Intensive Multidisciplinary Treatment of Severe Somatoform Disorder

A Prospective Evaluation

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Abstract: Chronic severe somatoform disorder (SFD) is resistant to treatment. In a prospective observational study, we evaluated an intensive multidisciplinary treatment focusing on body-related mentalization and acceptance. Patients included in the study were 183 (146 women, 37 men) of 311 eligible patients with chronic severe SFD, referred consecutively to a specialized tertiary care center between 2002 and 2009. Primary outcome measures were somatic symptoms (SCL-90) and health-related quality of life (EuroQol 5-Dimensional [EQ-5D]). These measures were assessed four times before treatment (on intake, twice during an observation period, at start of treatment) and four times after treatment (during follow-up for 2 years). Multilevel analysis was used to separate effects of time (maturation) and treatment. Results revealed significant improvements in SCL-90 somatic symptoms ($d = 0.51$), EQ-5D index ($d = 0.27$), and EQ visual analogue scale ($d = 0.56$). Significant reductions were also observed in SCL-90 anxiety, depression, and overall psychopathology as well as in medical consumption associated with psychiatric illness (Trimbos/iMTA Questionnaire for Costs Associated With Psychiatric Illness). Large interindividual differences were found in treatment outcome. The long-term improvement seen in many patients suggests that intensive multidisciplinary tertiary care treatment is a useful approach to chronic severe SFD.

Key Words: Somatoform disorder, treatment, outcome, body-related mentalization, acceptance

(*J Nerv Ment Dis* 2015;203: 141–148)

Somatoform disorder (SFD), in the current *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (*DSM-5*) classification system "somatic symptom and related disorders," is characterized by persistent physical symptoms that suggest the presence of a medical condition but are not explained fully by this condition or by the direct effects of a substance or another mental disorder (American Psychiatric Association, 2000). SFD is a common disorder with an estimated prevalence of approximately 6% in the general population, 16% in primary care, and up to 33% in secondary care (Baumeister and Härter, 2007; Creed et al., 2011; Fink et al., 2004; Steinbrecher et al., 2011; Waal et al., 2004; Wittchen et al., 2010). Patients with SFD usually have high functional impairment (Waal et al., 2004), are considered difficult to treat (Hahn et al., 1994; Woivalin et al., 2004), show high health care use (Barsky et al., 2006; Sammet et al., 2007), and have been related to substantial social and economic costs (Konnopka et al., 2012).

Psychological treatment with attention to somatic, psychological, and social factors has been proposed as the preferred treatment option for SFD, given the medically untreatable nature of the physical symptoms as well as the disturbed behavioral, cognitive, and emotional processes (Bass and Murphy, 1995; Kroenke, 2007). Psychological interventions shown to be effective for SFD are cognitive behavioral therapy (CBT) (Kroenke, 2007), short-term insight-focused psychotherapy (Abbass et al., 2009), and mindfulness-based cognitive therapy (Lakhan and Schofield, 2013). Acceptance-based interventions are known to be effective for chronic pain (Veehof et al., 2011), but these have not yet been evaluated for SFD. However, without further evaluation, the effectiveness of psychological treatment of SFD cannot be extrapolated to patients with chronic severe SFD requiring treatment in tertiary care. Patients with chronic severe SFD are characterized by the following: (1) polysymptomatic medically unexplained syndromes that have lasted for several years; (2) severe psychosocial and physical impairments; (3) high comorbidity with (*DSM-IV*) axis I, axis II, and axis III disorders; and (4) insufficient recovery after previous treatments in primary and/or secondary care. These patients are generally more impaired and have more comorbid psychiatric disorders than patients seen in primary care (Feltz-Cornelis et al., 2012). Furthermore, severity of symptoms has been related to increased cost (Konnopka et al., 2013). A recent meta-analysis indicated that psychological treatment can also be beneficial for SFD patients treated in secondary and tertiary care (Koelen et al., 2014). However, only limited studies involved patients with chronic severe SFD who had a history of ineffective treatment in primary or secondary care.

An intensive multidisciplinary tertiary care treatment program was developed in the Netherlands specifically for patients with chronic severe SFD and comorbid psychiatric disorders, who were classified as resistant to treatment because they did not improve as a result of first-choice psychological interventions, mostly CBT. This failure to improve is believed to result from interpersonal problems (Waller et al., 2004) and deficits in general (body-related) mentalizing ability (Luyten et al., 2012; Subic-Wrana et al., 2010). Cognitive intervention is hampered when mentalizing abilities are low and patients have difficulty verbalizing their cognitions, emotions, and behavior. For this reason, the tertiary care treatment starts with a focus on body-related mentalization skills, to teach the patients to become aware of and recognize their bodily signals as well as attach words and mental meaning to them (Spaans et al., 2009). Deficits in body-related mentalization skills are targeted with psychotherapy, psychosomatic physiotherapy, psychomotor therapy, and art therapy. Once these skills have improved, the treatment focus shifts to acceptance (acceptance and commitment therapy [ACT]), cognitive-behavioral modulation (CBT), and involvement of the family system (systemic therapy). Acceptance and cognitive-behavioral modulation are enhanced during (group and individual) psychological treatment; patients also learn self-regulation in their interaction with other patients and staff members as well as learn to experience safety by affirming their emotional and physical boundaries. Systemic psychotherapeutic components are added to help patients apply the acquired self-regulation skills within the dynamic home environment. This intensive multidisciplinary tertiary

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ISSN: 0022-3018/15/20302–0141
DOI: 10.1097/NMD.0000000000000250

care treatment, with core focus on body-related mentalization and acceptance, is delivered in either an outpatient (3 days a week) or an inpatient (5 days a week) program.

