

Is brief psychodynamic psychotherapy in primary fibromyalgia syndrome with concurrent depression an effective treatment? A randomized controlled trial

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ABSTRACT

Objective: There are no studies investigating the efficacy of short-term psychodynamic psychotherapy in primary fibromyalgia syndrome (FMS). We conducted a randomized controlled trial evaluating an adapted form of individual short-term psychodynamic psychotherapy (ASTPP) versus primary care management (TAU). The study focused on FMS patients with psychiatric comorbidity.

Methods: Forty-six female patients with FMS and an *International Classification of Diseases, 10th Revision* diagnosis of a comorbid depression or anxiety disorder were recruited in a hospital setting. Participants were randomized to receive either ASTPP (25 sessions, 1 session/week) or TAU (4 consultations/6 months). Outcome measures included the Fibromyalgia Impact Questionnaire (FIQ), the Hospital Anxiety and Depression Scale (HADS), the Pain Disability Index, the Symptom Checklist 27 and the health-related quality of life. Primary endpoints of the outcome assessment were the FIQ total score and the HADS depression scale at 12-month follow-up.

Results: Both treatments were effective in reducing the FIQ total score (ES=0.56 and ES=0.75, respectively). Intent-to-treat analyses failed to provide evidence suggesting a marked superiority of individual psychodynamic psychotherapy as compared to TAU.

Conclusions: A high-standard routine treatment focusing on the improvement of health behavior and including antidepressant and analgesic medication is equally effective as a short-term individual psychodynamic psychotherapy in improving fibromyalgia-related symptoms.

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1. Background

Fibromyalgia syndrome (FMS) is a chronic pain condition characterized by the key symptoms of widespread pain, fatigue, sleep disorder and psychological distress. Although the etiology of the syndrome is not yet fully understood, recent data suggest that a central mechanism either augmenting pain or attenuating the activity in descending antinociceptive pathways plays an important role [1]. A high prevalence of psychiatric comorbidity, in particular of depression, anxiety [2] and posttraumatic stress disorder [3], has been reported. The link between psychological distress and pain mechanisms has been extensively discussed with regard to depression without providing sufficient evidence to suggest a common pathogenetic pathway [4]). Depression and catastrophizing cognitions are consistently associated with the severity of pain and poor treatment outcome. However, this applies not only to fibromyalgia but also to various other pain conditions [5].

Aerobic exercise [6], antidepressant drugs [7] and psychotherapy are evidence-based and effective treatments in FMS [8,9]. Reviewing the literature on psychotherapeutic treatment in FMS, it is noteworthy that randomized controlled trials evaluating individual psychotherapy are rare. Most of the existing randomized comparison studies used group psychotherapy or group-based treatment programs as intervention. Of the 23 intervention studies reviewed by Glombiewski et al. [8], only 3 studies were performed in an individual treatment setting. Also, psychodynamic treatment approaches have rarely been investigated, although the efficacy of short-term psychodynamic psychotherapy has been substantiated recently for various disorders [10–12].

There are several reasons to explore the efficacy of different forms of psychotherapy for FMS patients. (a) Although the efficacy of psychological interventions such as cognitive-behavioral therapy (CBT) on a range of symptoms has been clearly established [8,9,13], the reported effect sizes are in the low or medium range. Integration of other treatment approaches might add to improve the outcome. (b) Considering that, in a subgroup of FMS patients, inter- and intrapersonal conflict due to developmental deficits [14–16] might result in heightened stress vulnerability, a psychotherapeutic

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approach focusing on this area could be promising. (c) In a randomized controlled trial on psychodynamic interpersonal therapy in irritable bowel syndrome with abdominal pain as outcome criterion, it was observed that changes of pain were correlated with changes in interpersonal relationships mediated by a decrease of psychological distress [17]. This finding suggests that interpersonal relationships can be a rewarding target for psychotherapeutic interventions leading not only to an improvement of psychological well-being but also to an amelioration of pain.

In the present study, we report on a randomized controlled trial in which a manualized form of individual short-term psychodynamic psychotherapy was evaluated. Since psychotherapy is moving in many ways towards an integration of different treatment components in the initial phase of treatment, some components of CBT were integrated. We expected a superior outcome of FMS symptoms and depression applying this adapted form of short-term psychodynamic psychotherapy (ASTPP) as compared to a primary care treatment (TAU).

