup> In the population control group 6 people had died at follow-up (at baseline, 4 were self-supporting, 1 was unemployed, and 1 was receiving disability pension).

Comparison with other studies

To the best of our knowledge long time follow-up data on the social and economic consequences of somatization disorder or functional somatic syndromes have not been previously analyzed on the basis of data obtained from valid central registries. Much of the evidence regarding risk factors comes from cross-sectional studies, interviews, and self-reports [21,22].

According to the OECD's Health Data 2009 [23], Denmark's health costs per person, public and private, equaled \$3512 (in the US the equivalent figure is \$7290). Our trial reduced the annual mean total health care costs from \$5325 to \$3644, which is very close to the average annual cost per person. In 2006, Allen et al. [12] reported on health care utilization pre and post-treatment in a study testing a psychiatric consultation intervention plus 10 sessions of individual cognitive behavioral therapy for somatization disorder. They found a reduction from a median of \$1944 pre-treatment to \$1205 post-treatment. The costs related to the treatment were excluded from the analysis. Their analysis was only conducted on participants with complete records of health care data (68% of the 84 included patients). We reduced total health care costs from a median of \$2971 (2007 US \$) pre-treatment to \$1593 post-treatment. Our study may be less biased than the study by Allen et al. Firstly, we used register data that were available for 100% of the included patients. Secondly, all Danish citizens are covered and registered by the national health care system.

A lack of education is often found to be a risk factor for bodily distress [1,21,22] even if this general observation may seem to be contradicted since both Allen et al. and we found that about 37% of the patients suffering from somatization disorder had a college degree; a figure similar to that observed for the matched population control group. Allen et al. investigated self-selected patients from university clinics, which may have explained the high proportion of well-educated people. We investigated referred patients from both urban and rural areas; the majority were out of work and had no or little education; and since the entire Danish population is covered by the health care system, our sample may not have been biased towards a more educated population. These findings highlight the significance and high prevalence of BDS, even in a well-educated population. They also point to the importance of a multi-factual illness understanding and approach, as BDS cannot be explained only as a social problem. However, since the age range was 20–50 years, in 5 or 10 years the proportion of participants with a higher education may shift to be very different for BDS patients when compared to the population controls. Kuyken et al. [24] found that mindfulness-based cognitive therapy (MBCT) may be a cost-effective

**Table 4**  
Health care costs for BDS patients

	Total BPS patients N = 119			Mindfulness therapy N = 59			Enhanced treatment as usual N = 60		
	Mean (SD)	Median P25–P50– P75	Wilcoxon matched pairs signed rank Difference = 0	Mean (SD)	Median P25–P50– P75	Wilcoxon matched pairs signed rank Difference = 0	Mean (SD)	Median P25–P50– P75	Wilcoxon matched pairs signed rank Difference = 0
<i>Total health care costs</i>									
One year prior to baseline	5325 (9319)	1459–2971–6435	Z = 3.8	4643 (5125)	1205–3013–6526	Z = 2.5	5996 (12,122)	1513–2950–6352	Z = 2.9
Baseline and one year ahead	3644 (5791)	608–1593–3623	p = .0001	3937 (6117)	714–1805–3894	p = .0112	3355 (5488)	582–1563–2843	p = .0034
<i>General hospital</i>									
One year prior to baseline	3214 (4171)	300–1591–4739	Z = 4.9	3347 (4427)	377–1916–4845	Z = 4.0	3083 (3936)	291–1484–3707	Z = 2.9
Baseline and one year ahead	1771 (3411)	0–230–1842	p < .0001	1633 (3083)	0–172–1842	p = .0001	1906 (3727)	0–294–1828	p = .0039
<i>Primary care</i>									
One year prior to baseline	468 (386)	226–370–571	Z = 4.4	466 (456)	238–357–535	Z = 3.1	470 (306)	219–399–654	Z = 3.1
Baseline and one year ahead	373 (480)	142–266–453	p = .0001	383 (621)	138–240–427	p = .0014	363 (286)	157–283–473	
<i>Psychiatric services</i>									
One year prior to baseline	1028 (8268)	0–0–0	Z = –8.4	151 (920)	0–0–0	Z = –6.7	1891 (11,591)	0–0–0	
Baseline and one year ahead	1967 (2157)	564–1128–3102	p = .0001	3211 (2407)	2778–3102–3325	p = .0001	744 (737)	547–564–564	p = .0001

Prices are given in 2007 US \$. No differences were observed between groups, except for psychiatric costs which were significantly higher in the *mindfulness therapy* group than in the *enhanced treatment as usual* group (Wilcoxon Mann–Whitney Z = –8.773, p < .0001).