The aim of the current prospective observational study was to evaluate the long-term (2-year follow-up) outcome of this intensive multidisciplinary tertiary care treatment focusing on body-related mentalization and acceptance in patients with chronic severe SFD. This study was undertaken as part of the Standard Evaluation Project, a national project to gain insight into the quality, effectiveness, and costs of psychological treatments in the Netherlands.

The primary outcome measures were somatic symptoms and health-related quality of life. Secondary outcome measures were anxiety, depression, and overall psychopathology as measures of psychological distress as well as self-reported health care use. The treatment was expected to reduce somatic symptoms, increase health-related quality of life, and reduce health care use. There were no clear expectations regarding measures of psychological distress: it can be argued that a deficit in general (body-related) mentalizing ability in patients with chronic severe SFD may be associated with an inability to perceive and report psychological distress. Hence, in some patients, successful treatment will lead to a *reduction* in psychological distress, whereas in other patients—as a result of increased mentalizing abilities—successful treatment might lead to an *increase* in self-reported distress. Differences in treatment outcome between the inpatient and the outpatient group, as well as interindividual differences, were also exploratorily examined.

METHODS

Participants

Participants were patients with chronic severe SFD referred to the Eikenboom Altrecht tertiary care center for psychosomatic medicine in Zeist, the Netherlands. All consecutively referred patients in the period 2002 to 2009 were screened for eligibility for treatment. The main treatment inclusion criterion was the presence of SFD as the primary disorder according to *DSM-IV-TR* criteria, as diagnosed by trained psychologists and confirmed by the resident psychiatrist. Treatment exclusion criteria were a) diagnosis of hypochondriasis or body dysmorphic disorder; b) diagnosis of addiction, bipolar disorder, or psychosis; c) crisis situation requiring immediate attention (*e.g.*, high suicidality); and d) patients under treatment by a specialized physician outside the center. Treatment inclusion was based on an initial diagnostic screening, a 4-week observation period, and the patient's informed consent to accept the treatment offered. Approximately 50% of the referred patients ended up being included in the treatment.

On average, patients eligible for treatment in the center had experienced medically unexplained symptoms for 10.1 years and had received 5.5 previous treatments for the current SFD in primary and/or secondary care (van der Boom and Houtveen, 2014). Furthermore, 49.4% were diagnosed with a mood disorder; 62.1%, with an anxiety disorder; and 50.6%, with a personality disorder. Comorbid medical diseases (functional somatic syndromes excluded) were diagnosed in 53.2% of the patients. Daily functioning was impaired in 84.7% of the patients; occupational functioning, in 93.8%; and social functioning, in 75.6%. Impairments in all three areas of functioning were experienced by 65.0% of the patients.

All patients eligible for treatment were included in the study, unless either treatment was aborted prematurely, too few questionnaires were returned (at least one valid pretreatment and one valid posttreatment observation), or informed consent to participate in the study was not obtained.

Treatment and Groups

The patients received intensive multidisciplinary treatment developed for chronic severe SFD in tertiary care clinical practice, focusing on body-related mentalization, ACT, cognitive-behavioral modulation, and the dynamic family environment. They received either an outpatient or a (residential) inpatient program, lasting 6 months. The treatment period was extended (when needed) in approximately 20% of the patients. The outpatient group followed the therapy program for 3 days a week and slept at home. The inpatient group was residential in the clinic for five nights a week and went home on weekends. Patients were referred to the inpatient program if they were considered (during intake) too badly impaired in daily living activities or if their travel distance exceeded 70 km (43 miles).

The treatment for both the outpatient and inpatient groups comprised mostly group sessions (psychotherapy, art therapy, psychosomatic education, psychomotor therapy, and goal-oriented activation) combined with individual therapy (psychosomatic physical therapy) and some individual counseling sessions to monitor the progress of the treatment. In the outpatient group, the patients received on average 11 group sessions of 1 hour and 3 individual sessions (2 sessions of psychosomatic physical therapy and 1 session of individual counseling) a week. In the inpatient group, the patients received on average 15 (3 per day) group sessions of 1 hour and 3 individual sessions a week (2 sessions of psychosomatic physical therapy and 1 session of individual counseling). Rest (60–90 minutes per day) was a standard part of both outpatient and inpatient therapy. The multidisciplinary components were carried out by a team of 10 to 15 psychological, paramedical, and medical professionals (*i.e.*, psychologists, psychiatrists, physical therapists, psychomotor therapists, art therapists, medical doctors, and nurses). All therapists were fully qualified and participated in an ongoing process of internal training and supervision with regard to body-related mentalization skills as well as techniques and procedures from ACT. The treatment program had been tailored to patients with severe impairments; consequently, nonattendance at therapy sessions was incidental.

Outcome Measures

The primary outcome measures of the current study were somatic symptoms and health-related quality of life. Anxiety, depression, overall psychopathology, and medical consumption were included as secondary outcomes.

