

English Version of "Multimodale Therapie des Fibromyalgiesyndroms. Systematische Übersicht, Metaanalyse und Leitlinie".  
DOI 10.1007/s00482-012-1173-1  
© Deutsche Schmerzgesellschaft e.V.  
Published by Springer-Verlag -  
all rights reserved 2012

**B. Arnold<sup>1</sup> · W. Häuser<sup>2</sup> · M. Arnold<sup>3</sup> · M. Bernateck<sup>4</sup> · K. Bernardy<sup>5</sup> · W. Brückle<sup>6</sup> · E. Friedel<sup>7</sup> · H.J. Hesselshwerdt<sup>8</sup> · W. Jäckel<sup>9</sup> · V. Köllner<sup>10</sup> · E. Kühn<sup>11</sup> · F. Petzke<sup>12</sup> · M. Settan<sup>13</sup> · M. Weigl<sup>14</sup> · E. Winter<sup>15</sup> · M. Offenbacher<sup>16</sup>**

<sup>1</sup> Abteilung Schmerztherapie, Klinikum Dachau

<sup>2</sup> Innere Medizin 1, Klinikum Saarbrücken

<sup>3</sup> Helmholtz Zentrum München, Deutsches Forschungszentrum für Gesundheit und Umwelt (GmbH), München

<sup>4</sup> Interdisziplinäre Schmerzambulanz, Medizinische Hochschule Hannover

<sup>5</sup> Klinik Der Fürstenhof Bad Pyrmont

<sup>6</sup> Abteilung für Schmerztherapie, Berufsgenossenschaftliche Universitätsklinik Bergmannsheil GmbH, Ruhr Universität Bochum

<sup>7</sup> Klinik Bad Kissingen

<sup>8</sup> Abteilung Orthopädie und Rheumatologie, Theresienklinik, Bad Krozingen

<sup>9</sup> Abteilung Qualitätsmanagement und Sozialmedizin, Universität Freiburg

<sup>10</sup> Fachklinik für Psychosomatische Medizin, Bliestal Kliniken, Blieskastel

<sup>11</sup> Deutsche Rheuma-Liga, Ellwangen

<sup>12</sup> Schmerz-Tagesklinik und –Ambulanz, Universitätsmedizin Göttingen, Georg-August Universität Göttingen

<sup>13</sup> Deutsche Fibromyalgie Vereinigung, Seckach

<sup>14</sup> Klinik für Physikalische Medizin und Rehabilitation, Klinikum Großhadern, München

<sup>15</sup> Klinik für Anästhesiologie, Klinik Havelhöhe, Berlin

<sup>16</sup> Humanwissenschaftliches Zentrum, Ludwig-Maximilians-Universität München

# Multicomponent therapy of fibromyalgia syndrome

## Systematic review, meta-analysis and guideline

For the planned revision of the guideline, the steering group of the workgroup posed the following questions:

1. Is multicomponent therapy in FMS effective short-term and long-term?
2. What study duration is needed for a multicomponent therapy to be effective?
3. Which patients should be offered a multicomponent therapy?
4. What are the crucial components in multicomponent therapy?

### Materials and methods

Details on literature search and analysis as well as on the development process of the recommendations are listed in the article "Methodological fundamentals used in developing the guideline" in this issue.

### Results

The following conclusions are valid for adult patients. For multicomponent therapy of chronic pain in several body parts of children and adolescents, see article "Definition, diagnosis and therapy of chronic widespread pain and so-called fibromyalgia syndrome in children and adolescents". Key recommendations are italicized.

### Multicomponent therapy

**Evidence-based recommendation**  
**Multicomponent therapy should be applied. EL1a, strong recommendation, strong consensus**

### Duration of multicomponent therapy

**Evidence-based recommendation**  
**Duration of therapy should be at least 24 h. EL1a, strong recommendation, strong consensus**

**Comment to the two recommendations above.** In the German Operation and Procedure Code ("Operationen- und Prozedurenschlüssel", OPS), multicomponent therapy is applicable in the context of a multicomponent complex treatment such as inpatient/outpatient multicomponent pain therapy (OPS items 8-91c and 8-918.x, respectively) or an inpatient psychosomatic-psychotherapeutic clinical treatment (OPS items 9-60.x to 9-64.x).

