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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.

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 (α=.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 (α=.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.