Somatic Symptoms, Anxiety, Depression, and Overall Psychopathology

These outcomes were measured with the Dutch version of the SCL-90 (Arrindell and Ettema, 2003). This questionnaire is designed to provide an overview of a patient's symptoms and their intensity at a specific point in time. An eight-dimensional model of primary factors underlying the Dutch SCL-90 (agoraphobia, anxiety, depression, somatization, cognitive-performance deficits, interpersonal sensitivity-mistrust, acting-out hostility, sleeping problems) and some additional items combine into an overall psychopathology score, the Dutch equivalent of the Global Severity Index. The 90 items are rated on a 5-point Likert scale, ranging from 1, "not at all," to 5, "extremely." Several studies have demonstrated the reliability, validity, and utility of this instrument. The somatization subscale is used as the primary outcome metric for somatic symptoms.

Health-Related Quality of Life

Health-related quality of life was measured with the EuroQol 5-Dimensional (EQ-5D) (Brooks, 1996). This instrument measures health status on five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), which each have three levels: (1) no problems, (2) some problems, and (3) extreme problems. The combination of scores defines a total of 243 different possible health states, and each of these is weighted to arrive at a single index score between −0.33 (worst possible health state) and 1.00 (best possible

health state). The Dutch norm scores were used for calculating the mean EQ-5D index values (Lamers et al., 2005). The EQ-5D also provides a subjective overall rating of the patient's own state of health on the day of administration, by means of a 0-to-100 visual analogue scale (EQ VAS).

Medical Consumption

Medical consumption was assessed using the Trimbos/iMTA Questionnaire for Costs Associated With Psychiatric Illness (TiC-P) (Hakkaart-vanRoijen, 2002). This is a generally applied tool to estimate health care use and production losses by self-report from recipients (patients with mental health problems) in the Dutch health care setting. Health care use was estimated by the TiC-P with a 29-item questionnaire, about the number of visits to the general practitioner, visits to medical specialists, hospital days, and use of medication during the preceding 4 weeks. The total number of visits, hospital days, and medication was multiplied by the Dutch unit prices (year 2006) of the corresponding health care services, to obtain costs per 4 weeks.

Procedure

The study protocol was approved by the institutional review board of Altrecht, Zeist, the Netherlands, and the subjects provided written informed consent. The patients came to the center for an initial diagnostic screening (start of the intake procedure), followed by a 4-week observation period, before starting either the 3-day-weekly outpatient or the 5-day-weekly inpatient multidisciplinary treatment program. Treatment did seldom start immediately after observation: because of limited capacity at the center, most patients were put on a waiting list and stayed at home after screening and after the observation period. There were other reasons for delaying the start of treatment, such as the need for a medication reduction program or finishing a legal procedure.

Assessments were part of a standard clinical evaluation carried out by trained clinical staff and took 2 hours on average. The patients completed the questionnaires eight times: (1) at the start of the intake procedure; (2) at the beginning and (3) end of the observation period; (4) at the beginning and (5) end of the intensive treatment period; as well as (6) six months, (7) one year, and (8) two years after the treatment. For the first five observations, the questionnaires were taken at the treatment center. The three follow-up questionnaires were sent and returned by mail.

Design and Data Analysis

In this observational study, two (nonequivalent) patient groups (*i.e.*, 3-days-a-week outpatients and 5-days-a-week inpatients) were repeatedly observed, on eight measurement occasions. The study uses an interrupted time-series design in which the change between the start and end of treatment is evaluated (*i.e.*, between measurement occasions 4 and 5).

Statistical analyses were performed using IBM SPSS statistics version 20. Variables were tested for linearity and normality. Data with skewed score distributions were ^{10}log transformed. Effect sizes were computed on the basis of the difference between the mean-aggregated posttreatment occasions and the mean-aggregated pretreatment occasions; the repeated-measures variant of Cohen's *d* using pooled standard deviations corrected for the paired-sample correlation was used (Morris and DeShon, 2002).

Because of the two-level data structure and unbalanced data (*i.e.*, unequal numbers of observations per cell as a result of missing values), linear mixed-model multilevel analysis was used as the main statistical analysis method. Maximum likelihood estimation was selected, and a random intercept was added to the model allowing individual differences in baseline values. We first tested whether a significant overall difference existed between the eight measurement occasions: measurement occasion (8), inpatient versus outpatient group (2), and their interaction were included as independent variables. Next, post hoc least significant difference (LSD) pairwise comparison tests adjusted for multiple comparisons were performed.

To test for a specific change between pretreatment and posttreatment measurements (*i.e.*, a change between measurement occasion 1 to 4 versus 5 to 8 in the interrupted time series), a linear regression model was tested, including both a repeated-measure contrast based on the subject-specific assessment time (in days relative to the start of treatment) and a planned pretreatment-to-posttreatment contrast that specifically models the difference before and after treatment (score 0 for the first four observations and score 1 for the last four observations). Hereby, the analysis takes into account maturation and the large interindividual differences in the time intervals between measurement occasions. However, this test may be too conservative because the effects of assessment time and pretreatment-to-posttreatment differences are correlated. Therefore, a model with treatment effect only (*i.e.*, without subject-specific assessment times) was also computed. Finally, group differences and interindividual differences (*i.e.*, random slopes) were examined in the regression model with treatment contrast only, and percentages of patients who improved more than 1 SD (which is considered a significant clinical change) were computed. Two-tailed *p*-values were reported, and a value of less than 0.05 was considered significant.