According to OPS item 8-918.x, a multicomponent pain therapy requires inter-

disciplinary diagnostics by at least 2 distinct disciplines (obligatory one psychiatric, psychosomatic or psychological discipline) and is defined by the simultaneous application of at least 3 of the following therapies under medical administration: psychotherapy, special psychotherapy, relaxation techniques, ergotherapy, medical training therapy, sensomotoric training, employment training, art or music therapy or other practicing therapies. Furthermore, multicomponent pain therapy involves monitoring of the treatment progress via a standardized therapeutic assessment through interdisciplinary team meetings [7]. In the literature, “multidisciplinary approaches” in FMS are defined as the combination of at least one activating procedure (endurance, strength or flexibility training) with at least one psychotherapeutic procedure (patient education and/or cognitive behavioral therapy) [4]. Accordingly, studies combining at least one activating with at least one psychotherapeutic procedure were classified as “multicomponent studies” and therefore included into the analysis. Literature search obtained 760 such studies. One study was excluded as the clinical endpoints did not meet the criteria for inclusion [21]. A second study was excluded because multicomponent therapy was combined with amitriptyline treatment [22]. The outcomes of one study were published twice [17, 18]. All studies that were included in the analysis met the criteria of a multidisciplinary therapy. Whether these studies meet the criteria of a multicomponent therapy (monitoring of the treatment progress via a standardized therapeutic assessment through interdisciplinary team meetings) could not be investigated based on the published study descriptions.

Seventeen studies with 18 study arms, 1,572 patients and an average study duration of 11 weeks (3–26 weeks) were analyzed [2, 3, 4, 6, 8, 9, 10, 12, 13, 14, 15, 16, 18, 19, 21, 23, 24]. In 8 studies, follow-ups after an average of 8 months (range 4–24 months) were conducted (Evidence Report Tab. 35).

The quality of evidence was moderate (high quality of methods, moderate external validity) (Evidence Report, Tab. 36).

Multicomponent therapy was highly effective. The standardized mean differences (SMDs) of multicomponent therapy vs. controls at the end of therapy were low for pain and fatigue and moderate for quality of life. The SMDs for multicomponent therapy vs. controls at follow-up were low for fatigue and quality of life (Evidence Report, Tab. 37 and Fig. 11). Subgroup analysis showed that significant effects on pain, fatigue and quality of life were obtained only at a study duration of 24 h or more (the maximum within the included studies was 64 h) [10]. The acceptance was moderate [dropout rate 107/712 (12%)] and was not significantly different compared to controls (Evidence Report Fig. 11). Side effects were not systematically determined (or reported, respectively). According to clinical experience, multicomponent therapy has no significant side effects.

As in the majority of the analyzed studies patients with comorbid depression or anxiety disorder were excluded, multicomponent therapy in more severe cases is not sufficiently represented. For treatment in cases of more severe disease progression, more intensive multicomponent programs are recommended (see recommendation in the article “Fibromyalgia syndrome: general principles of and coordination of clinical care and patient education”).

## Discussion

Quantitative data analysis confirmed the outcome of the first version of this guideline [1] where multicomponent therapy (MT) was strongly recommended.

The following recommendations should be considered to avoid methodological constraints in future studies of MT in FMS:

1. medication and concomitant treatment should be documented along the study progress and should be taken account of as covariates,
2. comorbidity of mental conditions, psychosocial stress and coping with stress should be determined at the beginning, the end, and at follow-up of therapy and should also be included as covariates,

3. predefined dichotomous parameters of the outcome (return to employment, number of patients with defined reduction of pain etc.) allow for the determination of prognostic parameters to MT,
4. identification of predictors of positive as well as negative outcomes of therapy,
5. randomized comparative clinical trials to identify the crucial components in MT,
6. randomized comparative clinical trials on the efficiency of MT dependent on therapy intensity including the documentation of long-term effects, and
7. randomized comparative clinical trials to identify the needed duration of therapy in a multicomponent program dependent on the severity of disease.

## Conclusion for clinical practice

**The review of more recent literature confirmed the strong recommendation of multicomponent therapy as given in the first version of this guideline. In the analyzed studies, multicomponent therapy was defined as a combination of one somatically activating therapy with one psychological procedure and was implemented in an outpatient setting. The studies included in the analysis did not meet the high quality standards of an inpatient/outpatient multicomponent therapy as specified in the German OPS. There are no studies at hand which could validate the recommendation of a scaling of the intensity of treatment based on case severity. Therefore, the recommendation of the application of more intensive multicomponent programs in cases of more severe disease progressions relies on clinical consensus.**

## Corresponding address

**Dr. B. Arnold**  
Abteilung Schmerztherapie, Klinikum Dachau  
Krankenhausstr. 15, 85221 Dachau  
Germany  
bernhard.arnold@amperkliniken.de

**Conflict of interest.** See Tab. 5 in “Methodological

fundamentals used in developing the guideline" by W. Häuser, K. Bernardy, H. Wang, and I. Kopp in this issue.