2. Methods

2.1. Design

A two-arm randomized comparison study was conducted in which female patients were randomly assigned to either (a) an ASTPP or (ii) an active control intervention equating a high-standard primary care management (TAU). In addition, both groups received a written patient information brochure with detailed information about FMS and advice to improve levels of physical activity and other aspects of health behavior. Primary endpoints were measures of the Fibromyalgia Impact Questionnaire (FIQ) and the Hospital Anxiety and Depression Scale (HADS) at follow-up 12 months postintervention.

Baseline measurements were completed after determination of eligibility (preintervention baseline, 0 week), and patients were subsequently allocated to one of the two study arms. Patients were again assessed at the end of the intervention in week 25. Follow-up measurement was performed at 12 months posttreatment. For the main outcome analysis, variables from preintervention to 12-month follow-up were assessed.

2.2. Power calculation

The short-term outcome of psychodynamic psychotherapy of somatic symptom disorder according to a meta-analytic integration of studies amounted to an ES of $d=0.58-0.78$ [12]. Based on an assumed effect size of 0.75, a sample size of $n=23$ per group or 46 patients overall would result in $1-\beta=.80$ ($\alpha=.05$). Based on an assumed effect size of $d=0.60$, a sample of $n=36$ had to be included in each group or a total sample of $N=76$ in order to achieve $1-\beta=.80$ ($\alpha=.05$). Considering the treatment dose of 25 sessions of individual psychotherapy in our study, the sample size was determined according to an effect size estimation of 0.75.

2.3. Participants

Women, 18–70 years of age, who currently suffered from fibromyalgia as defined by the American College of Rheumatology (ACR) criteria [18] were eligible for the trial. The intervention was designed to focus on a subgroup of patients with substantial psychological comorbidity. Therefore, only participants suffering from current depression or anxiety disorder [International Classification of Diseases, 10th Revision (ICD-10) diagnosis of a major depressive episode, recurrent depression, dysthymia, depressive adjustment disorder or anxiety disorder] were included. Additional inclusion criteria were command of the German language and informed consent. Exclusion criteria were severe or life-threatening diseases, psychiatric or neuropsychiatric conditions associated with cognitive impairment

and/or suicidal ideation, current psychotherapy or participation in other clinical trials. Participants were recruited via patient self-help groups, news media and referrals from the Department of Rheumatology at the University of Freiburg Medical Center. During an intake examination at the hospital (Department of Psychosomatic Medicine and Psychotherapy), patients were evaluated for eligibility criteria and were examined by an experienced physician, either a rheumatologist (M.L.) or a neurologist (R.K), both trained in psychosomatic medicine, who employed the ACR criteria to confirm the diagnosis of fibromyalgia and the ICD-10 criteria for depressive or anxiety disorder.

Informational brochures were then provided explaining the two interventions as alternative treatments potentially capable of enhancing the well-being of fibromyalgia patients. No suggestion was made about the superiority of either treatment. Information was collected concerning ongoing medical, pharmacological or other interventions for the disorder, but participants were not asked to discontinue the respective treatments (with the exception of concurrent psychotherapy or psychiatric treatment, which was considered as an exclusion criterion). The study was approved by the University of Freiburg Ethics Committee, and all patients completed informed consent prior to enrolment.

Fig. 1 summarizes the flow of patients through the trial. The criteria for inclusion into the intention-to-treat (ITT) sample were randomization and participation in at least one session. This procedure was chosen because the therapist (ASTPP) or the responsible physician (control condition) could exclude patients before commencement of intervention on the basis of new information she had acquired during the intake session (e.g., suicidal ideation) which had occurred after randomization.

The ITT sample consisted of 46 women. The per-protocol sample comprised all patients who had participated in at least 50% of the allocated intervention and provided data at both preintervention and 12-month follow-up ($N=35$, dropout rate $n=11$, 23.9%).

2.4. Randomization and allocation concealment

Consenting eligible patients were randomly assigned to one of the two study arms. Patients were randomized in blocks of 10 either to the treatment group or to the control condition according to a 1:1 schedule made beforehand. Information regarding eligible patients entering the trial was sent to a study coordinator, who otherwise had no contact with the patients and who was not involved in either intervention. She independently randomized the patients and sent the result of the randomization back to the clinical coordinator, who initiated the respective intervention. Patients in both arms were told that the treatments were to be compared, one treatment based on clarifying interpersonal issues and distressing life events and the other based on health support techniques entailing relaxation and physical activity. All patients participating in one of the two treatment arms were also offered participation in their treatment of choice after completion of the trial.