RESULTS

Participants

Figure 1 shows a flow diagram of all 311 consecutively referred patients in the period 2002 to 2009 who were considered eligible for treatment and who started the treatment as well as the subgroups of patients who were excluded and included in the current treatment evaluation study. Of the patients included, 74 (20 men, 54 women) followed the 3-day outpatient treatment program and 109 (17 men, 92 women) followed the 5-day inpatient treatment program. Table 1 presents their characteristics including *DSM-IV* diagnoses. No significant differences in diagnosis were found between the outpatient and inpatient groups ($\chi^2_5 = 6.31$, $p = 0.28$).

Assessment Intervals

On average, treatment started approximately a year after start of intake (mean, 47.6 weeks; SD, 20.1), 16 weeks after start of the observation period (mean, 15.9; SD, 9.8), and 8 weeks after end of the observation period (mean, 7.9; SD, 7.1). An average treatment period lasted 26.1 weeks (SD, 5.8). The average 6-month follow-up moment was 56.3 (SD, 8.3) weeks after start of treatment, the average 1-year follow-up moment was 81.9 (SD, 9.1) weeks after start of treatment, and the average 2-year follow-up moment was 133.3 (SD, 11.7) weeks after start of treatment. The mean number of pretreatment and posttreatment observations available per subject was 4.1.

Primary Outcomes

Somatization Subscale of the SCL-90

Mixed-model multilevel analyses (using ^{10}log-transformed values) yielded a significant fixed-effect difference between the eight measurement occasions on the somatization subscale ($F[7,588.0] = 12.0$, $p < 0.001$). Figure 2 shows the estimated marginal (EM) means for somatization (and the other SCL-90 subscales), and it also depicts the significant LSD post hoc test results of the differences between the measurement occasions before treatment, all the differences related to the start treatment occasion, and the differences between the measurement occasions after the treatment. All mean posttreatment somatization scores were significantly lower than the mean start of

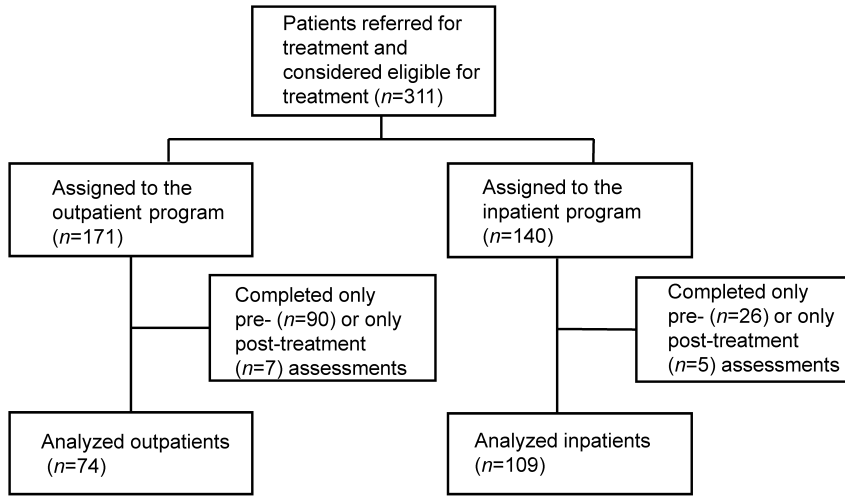

FIGURE 1. Flow diagram of the patients included in the treatment evaluation study.

treatment value. A medium effect size ($d = 0.51$) was found for somatization (Table 2).

A multilevel linear regression model was tested including both the repeated-measure contrast based on the subject-specific assessment times (in days relative to the start of treatment) and the pretreatment-to-posttreatment contrast that specifically models the difference before and after treatment (score 0 for the pretreatment observations and 1 for the posttreatment observations; see *Methods*). The model with only assessment time yielded a significant regression coefficient ($p < 0.001$) for somatization. However, when the treatment contrast was added to this model, the contribution of assessment time became nonsignificant ($t_{time} = -1.82$, $p = 0.07$; $t_{treatment} = -4.02$, $p < 0.001$), demonstrating a specific treatment effect. Table 3 shows the beta value and significance for the regression model including the treatment contrast only (*i.e.*, without including the subject-specific assessment times).

EQ-5D Index and EQ VAS

Mixed-model multilevel analyses yielded significant fixed-effect differences between the eight measurement occasions for EQ-5D index ($F[7,589.0] = 6.19$, $p < 0.001$) and EQ VAS ($F[7,573.5] = 14.50$, $p < 0.001$). Figure 3 shows the EM means and the significant LSD post hoc test results of the differences between the measurement occasions before treatment, all the differences related to the start treatment occasion, and the differences between the measurement occasions after the treatment. All mean posttreatment scores were significantly higher than the mean start of treatment value. A small effect size was found for EQ-5D index, and a medium effect size was found for EQ VAS (Table 2).