## References

- Arnold B, Häuser W, Bernardy K et al (2008) Multimodale Therapie des Fibromyalgiesyndroms. *Schmerz* 22:334–338
- Brockow T, Wagner A, Franke A et al (2007) A randomized controlled trial on the effectiveness of mild water-filtered near infrared whole-body hyperthermia as an adjunct to a standard multimodal rehabilitation in the treatment of fibromyalgia. *Clin J Pain* 23:67–75
- Buckelew SP, Conway R, Parker J et al (1998) Biofeedback/relaxation training and exercise interventions for fibromyalgia: a prospective trial. *Arthritis Care Res* 11:196–209
- Burckhardt CS, Mannerkorpi K, Hedenberg L, Bjelle A (1994) A randomized, controlled clinical trial of education and physical training for women with fibromyalgia. *J Rheumatol* 21:714–720
- Burckhardt CS (2006) Multidisciplinary approaches for management of fibromyalgia. *Curr Pharm Des* 12:59–66
- Cedraschi C, Desmeules J, Rapiti E et al (2004) Fibromyalgia: a randomised, controlled trial of a treatment programme based on self management. *Ann Rheum Dis* 63:290–296
- Deutsches Institut für Medizinische Information und Dokumentation. Operationen- und Prozedurenschlüssel (OPS) Version 2011 <http://www.dim-di.de/static/de/klassi/prozeduren/ops301/opshtml2011/index.htm>. Accessed 26 April 2012
- Fontaine KR, Conn L, Clauw DJ (2010) Effects of lifestyle physical activity on perceived symptoms and physical function in adults with fibromyalgia: results of a randomized trial. *Arthritis Res Ther* 12: R55
- Gowans SE, deHueck A, Voss S, Richardson M (1999) A randomized, controlled trial of exercise and education for individuals with fibromyalgia. *Arthritis Care Res* 12:120–128
- Hammond A, Freeman K (2006) Community patient education and exercise for people with fibromyalgia: a parallel group randomized controlled trial. *Clin Rehabil* 20:835–846
- Häuser W, Bernardy K, Arnold B et al (2009) Efficacy of multicomponent treatment in fibromyalgia syndrome: a meta-analysis of randomized controlled clinical trials. *Arthritis Rheum* 61:216–224
- Keel PJ, Bodoky C, Gerhard U, Müller W (1998) Comparison of integrated group therapy and group relaxation training for fibromyalgia. *Clin J Pain* 14:232–238
- King SJ, Wessel J, Bhambhani Y et al (2002) The effects of exercise and education, individually or combined, in women with fibromyalgia. *J Rheumatol* 29:2620–2627
- Lemstra M, Olszynski WP (2005) The effectiveness of multidisciplinary rehabilitation in the treatment of fibromyalgia: a randomized controlled trial. *Clin J Pain* 21:166–174
- Lera S, Gelman SM, López MJ et al (2009) Multidisciplinary treatment of fibromyalgia: does cognitive behavior therapy increase the response to treatment? *J Psychosom Res* 67:433–441
- Mannerkorpi K, Nyberg B, Ahlmen M, Ekdahl C (2000) Pool exercise combined with an education program for patients with fibromyalgia syndrome. A prospective, randomized study. *J Rheumatol* 27:2473–2481

Schmerz 2012 · DOI 10.1007/s00482-012-1173-1

© Deutsche Schmerzgesellschaft e.V. Published by Springer-Verlag - all rights reserved 2012

B. Arnold · W. Häuser · M. Arnold · M. Bernateck · K. Bernardy · W. Brückle · E. Friedel · H.J. Hesselshwerdt · W. Jäckel · V. Köllner · E. Kühn · F. Petzke · M. Settan · M. Weigl · E. Winter · M. Offenbächer

## Multicomponent therapy of fibromyalgia syndrome. Systematic review, meta-analysis and guideline

### Abstract

**Background.** The scheduled update to the German S3 guidelines on fibromyalgia syndrome (FMS) by the Association of the Scientific Medical Societies ("Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften", AWMF; registration number 041/004) was planned starting in March 2011.