2.5. Interventions

The experimental intervention consisted of 25 weekly sessions of psychodynamic psychotherapy specifically adapted to the needs of patients with pain symptoms. Sessions lasted between 50 min and 1 h. The treatment approach is based on a dysregulation model of psychosomatic illness [19,20] and on research on attachment styles and affect regulation in somatoform disorder [21–23]. Problems in self- and affect recognition are associated with a higher vulnerability to stress [24,25]. The adopted treatment concept integrates components of interpersonal therapy [26] and overlaps theoretically and technically with modern variants of psychodynamic therapy [27]. Our treatment concept was first published in 2002 [28] and tested in a pilot study between 2002 and 2005.

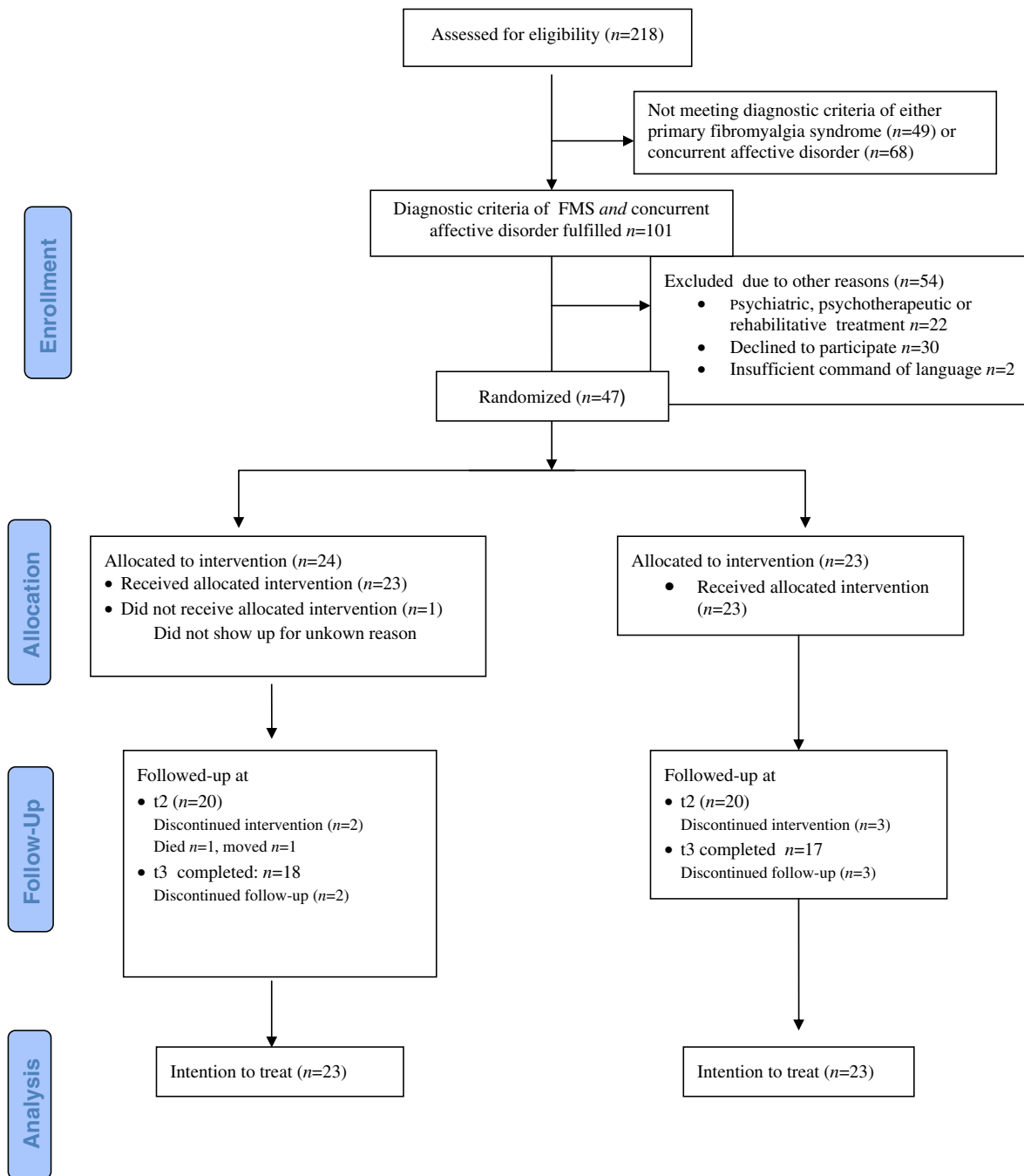


Fig. 1. Consort flow chart.