**Table 5**  
Potential risk factors for BDS

	BDS patients N = 119	Population controls N = 5950	Wilcoxon Mann–Whitney	p
	Mean (SD), p25–p50–p75	Mean (SD), p25–p50–p75	Z	
<i>5 years back in time</i>				
Weeks of self-support	120 (89), 32–133–198	213 (79), 205–256–260	11,914	<.0001
Weeks of sickness benefit	52 (48), 7–49–90	8 (20), 0–0–0	–13,087	<.0001
Weeks of unemployment	39 (65), 0–0–58	21 (49), 0–0–12	–3814	<.0001
			$\chi^2$ (df)	
Full self-support	5 (4%)	2485 (42%)	1001 (2)	<.001
57–259 weeks	77 (65%)	2898 (49%)		
<57 weeks	37 (31%)	567 (9%)		
No sickness benefit	24 (20%)	3675 (62%)	345 (2)	<.001
1–26 weeks	22 (19%)	1723 (29%)		
>26 weeks	73 (61%)	552 (9%)		
No unemployment	62 (52%)	4016 (68%)	18 (2)	<.001
1–79 weeks	33 (28%)	1349 (23%)		
>79 weeks	24 (20%)	585 (9%)		
<i>10 years back in time</i>				
Weeks of self-support	299 (159), 160–334–423	429 (142), 400–503–520	10,281	<.0001
Weeks of sickness benefit	69 (60), 15–61–106	13 (29), 0–1–11	–12,4	<.0001
Weeks of unemployment	80 (114), 0–25–107	44 (88), 0–0–45	–5482	<.0001
			$\chi^2$ (df)	
Full self-support	5 (4%)	1677 (28%)	60 (2)	<.001
181–519 weeks	82 (69%)	3703 (62%)		
<181	32 (27%)	570 (10%)		
No sickness benefit	17 (14%)	2860 (48%)	301 (2)	<.001
1–51 weeks	34 (29%)	2547 (43%)		
>51 weeks	68 (57%)	542 (9%)		
No unemployment	33 (28%)	3093 (52%)	29 (2)	<.001
1–157 weeks	64 (54%)	2271 (38%)	11,914	
>157 weeks	22 (18%)	586 (10%)	–13,087	

option in the long term. MBCT was more effective than maintenance antidepressant medication, but there was no difference in the average cost between the two groups. A cost-effectiveness analysis suggested that the additional cost of MBCT may be justified in terms of improvements in the proportion of patients who relapse; but only if the willingness to pay for such improvements is \$1000 or above.

#### Strengths and limitations

Our findings are strengthened by a relatively small number of patients who needed to be screened and assessed in order to identify the 119 included patients in the randomized controlled trial. Also, the drop-out rate was small; the attendance was high; we used manually-defined treatments provided by competent clinicians; and the treatment acceptance and participant satisfaction rates were high [17].

The main strengths of the social and economic analyses were the follow-up design, the relatively large number of included patients, and a very large control group. The data were obtained from central registers, which excludes recall bias and bias due to subjective parameters. The only inclusion criteria for the matched population controls were: 1) that they were alive at baseline, and 2) that they were not included in the present randomized trial. Thus, the population control group represents the background population. Potential limitations may apply to the use of register data in the sense that their data might not be entirely accurate. However, Denmark has a rich tradition for registration that provides a unique data resource, so any such bias is considered to be negligible. We had information only about public and national social and health care costs; therefore, any costs related to alternative treatments are not included in the analysis. Moreover, we had no information on medical diagnoses in the control group. Also, the participants (patients and population controls) may have registered as self-supporting although they may, in fact, not have been able to work due to social or health problems, because they did not formally satisfy the criteria for receipt of transfer payment. However, being excluded from the social system in Denmark is a very rare possibility.

#### Policy implications and recommendations

For health care planners and clinicians, economic and social analyses of medical disorders and treatments are increasingly important. In line with previous research, this study shows that BDS is a disorder that may have severe economic and social consequences [1]. This study with a 15-month follow-up shows promising results from the implementation of *mindfulness therapy* for patients suffering from BDS. The effects of *mindfulness therapy* after 15 months are unknown. BDS may be detected years before it is formally diagnosed by investigating persons with accumulated weeks of sickness benefits or unemployment. We expect that earlier and perhaps more intensive treatments may be of significant benefit to patients, employers, and the society. Further research is needed to test this hypothesis.

MBCT is now being recommended by the UK's best practice advisory board for NHS–NICE (National Health Service–National Institute of Health and Clinical Excellence); however, challenges related to the implementation of evidence-based mindfulness approaches are reported from the UK [25]. Few teachers are competent in its delivery and several reviews, books, and papers have pointed out the importance of the teachers' competence [26–30]. Thus, competent teachers are recommended, and the successes and failures of implementing *mindfulness therapy* need to be investigated.

#### Conclusions

Preliminary evidence suggests that *mindfulness therapy* may prevent disability pension at 15-month follow-up and may reduce health care costs compared to *enhanced treatment as usual*. Thus, *mindfulness therapy*

may have a potential to significantly reduce societal costs, improve function, and increase effectiveness of care.

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The sponsors of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data, and all the named authors had final responsibility for the decision to submit the manuscript for publication.

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