**Materials and methods.** The development of the guidelines was coordinated by the German Interdisciplinary Association for Pain Therapy ("Deutsche Interdisziplinäre Vereinigung für Schmerztherapie", DIVS), 9 scientific medical societies and 2 patient self-help organizations. Eight working groups with a total of 50 members were evenly balanced in terms of gender, medical field, potential conflicts of interest and hierarchical position in the medical and scientific fields. Literature searches were performed using the Medline, PsycInfo, Scopus and Cochrane Library databases (until December 2010). The grading

of the strength of the evidence followed the scheme of the Oxford Centre for Evidence-Based Medicine. The formulation and grading of recommendations was accomplished using a multi-step, formal consensus process. The guidelines were reviewed by the boards of the participating scientific medical societies.

**Results and conclusion.** The use of multicomponent therapy (the combination of aerobic exercise with at least one psychological therapy) for a minimum of 24 h is strongly recommended for patients with severe FMS. The English full-text version of this article is available at SpringerLink (under "Supplemental").

### Keywords

Fibromyalgia syndrome · Review, systematic · Meta-analysis · Guideline · Multimodal therapy

## Multimodale Therapie des Fibromyalgiesyndroms. Systematische Übersicht, Metaanalyse und Leitlinie

### Zusammenfassung

**Hintergrund.** Die planmäßige Aktualisierung der S3-Leitlinie zum Fibromyalgiesyndrom (FMS; AWMF-Registernummer 041/004) wurde ab März 2011 vorgenommen.

**Material und Methoden.** Die Leitlinie wurde unter Koordination der Deutschen Interdisziplinären Vereinigung für Schmerztherapie DIVS von 9 wissenschaftlichen Fachgesellschaften und 2 Patientenselbsthilfeorganisationen entwickelt. Acht Arbeitsgruppen mit insgesamt 50 Mitgliedern wurden ausgewogen in Bezug auf Geschlecht, medizinischen Versorgungsbereich, potentielle Interessenkonflikte und hierarchische Position im medizinischen bzw. wissenschaftlichen System besetzt. Die Literaturrecherche erfolgte über die Datenbanken Medline, PsycInfo, Scopus und Cochrane Library (bis Dezember 2010). Die Graduierung der Evidenzstärke er-

folgte nach dem Schema des Oxford Center for Evidence Based Medicine. Die Formulierung und Graduierung der Empfehlungen erfolgte in einem mehrstufigen, formalisierten Konsensusverfahren. Die Leitlinie wurde von den Vorständen der beteiligten Fachgesellschaften begutachtet.

**Ergebnisse und Schlussfolgerung.** Der Einsatz von multimodaler Therapie (Kombination von aerobem Training mit mindestens einem psychologischen Verfahren) mit mindestens 24 h Therapiedauer wird für Patienten mit schwereren Verläufen des FMS stark empfohlen.

### Schlüsselwörter

Fibromyalgiesyndrom · Systematische Übersicht · Metaanalyse · Leitlinie · Multimodale Therapie

- Mannerkorpi K, Ahlmen M, Ekdahl C (2002) Six- and 24-month follow-up of pool exercise therapy and education for patients with fibromyalgia. *Scand J Rheumatol* 31:306–310

- Mannerkorpi K, Nordeman L, Ericsson A et al (2009) Pool exercise for patients with fibromyalgia or chronic widespread pain: a randomized controlled trial and subgroup analyses. *J Rehabil Med* 41:751–760

19. Rooks DS, Gautam S, Romeling M et al (2007) Group exercise, education, and combination self-management in women with fibromyalgia: a randomized trial. *Arch Intern Med* 167:2192–2200
20. Skouen JS, Grasdal A, Haldorsen EM (2006) Return to work after comparing outpatient multidisciplinary treatment programs versus treatment in general practice for patients with chronic widespread pain. *Eur J Pain* 10:145–152 (excluded: target variables not suitable for analysis)
21. Souza JB, Bourgault P, Charest J, Marchand S (2008) Interactional school of fibromyalgia: learning to cope with pain – a randomised controlled study. *Rev Bras Reumatol* 48:281–225
22. Targino RA, Imamura M, Kaziyama HH et al (2008) A randomized controlled trial of acupuncture added to usual treatment for fibromyalgia. *J Rehabil Med* 40:582–588 (excluded: combination with defined medication)
23. Koullil S van, Lankveld W van, Kraaimaat FW et al (2010) Tailored cognitive-behavioral therapy and exercise training for high-risk patients with fibromyalgia. *Arthritis Care Res (Hoboken)* 62:1377–1385
24. Zijlstra TR, Laar MA van de, Bernelot Moens HJ et al (2005) Spa treatment for primary fibromyalgia syndrome: a combination of thalassotherapy, exercise and patient education improves symptoms and quality of life. *Rheumatology (Oxford)* 44:539–546