The treatment content is structured according to different phases. During the initial phase lasting three to five sessions, the focus is on establishing a trustful and supportive relationship. Patients give an account on their medical history including their own view concerning the causes of their symptoms and their often disappointing experiences within the health care system. Issues of pain behavior and dysfunctional coping are addressed. In the second phase, the focus is shifting gradually towards interpersonal problems linking adverse psychosocial experiences and intrapsychic conflict with bodily complaints and emotions. During this phase, issues of self-management, self- and bodily awareness, and affect regulation are in the foreground. Difficulties in these areas are linked to attachment history including experiences of emotional deprivation, loss and trauma.

The final phase aims to stabilize changes and concentrates on termination issues. This includes the planning of additional psychotherapeutic or pharmacological interventions for target symptoms and a review of the accomplishment of initial treatment goals.

The therapists were four female psychologists who, at the time of the study, were in advanced training (minimum 3 years) at the Psychoanalytic Training Institute of Freiburg University Medical Center. All therapists had a minimum of 1 year of psychiatric and 1 year of psychosomatic resident training. The therapists were instructed about the concept and treatment strategies of ASTPP in two training sessions each lasting for 2 hours in which the manual was introduced using standardized training cases. Adherence to the treatment manual was sustained by regular supervision after every fourth session by the principal investigator (C.E.S.). In addition,

therapists had to fill out adherence scales during the therapy after sessions 1, 8, 16 and 25.

Patients were informed about the content and the basic strategies of the intervention in the beginning of the respective treatment.

2.6. Active control group (TAU)

The active control group was planned to control for the specific aspects of the psychotherapeutic intervention and was aimed to equate a good primary care standard.

It comprised four contacts during a 6-month period, each lasting about 10 to 15 min, in which patients were advised with regard to medication and health behavior and were especially encouraged to increase physical activity and gentle stretching exercises. The primary care intervention was also manualized and administered in the outpatient department of Freiburg University Medical Center, Department for Psychosomatic Medicine and Psychotherapy. The responsible physician delivering the primary care treatment was a medical doctor trained in neurology or rheumatology.

None of the therapists in the treatment arm had any other relationship with the study other than providing the treatment.

2.7. Primary outcome measures

2.7.1. Fibromyalgia-related symptoms

Symptoms of the FMS were measured using the FIQ [29,30]; German version [31]). The questionnaire is composed of 10 questions. The first item contains 11 subitems related to physical functioning. Two additional items refer to overall well-being and the ability to work. On the following seven visual analogue scales, common symptoms associated with fibromyalgia such as pain, fatigue, stiffness and mood are evaluated. The questionnaire has good psychometric properties and is sensitive for therapeutic change.

In the present study, an anchor-based estimate of the minimal clinically important difference (MCID) was based on the FIQ. Bennett et al. [32] empirically determined a 14% change in the FIQ as an MCID.

2.7.2. Depression and anxiety

The HADS [33] screens for depression and anxiety specifically in populations suffering from physical illness. The questionnaire consists of two subscales: one for anxiety and one for depression.

2.8. Secondary outcome measures

2.8.1. Psychological distress

Self-reported symptoms of psychological distress were assessed using the Symptom Checklist-27 (SCL-27 [34]), a short version of the Symptom Checklist-90-R [35,36].

2.8.2. Pain-related disability

The Pain Disability Index (PDI; German version [37]) is a seven-item instrument that assesses the degree (1–10 scale) to which chronic pain interferes with daily activities in seven domains. The PDI has shown good psychometric properties [38,39].

2.8.3. Health-related quality of life

Health-related quality of life was assessed using the Medical Outcomes Study 36-item Short Form (SF-36; German version [40]), a self-report questionnaire assessing health-related, but not pain-specific, functional interference in six domains summarized in two global scores: one for mental functioning and one for physical functioning [41].