The multilevel linear regression models with only assessment time yielded significant regression coefficients for both EQ measures (both $p < 0.001$). When the pretreatment-to-posttreatment contrast was added to the model, the variance was explained by both overlapping variables: EQ-5D index ($t_{time} = 2.15$, $p < 0.05$; $t_{treatment} = 1.80$, $p = 0.07$) and EQ VAS ($t_{time} = 2.42$, $p < 0.05$; $t_{treatment} = 3.89$, $p < 0.001$).

Secondary Outcomes

SCL-90 Anxiety, Depression, and Overall Psychopathology

Mixed-model multilevel analyses (using ^{10}log-transformed values) yielded significant fixed-effect differences between the eight measurement occasions for anxiety ($F[7,581.1] = 10.76$, $p < 0.001$), depression ($F[7,590.2] = 13.25$, $p < 0.001$), and overall psychopathology ($F[7,583.9] = 14.94$, $p < 0.001$). Small to medium effect sizes were found (Table 2).

The multilevel linear regression models with only assessment time yielded significant regression coefficients for all secondary SCL-90 measures (all $p < 0.01$). However, when the treatment contrast was added to the model, the contribution of time became nonsignificant for all variables demonstrating specific treatment effects: anxiety ($t_{time} = -0.26$, $p = 0.80$; $t_{treatment} = -4.45$, $p < 0.001$), depression ($t_{time} = 0.01$, $p = 0.99$; $t_{treatment} = -5.72$, $p < 0.001$), and overall psychopathology

TABLE 1. Patients' Characteristics

	Outpatients ($n = 74$)	Inpatients ($n = 109$)	All ($N = 183$)
General			
Age, mean (SD), yrs	40.5 (9.9)	40.6 (10.9)	40.5 (10.5)
Female, %	73.0	84.4	79.8
DSM-IV diagnoses			
Undifferentiated SFD	27	30	57 (31.1%)
SFD not otherwise specified	9	15	24 (13.1%)
Conversion disorder	11	31	42 (23.0%)
Pain disorder associated with psychological factors	4	6	10 (5.5%)
Pain disorder associated with both psychological factors and a general medical condition	21	24	45 (24.6%)
Somatization disorder	2	1	3 (1.6%)
Missing/lost	—	2	2 (1.1%)

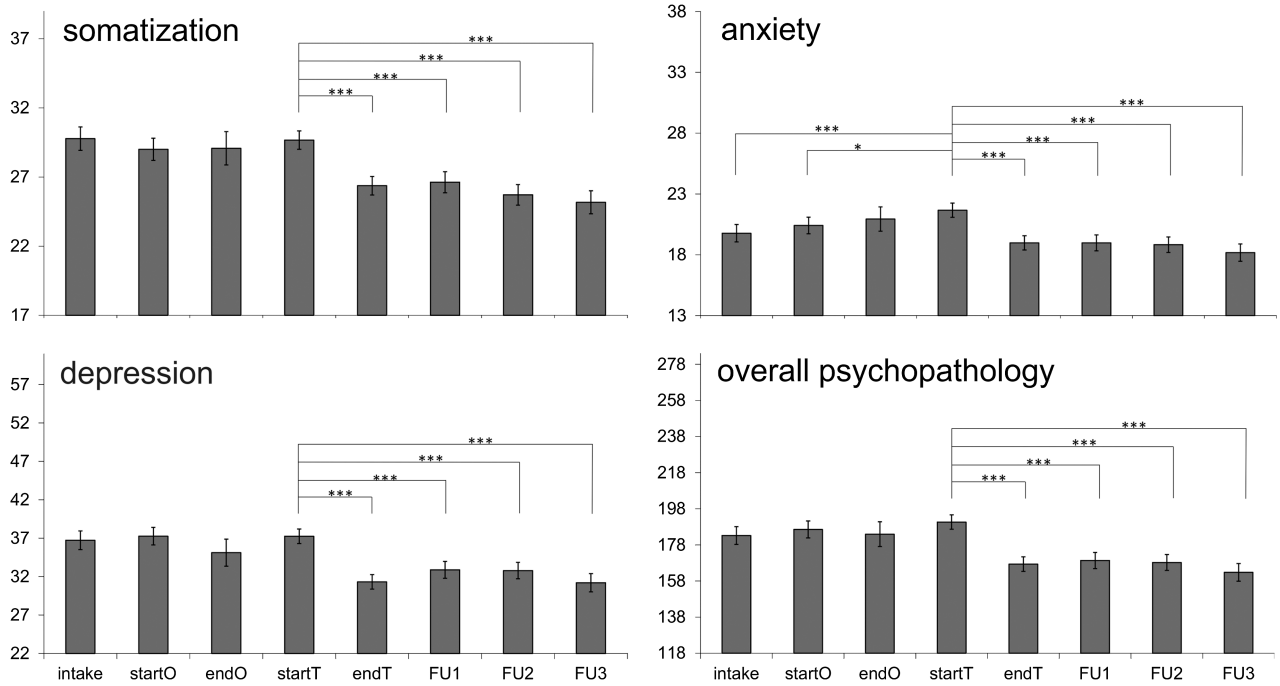

FIGURE 2. EM mean values (±standard error [of the mean]) for the SCL-90 subscales. The minimum *y* axis value is the mean score in a Dutch norm reference group of the general population (norm group II); the maximum *y* axis value is the high score in a Dutch norm reference group of psychiatric patients (norm group I). FU1 indicates 6-month follow-up; FU2, 1-year follow-up; FU3, 2-year follow-up; O, clinical observation; T, treatment; *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$ (two tailed).