2.8.4. Functional physical symptoms

Somatiform symptoms were assessed using the screening for somatiform disorders-7 (SOMS-7) [42], a self-rating questionnaire

comprising 23 items. The total score reflects the number and intensity of functional physical symptoms in the 7 days preceding assessment.

2.8.5. Co-occurring therapies

Co-occurring therapies were documented at all measurement points using a short patient diary. Items of this diary are as follows: pain medication, physical exercise, relaxation therapy, consultation of a general practitioner, consultation of other doctors and days off work (if applicable).

2.8.6. Psychiatric diagnoses

Psychiatric diagnoses were established according to the ICD-10 research criteria based on a thorough clinical assessment performed by a medical doctor trained in neurology and psychosomatic medicine (R.K.) or a medical doctor trained in rheumatology and psychosomatic medicine (M.L.). Interview data were collected during the initial assessment at the Department of Psychosomatic Medicine and Psychotherapy, Freiburg University Medical Center. The assessment included the evaluation of the medical and personal history, physical symptoms and complaints, and psychiatric history, and a medical and mental state examination. The results of the assessment were recorded in a standardized written report.

2.9. Statistical analysis

Results are based upon ITT analyses. Missing values of individual items of scales were replaced according to missing replacement procedure of the respective inventories. When not specified or when more items were missing than allowed for replacement using these procedures, overall scale values were replaced by a regression-based single imputation procedure (“predicted means”) by the software SOLAS 2.0. Predictors for the imputation process were the respective baseline values of age, group, educational background, housing situation and occupational level.

The baseline characteristics were compared between the groups using either χ^2 test or independent *t* tests depending on type of variable.

For the main outcome, the treatment effects in both groups were tested across the three measurements using linear mixed models by analyzing the differences between baseline and end of treatment or 12-month follow-up, respectively, and controlling for age and education. Secondary outcomes are reported equally. We calculated Cohen's *d* [43] as a within-group effect size (standardized effect size) reflecting differences between pretreatment and 12-month follow-up by computing the mean difference and dividing this by the standard deviation at baseline.

Concurrent treatments (antidepressant and analgesic medication, aerobic exercise) were not considered as outcome measures and were therefore not included in the ITT analysis. Frequencies are reported for both groups based on the completer sample. Group comparisons were calculated using χ^2 test.

3. Results

3.1. Patient characteristics at baseline

In total, 47 patients gave informed consent and were randomized to ASTEPP ($n=24$) or to TAU ($n=23$). One patient, who was randomized to the intervention group, did not show up for the treatment for unknown reason. The dropout rates between baseline and 12-month follow-up amounted to 25% in the intervention group and 26% in the control group. The baseline characteristics of the two study groups are given in Table 1.

In the intervention group, 70% ($n=16$) of the patients received a diagnosis of either a major depressive episode or a recurrent major depression, 13% ($n=3$) received a diagnosis of dysthymia, and 13% ($n=3$) received a diagnosis of a double depression. In the control group, 61% ($n=14$) of the patients received a diagnosis of either a major depressive episode or a recurrent major depression, 26% ($n=6$) received a diagnosis of dysthymia, and 13% ($n=3$) received a

Table 1
Demographic and clinical characteristics (n=46)

	ASTPP (n=23)	TAU (n=23)	P value
	N (%)	N (%)	χ^2 (df=1)
Demographic characteristics			
Married	18 (78.3)	18 (78.3)	1.00
Employed	13 (56.5)	10 (43.5)	.78
Education			
Secondary school	21 (91.3)	20 (87.0)	.64
A-level	2 (8.7)	3 (13)	.22
	Mean (S.D.)	Mean (S.D.)	t (44)
Age (years; M, S.D.)	48.70 (7.11)	48.83 (8.64)	.956
Illness duration (years)	8.41 (8.37)	7.83 (7.52)	.804

diagnosis of double depression. In both groups, 17% (n=4) had an anxiety disorder. Pearson's χ^2 tests yielded no significant differences. The average duration of illness amounted to 8.4 years (S.D. 8.37) in the intervention group and to 7.8 years (S.D. 7.5) in the control group, indicating that both groups included a substantial number of patients with chronic intractable symptoms.

3.2. Clinical outcomes

Table 2 shows the primary and secondary outcomes for the two conditions at the three assessment points. In terms of the primary outcome – the FIQ – both groups improved from baseline to t3 effect sizes amounting to 0.56 for the ASTPP group and to 0.75 for the control group. However, no significant differences between groups were

Table 2
Outcome measure scores at baseline, end of therapy and 12-month follow-up

	ASTPP	Effect size	TAU	Effect size	Group difference	P ^c
	Mean (S.D.)	Cohen's d ^a	Mean (S.D.)	Cohen's d ^a	Mean (95% CI) ^b	
Primary outcome						
FIQ total score						
Baseline	50.1 (2.5)	.56	54.2 (2.5)	.75	−4.1 (−11.33 to 3.16)	.262
End of therapy	46.7 (2.8)		50.9 (2.8)		−4.1 (−12.01 to 3.76)	.298
Follow-up	42.7 (3.5)		45.3 (3.5)		−2.5 (−12.57 to 7.60)	.622
Secondary outcome						
HADS depression						
Baseline	9.6 (0.9)	.14	9.3 (0.9)	−.10	.30 (−2.14 to 2.75)	.803
End of therapy	8.7 (0.9)		9.2 (0.9)		−.51 (−2.97 to 1.96)	.682
Follow-up	9.0 (1.0)		9.7 (1.0)		−.75 (−3.57 to 2.07)	.992
HADS anxiety						
Baseline	8.3 (0.9)	.16	8.4 (0.9)	.08	−.13 (−2.55 to 2.29)	.914
End of therapy	8.8 (0.8)		8.8 (0.8)		−.03 (−2.27 to 2.21)	.981
Follow-up	7.6 (0.8)		8.1 (0.8)		−.45 (−2.84 to 1.94)	.705
PDI total score						
Baseline	41.6 (2.6)	.52	40.3 (2.6)	.33	1.3 (−5.99 to 8.60)	.720
End of therapy	35.0 (3.2)		38.7 (3.2)		−3.7 (−12.81 to 5.42)	.418
Follow-up	34.5 (3.5)		36.5 (3.5)		−2.0 (−12.08 to 7.99)	.683
SCL-27 GSI						
Baseline	1.11 (0.14)	.28	1.11 (0.14)	.16	.01 (−.38 to .40)	.974
End of therapy	1.01 (0.14)		1.05 (0.14)		−.04 (−.44 to .36)	.848
Follow-up	.92 (0.15)		.97 (0.15)		−.05 (−.47 to .37)	.804
SF-36 physical health						
Baseline	28.9 (1.5)	.47	30.7 (1.5)	.24	−1.8 (−6.03 to 2.40)	.391
End of therapy	39.1 (2.0)		34.7 (2.0)		4.4 (−1.36 to 10.18)	.131
Follow-up	31.8 (1.9)		32.9 (1.9)		−1.2 (−6.44 to 4.12)	.661
SF-36 mental health						
Baseline	39.3 (2.2)	.42	37.6 (2.2)	.51	1.7 (−4.57 to 7.88)	.596
End of therapy	32.6 (2.0)		32.3 (2.0)		.31 (−5.35 to 5.97)	.913
Follow-up	43.5 (2.3)		39.4 (2.3)		4.1 (−2.37 to 10.58)	.209
SOMS complaints						
Baseline	22.7 (2.1)	.63	23.9 (2.1)	.30	−1.2 (−7.19 to 4.85)	.696
End of therapy	20.1 (2.1)		23.1 (2.1)		−3.0 (−9.07 to 3.04)	.322
Follow-up	17.5 (2.2)		22.0 (2.2)		−4.6 (−10.95 to 1.84)	.158

^a Within-group effect sizes from baseline to 12-month follow-up.

^b Confidence interval of the mean difference between groups (ASTPP minus active control group) at each assessment.

^c Mixed linear models, between-group effects for therapy controlling for age and education.

observed. The same applied to outcome measures of depression (HADS depression), anxiety (HADS anxiety), pain-related disability (PDI total score), psychological distress symptom check list-27, general symptom score (SCL-27, GSI) and health-related quality of life (SF-36) and to somatoform symptoms. Within-group effects sizes for these measures ranged between 0.08 (HADS anxiety, active control group) and 0.63 (SOMS, ASTPP). Also, on the secondary outcome measures, the statistical analyses did not show any significant differences between the intervention and control group.

Outcome measures for time, group, and interaction of time and group are shown in Table 3 based on the mixed-model analysis controlling for age and education. Significant changes were observed across time. However, no significant differences emerged with regard to group or group \times time interaction.