($t_{time} = -0.27$, $p = 0.79$; $t_{treatment} = -5.76$, $p < 0.001$). Table 3 shows the beta values and significances for the regression model including the treatment contrast only.

Medical Consumption Scale of the TiC-P

The scores on the TiC-P medical consumption scale (range, 0–8200) were severely skewed, which could not be solved by a transformation. As a result, the statistical assumptions needed to apply mixed-model multilevel analysis were not met. Furthermore, no reliable medical consumption estimation existed just after the observation period and just after the treatment period (because patients spent most of their time in the clinic), and these two scores had to be excluded. Finally, costs varied greatly during the remaining six measurement occasions per subject. To solve these problems, nonparametric statistical testing was applied to compare the available pretreatment and posttreatment costs. The mean-aggregated medical consumption before treatment was calculated for each participant by averaging all the expenses at the moment of intake, start of observation, and start of treatment. The mean-aggregated medical consumption after treatment was calculated by averaging all the expenses of the three follow-up moments (6 months, 1 year, and 2 years). This resulted in 183 valid pretreatment observations (median, 400; range, 0–7900 euro) and 136 valid posttreatment observations (median, 350; range, 0–4633 euro). A related-samples Wilcoxon's signed-rank test showed that posttreatment costs were significantly lower ($Z = -2.17$, $p < 0.05$).

Group and Individual Differences

The SCL-90

No significant overall difference between the treatment groups (inpatients versus outpatients) was found. A group by measurement occasion interaction effect was found for anxiety only ($F[7,581.1] = 2.21$, $p < 0.05$); the inpatients had lower anxiety scores during the start and end of the observation period (*i.e.*, measurement occasion 2 and 3 only). The amounts of fixed and random variances explained by the treatment contrast only (*i.e.*, without including subject-specific assessment times to the model) were computed. The models including only a fixed effect of the treatment contrast explained relatively little (8.7%–13.4%) variance on the time level (see Table 3, % I). When allowing random slopes (% II), more (31.8%–40.2%) variance was explained. The chi-square likelihood-ratio tests showed that the model fits including random slopes were significantly improved for all subscales (all $p < 0.001$), demonstrating individual differences. Table 3 also shows the percentages of patients who improved or deteriorated more than 1 SD (which is taken as cutoff value for a significant clinical change). Group differences were also examined using the regression model with the treatment contrast only. We did not find an overall difference between the inpatient and outpatient groups, nor did the effects of the treatment contrast significantly differ between the groups (*i.e.*, no group by treatment contrast interaction effects were found for the SCL-90 scales).

The EQ-5D

An overall difference between the treatment groups was found for EQ-5D index only ($F[1,211.6] = 4.90$, $p < 0.05$): the outpatients

TABLE 2. Pretreatment-to-Posttreatment Cohen's *d* Effect Sizes

	Outpatients		Inpatients		All	
Outcome	***n***	***d***	***n***	***d***	***n***	***d***
SCL-90 somatization	74	−0.58	109	−0.47	183	−0.51
EQ-5D index	73	0.47	104	0.15	177	0.27
EQ VAS	70	0.79	105	0.41	175	0.56
SCL-90 anxiety	74	−0.39	109	−0.35	183	−0.36
SCL-90 depression	74	−0.60	109	−0.46	183	−0.51
SCL-90 overall psychopathology	74	−0.58	109	−0.49	183	−0.52

TABLE 3. Beta Values, Percentages of Variance Explained, and Interindividual Differences (Across Both Groups)

Outcome Measure	*n*	β	SD	% I	% II	% imp	% det	*n* dys	% d imp
SCL-90 somatization	183	0.20***	0.27***	11.4	32.4	23.5	2.2	150	28.0
EQ-5D index	177	−0.14***	0.30***	4.7	24.8	23.0	8.7	112	34.8
EQ VAS	175	−0.24***	0.29***	12.3	30.3	33.9	7.7	109	46.8
SCL-90 anxiety	183	0.16***	0.27***	8.7	31.8	15.8	3.8	101	27.7
SCL-90 depression	183	0.22***	0.30***	12.1	35.2	18.6	3.8	128	26.6
SCL-90 overall psychopathology	183	0.21***	0.30***	13.4	40.2	20.8	2.7	131	29.0
TiC-P medical consumption	136	—	—	—	—	19.1	2.2	—	—

β indicates beta value for treatment contrast (fixed, model II); SD, individual differences in slope (random, model II); % I, explained repeated-measures variance for model I with treatment contrast as fixed factor; % II, explained variance for model II with treatment contrast both as fixed and as random factor; % imp, % det, percentages of patients who improved or deteriorated more than 1 SD; *n* dys, the number of patients who were classified as dysfunctional (*i.e.*, scoring lower than a cutoff point distinguishing between the functional and the dysfunctional population) before treatment. The cutoff points were computed separately for men and women for each measure based on Jacobson and Truax (1991): method 2 for SCL-90 and method 3 for EQ-5D index and EQ VAS; no norm values available for TiC-P; % d imp, percentage of the patients classified as dysfunctional who improved more than 1 SD (which is considered a significant clinical change).