3.3. Clinically significant change

Bennett et al. [30] empirically determined a 14% change in the FIQ total score as an MCID. In our sample, 9 patients of the intervention group and 11 patients of the control group showed at least a 14% improvement between baseline and 12-month follow-up. There were no group differences in improvement or impairment rates between the two treatment arms. Improvement rates were 48% for TAU and 39% for the ASTPP intervention, respectively.

3.4. Concurrent treatments

Concurrent treatments were not considered as outcome measures and were calculated based on the completer sample (Table 4).

Table 3

Outcome measure scores for time, group and interaction of time and group mixed linear models (MLM) controlling for age and education

	Significance <i>P</i>		
	Time	Group	Interaction time*group
FIQ total score	.000	.359	.862
HADS depression	.554	.786	.608
HADS anxiety	.034	.851	.805
PDI total score	.004	.712	.211
SCL-27 GSI	.057	.881	.900
SF-36 physical health	.000	.786	.263
SF-36 mental health	.000	.382	.535
SOMS complaints	.007	.292	.295

We compared the use of concurrent treatments with simple dichotomous variables (yes/no) at baseline and at 12-month follow-up for analgesics, antidepressants and aerobic exercise calculating Pearson's χ^2 . There were no significant differences between the two groups for analgesic and antidepressive medication at baseline and at 12-month follow-up. Aerobic exercise did not differ significantly between groups at baseline, but did differ at 12-month follow-up ($\chi^2 = 8.19$, $df = 1$, $P = .004$). At 12-month follow-up, 63% of patients in the control group were using aerobic exercise as compared to 100% in the intervention group.

4. Discussion

4.1. Summary of the results

This study examined the outcome of an adapted form of individual psychodynamic psychotherapy in female patients with primary FMS and comorbid depression. To our best knowledge, it is the first study investigating the efficacy of individual psychodynamic psychotherapy in fibromyalgia in a randomized controlled trial.

The main finding of the study was that no significant between-group differences of the intervention could be observed either on the primary outcome measure (FIQ) or on any of the secondary outcome measures. The hypothesis of a higher efficacy of the adapted form of psychodynamic psychotherapy as compared to a high-standard routine care in patients with primary FMS and a concurrent affective disorder therefore was not substantiated.

The results of the study showed an improvement between baseline and 12-month follow-up for both groups on various measures. For the primary outcome measure (FIQ), the within-group effect size reached 0.56 in the intervention group and 0.75 in the control group. On some of the secondary outcome measures, the within-group effect sizes were also in the medium range. However, the surprising finding was that the control group, which received an enhanced routine care

Table 4

Concurrent treatments at baseline, end of therapy and 12-month follow-up (completer sample)

	TAU	ASTPP	Comparison χ^2	<i>P</i>
Concurrent antidepressant medication, <i>n</i> (%)				
Baseline	14 (61); <i>n</i> =23	11 (52); <i>n</i> =21	0.32	.570
End of therapy	14 (70); <i>n</i> =20	7 (44); <i>n</i> =16	2.52	.112
Follow-up	11 (69); <i>n</i> =16	8 (44); <i>n</i> =18	2.03	.154
Concurrent analgesic medication, <i>n</i> (%)				
Baseline	21 (91); <i>n</i> =23	16 (76); <i>n</i> =21	1.87	.171
End of therapy	15 (75); <i>n</i> =20	12 (75); <i>n</i> =16	0.00	1.00
Follow-up	12 (75); <i>n</i> =16	12 (67); <i>n</i> =18	0.28	.595
Concurrent aerobic exercise, <i>n</i> (%)				
Baseline	16 (70); <i>n</i> =23	19 (90); <i>n</i> =21	2.95	.086
End of therapy	13 (68); <i>n</i> =19	17 (100); <i>n</i> =17	6.44	.011
Follow-up	10 (63); <i>n</i> =16	18 (100); <i>n</i> =18	8.196	.004

according to a standardized protocol comprising regular appointments with a clinically experienced rheumatologist, performed unexpectedly well, leading to an absence of statistical differences between the outcomes of the two comparison groups.

4.2. Comparison with previous findings

In a recently published study on the efficacy of brief psychodynamic interpersonal psychotherapy in patients with multisomatoform disorder [44] mainly with pain as the leading symptom, the authors reported a significant improvement of the physical quality of life at follow-up 9 months posttreatment. This study also applied individual psychodynamic psychotherapy as experimental condition. The between-group effect size for the primary outcome measure amounted to 0.42. In this study, the enhanced medical care also turned out to be relatively effective, but only during the treatment phase, whereas the results fell back during the follow-up period.