*$p < 0.05$.

**$p < 0.01$.

***$p < 0.001$ (*t*-test for beta, Wald's *Z* test for standard deviation).

had higher scores on EQ-5D index than the inpatients. A group by measurement occasions interaction effect was found for both EQ-5D index (F[7,589.0] = 2.44, $p < 0.05$) and EQ VAS (F[7,573.5] = 2.84, $p < 0.01$): the increase was larger for the outpatients than the inpatients (Fig. 3). Table 3 shows the explained variances for the model including the treatment contrast only (*i.e.*, without subject-specific assessment times). Again, more variance (4.7% *vs.* 24.8% and 12.3% *vs.* 30.3%) was explained (and the fit index was significantly improved) by allowing random slopes, demonstrating individual differences in the effects of the treatment. Group differences were also explored using the regression model with the treatment contrast only. An overall difference between the inpatient and outpatient groups was found for EQ-5D index ($p < 0.01$), and a group by treatment contrast effect was found for EQ-5D index ($p < 0.01$) and EQ VAS ($p < 0.001$): the outpatients had a higher health-related quality of life and improved more in therapy.

The TiC-P

Specific (simple effect) tests for each group (inpatients and outpatients) showed that the reduction in costs was significant only for the inpatient group (median pretreatment, 650; median posttreatment, 400; $p < 0.05$) and not for the outpatient group (median pretreatment, 300; median posttreatment, 275; $p = 0.21$).

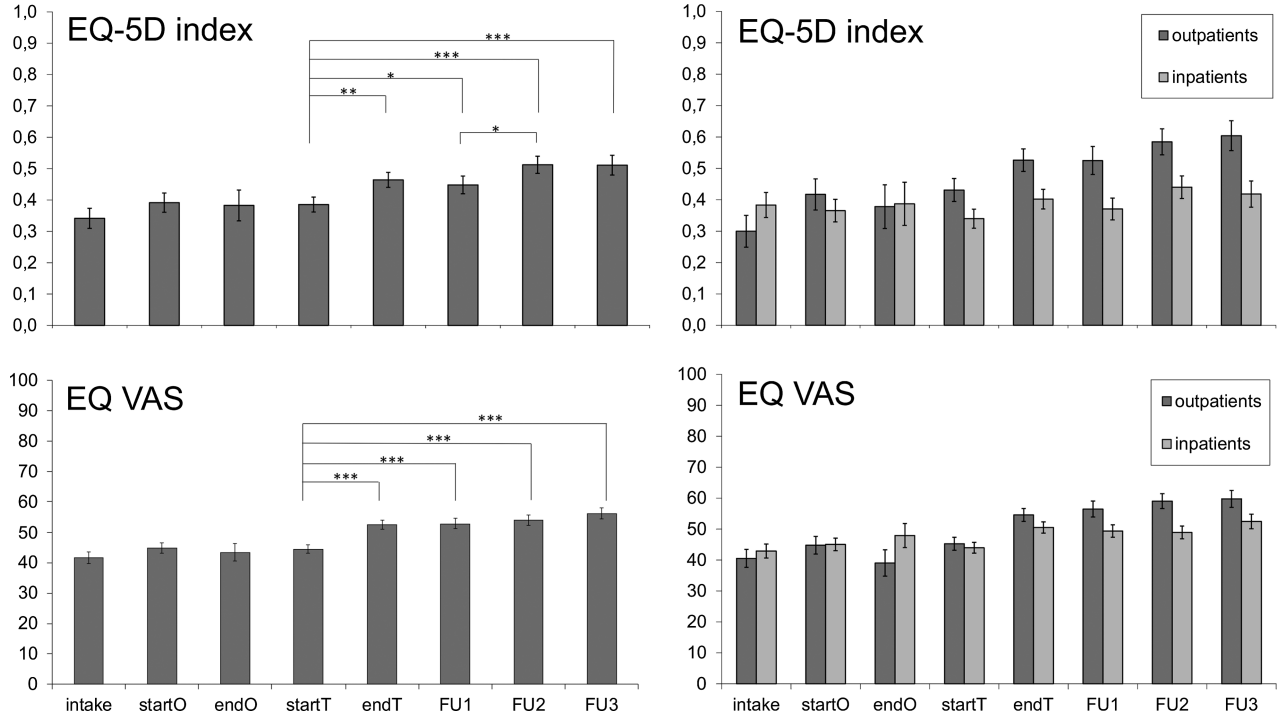

FIGURE 3. EM mean values (±standard error [of the mean]) for EQ-5D index and EQ VAS. FU1, 6-month follow-up; FU2, 1-year follow-up; FU3, 2-year follow-up; O, clinical observation; T, treatment; *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$ (two tailed).

DISCUSSION

This study observed improvement in the primary outcome measures: a reduction in somatic symptoms and an increase in health-related quality of life. Moreover, these improvements were maintained during the 2-year follow-up period of the study.

Overall (across patients), a reduction was also found for the secondary outcome measures reflecting psychological distress. We argued in the introduction that, in some tertiary care patients with chronic severe SFD, the observation and self-reports of psychological distress (anxiety, depression, overall psychopathology) might be hampered by deficits in (body-related) mentalizing ability and that successful treatment might lead to an increase in self-reported distress. A decrease and not an increase in self-reported psychological distress was observed across patients. The large interindividual differences found, however, suggest that this does not hold for all patients. Repeated assessments during the treatment period and case-series analyses are needed to assess and clarify the course of self-reported distress in specific (subgroups of) individuals.