Psychiatric comorbidity in other studies has often been considered as an exclusion criterion [9]. The fact that, in our own study, a concurrent affective disorder was explicitly defined as an inclusion criterion may have led to a sample with more complex morbidity. Studies evaluating the outcome of psychological interventions [8] usually applied a group setting with an average dose of about 27 sessions [9]. This equates roughly to the dose provided in the ASTPP intervention arm in our study. Based on the within-group comparisons in our study, both interventions, ASTPP and TAU, improved fibromyalgia-related symptoms of pain, sleep disorder and fatigue. In the psychodynamic treatment arm, in addition, pain-related disability, psychological distress and somatoform symptoms improved, whereas none of the two interventions decreased depressive symptoms (HADS).

The evaluation of outcome in the study presented was confounded by the effects of concurrent treatments, e.g., medication and aerobic exercise. The efficacy of both forms of treatment is well established. The problem of concurrent treatment has been handled differently in FMS outcome research. Often these treatments were not reported [9]. Some studies did allow explicitly for a flexible medication (e.g., [45]). Since the efficacy of antidepressant treatment and aerobic exercise is empirically well substantiated [6,7], it is difficult to exclude these therapeutic options, although they may interfere with the assessment of psychotherapeutic outcome. Randomization in our study was not stratified with regard to medication, but there were no significant differences in analgesic and antidepressant medication between the two groups at baseline.

Studies evaluating the efficacy of psychological interventions in FMS were often performed in a group setting. All studies, which demonstrated the effectiveness of CBT in fibromyalgia, for example, were carried out with CBT as a group therapy. Advantages of group psychotherapy are due to the participants' experience of mutual reassurance and cohesiveness. In psychotherapeutic intervention studies using a group setting, treatment effects that are attributed to the therapeutic method might be confounded by the setting. Outcome research on psychotherapeutic interventions in fibromyalgia therefore should consider more systematically the setting as a psychotherapeutic factor. It might turn out that a group setting is providing a better therapeutic milieu for patients to experience mutual acceptance and support leading to better treatment results. Future studies on psychodynamic psychotherapy should address the efficacy for FMS in a group setting.

4.3. Strengths and limitations

Strengths of the study include the controlled trial; the focus on a defined subgroup of fibromyalgia patients, for which psychological interventions are of particular interest; the monitoring of concurrent

treatments; and a 12-month follow-up period allowing to evaluate long-term effects of the intervention.

The small sample can be considered as a limitation. The sample size was determined to detect a medium to large effect size of 0.75 with a power of $1 - \beta = .80$ ($\alpha = .05$). Smaller effect sizes thus might remain unobserved. The differences between the two comparison groups in our study were relatively small, so it is doubtful whether they could be expected to become significant with a greater sample size. It can be hypothesized however that the design of an add-on treatment concept using antidepressant and analgesic medication and aerobic exercise as a basis in both treatment arms has contributed to the positive results in both groups masking potential effects of the psychotherapeutic intervention. The concurrent treatment might also offer an explanation why the intervention in the control condition was equally effective even though the dose of the therapeutic contact was considerably lower.

The generalizability of the results may be limited due to selection biases. The patient recruitment was difficult for several reasons. The diagnosis of a comorbid affective or anxiety disorder as an inclusion criterion leads to a considerable loss of eligible patients. Furthermore, some patients declined to be randomized to the two relatively different treatment options. As observed often in psychotherapy research, randomization especially to psychotherapeutic interventions which require substantial motivation and introspection is difficult. The process of randomization excludes all those who definitively wish to undergo psychotherapy as well as those to whom the opposite applies.

Another limitation of the study is that the evaluators were not blinded to the kind of therapy the patients received. Outcome measures however were all self-report questionnaires. The adherence to the treatment manual was assured by supervision and checked by an adherence scale, but no systematic analysis of the adherence based on audiotaped protocols of the respective sessions was performed.

In sum, the study failed to provide evidence suggesting a marked superiority of individual psychodynamic psychotherapy as compared to a qualitatively high-standard primary care treatment of FMS. Both treatment conditions were associated with an improvement of fibromyalgia-related symptoms but without differences between the two groups.

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