A small but significant reduction was also found for the secondary outcome measure of health care use. Our estimation of medical costs, however, was based on relatively unreliable retrospective self-reports of the number of visits, hospital days, and medication (using the TiC-P) multiplied by the Dutch unit prices; future studies could use real health care costs by using data from health care insurance companies.

The outpatient and inpatient groups showed similar improvements in somatic symptoms. However, the outpatient group improved most on health-related quality of life. How can these group differences be explained? A core criterion for enrollment in the inpatient program was severe physical impairment in daily living activities. Perhaps it was more feasible for the relatively less impaired outpatients to gain improvement in health-related quality of life than for more severely impaired inpatients. With respect to the secondary outcomes, only the inpatient group showed some reduction in health care use. This might be due to the inpatient group having larger pretreatment costs (median 650 *vs.* 300), leaving more room for a posttreatment reduction. Thus, although our results indicate that an improvement in quality of life and a reduction in medical consumption are possible in patients with chronic severe SFD, the group differences observed suggest that individual treatment effects may depend on individual characteristics, such as the initial level of physical impairment and health care use.

With respect to the size of the effects found, medium effects were found for somatic complaints and the overall health state rating (EQ VAS), and small effects were found for the health-related quality of life index (EQ-5D index). Small to medium effects were also observed for the secondary outcomes. These findings are promising because only patients with chronic severe SFD were included—patients who tend to be resistant to treatment (Feltz-Cornelis et al., 2012). Most of the patients included in our study had a history of unsuccessful treatments or had been excluded from other treatment programs. For this patient group with very severe, chronic SFD, even a small improvement can have a significant impact on daily life functioning and other outcomes when the effect is maintained. In our study, the small to medium effect-size improvements were observed during a 2-year follow-up period, suggesting maintenance of effects.

Despite differences in intensity of the 3-day outpatient program versus the 5-day inpatient program, no striking differences in effect size were found between the two programs. This can partially be explained because differences in intensity between the programs were actually relatively small, as a result of more rest periods between therapy sessions in the 5-day program compared with the 3-day program. Confounding by indication, such as the severity of impairment in daily living activities, however, prevents us from drawing any strong conclusions on cost-effectiveness.

Interindividual differences in the effects of the treatment were clearly present. This was demonstrated by allowing random slopes in the model. From the patients with dysfunctional scores at the start of treatment, 28% improved more than 1 SD on somatic symptoms and 35% and 47% improved more than 1 SD on the health-related quality of life index and VAS scores. Moreover, individual patients improved or deteriorated on different measures. Our multidisciplinary treatment approach, focusing on body-related mentalization, acceptance, cognitive-behavioral modulation, and the dynamic family environment, consists of multiple components—with verbal and nonverbal aspects—such as CBT, insight-focused psychotherapy, ACT, and systemic therapy, combined with psychosomatic physiotherapy, psychomotor therapy, and art therapy. Specific combinations of these components will have produced or mediated subject-specific beneficial effects in individual patients. In future studies, a case-series design can be used by means of multiple repeated observations during treatment to determine the most effective treatment components for an individual patient using patient-specific outcomes.

Strengths of the current prospective evaluation study were the large number of patients included, the long follow-up period, and the multiple repeated measurements before and after therapy. A strong aspect of the data analysis was the use of a multilevel regression model including both the subject-specific assessment times (in days relative to the start of treatment) and a treatment contrast that specifically modeled the difference before and after treatment. Hence, the analysis separated interindividual differences in the time duration between assessments (maturation) and the effect of the treatment, which improved the internal validity. A limitation of the current observational treatment evaluation study was that only one treatment was evaluated (*i.e.*, without a comparison group). In future research, new interventions can be compared with the currently evaluated treatment, which can then be considered a treatment-as-usual control group. Other limitations were the missing values and the unbalanced data structure; because of various reasons and events, some patients aborted their treatment prematurely (*e.g.*, were confronted with medical conditions, severe psychopathological symptoms, or life events that needed acute attention or were insufficiently motivated to participate in intensive treatment) or did not complete sufficient questionnaires.

CONCLUSIONS

The results of the current observational study indicate long-term effectiveness of an intensive multidisciplinary treatment with a core focus on body-related mentalization and acceptance. This suggests that—on average—even chronic and severely impaired SFD patients can be treated successfully with this treatment approach in tertiary care. These findings, based on a large patient group and a long follow-up period, extend previous findings regarding the outcomes of psychological treatment of SFD in general (Kroenke, 2007) and, more specifically, of more severe SFD in secondary and tertiary care (Koelen et al., 2014). Further studies are needed to determine the most effective components of this treatment and to examine ways to improve customization of these components to the individual patient.

ACKNOWLEDGMENTS

The authors thank Lucie Veselka for her assistance with setting up the study and the data collection and Floor Kraaimaat, Kees Jan van der Boom, and Gillian Griffiths for their suggestions to improve the manuscript.

DISCLOSURES

The authors declare no conflict of interest.

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