Treatment methods for rehabilitation of fibromyalgia

A systematic review

SBU ASSESSMENTS | ASSESSMENT OF METHODS IN HEALTH CARE AND SOCIAL SERVICES

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Executive summary

Background

Fibromyalgia is characterized by widespread musculoskeletal pain. In addition, people with fibromyalgia often experience sleep problems and fatigue. Comorbidity with depression and anxiety is common. There is no cure for fibromyalgia, rather the goal of treatment is to improve health and to restore function and quality of life.

Aim

The aim of the review is to present the current evidence for long-term effects on health of treatments used for rehabilitation of people with fibromyalgia, measured as quality of life, physical, psychological and social function, and pain.

The review did not include multimodal or multidisciplinary forms of rehabilitation which are instead covered in www.sbu.se/341e.

Method

A systematic review was conducted in accordance with the PRISMA statement. The protocol is registered in Prospero. The certainty of evidence was assessed with GRADE.

Inclusion criteria

The review was limited to treatments of relevance for Swedish healthcare and to treatments used for long-term improvement of fibromyalgia. Studies had to fulfil the following criteria for inclusion in the review:

- *Population* – adults (≥18 years) diagnosed with fibromyalgia.
- *Intervention* – treatments aimed at improving fibromyalgia or consequences of the condition.
- *Control* – other relevant treatments, no treatment, or treatment as usual.

Conclusions

- Few high-quality studies of treatments for fibromyalgia study long-term effects on health. We identified some studies of psychological therapies, psycho-educative interventions, interventions that promote physical activity and acupuncture. However, the studies identified were too few and too small to allow us to reliably judge the health effects of the interventions.
- Results for two pharmacological substances, *Duloxetine* and *Pregabalin* show that, when measured three months after initiated treatment, patients assess themselves as improved (low certainty of evidence); that *Duloxetine* can reduce pain interference and depressive symptoms (low certainty of evidence); and that *Pregabalin* can reduce symptoms of fibromyalgia and pain intensity, and improve sleep quality (low certainty of evidence).

Comment

Participants in the included studies may differ somewhat from fibromyalgia patients in the clinic today. A majority of the studies established a diagnosis of fibromyalgia using the 1990 criteria from American College of Rheumatology (ACR-1990). The criteria have been revised since and differences between the earlier and later versions of the ACR-criteria affect who gets diagnosed. Moreover, in the clinic patients often have comorbid conditions in addition to fibromyalgia.

The differences between fibromyalgia patients diagnosed with fibromyalgia before and after the criteria changed, as well as the presence of comorbid conditions, may affect both the need for, and the effects of treatments. Investigations of treatment effects in such subgroups of fibromyalgia patients are needed.

- *Outcomes* – effects on health: pain, quality of life, and mental, physical or social function.

- *Study design* – prospective and controlled clinical trials, with or without randomised allocation.

- *Length of follow-up* – at least 3 months after initiated treatment. In addition, temporary interventions, i.e. all treatments except continuous pharmacological therapies, must report a follow-up directly after termination of treatment

- *Language* – English, Swedish, Danish or Norwegian

Exclusion criteria

We chose not to include:

- Studies that allowed participants with other primary conditions, apart from fibromyalgia

- Studies with fewer than 20 participants per comparison group

Search period: From 2000 to 2021. Final search February, 2021.

Databases searched: Cochrane (Wiley), Embase (Elsevier), Medline (OvidSP), PsycINFO (Ebsco), Scopus (Elsevier) and CINAHL (Ebsco)

Risk of bias: All relevant studies were assessed for risk of bias. Studies with results assessed as of low or moderate risk of bias were included in analyses. Studies with results assessed as of high risk of bias were not included.

Client/patient involvement: No

Results

A total of 34 studies are included in the assessments of health effects of different treatments:

- Pharmacological substances: 6 studies
- Psychological therapies: 15 studies
- Physical activity and acupuncture: 9 studies
- Psychoeducation: 4 studies

Interventions investigated in at least two studies are included in the assessments of health effects. We also identified interventions for which we only could include a single study. They were not assessed but we report them for information. Studies which investigated effects of multimodal treatments are reported in www.sbu.se/341.

Pharmacological treatments

We evaluated the effects of two different substances for long-term improvement of fibromyalgia symptoms: *duloxetine* and *pregabalin*. For both substances the assessments included three original studies (Table 1).

Table 1 Pharmacological therapies compared to placebo: effects during treatment.

Outcome		**Duloxetine 3 months after initiation of treatment**		**Pregabalin 3 months after initiation of treatment**	
Fibromyalgia symptoms	FIQ	↑*	⊕○○○**	↑*	⊕⊕○○**
Quality of Life	Mental QoL	↑	⊕⊕○○	↔	⊕○○○
	Physical QoL	↔	⊕○○○	↔	⊕○○○
	Global change	↑	⊕○○○	↑	⊕⊕○○
Body Functions					
Pain	Pain intensity	↔	⊕○○○	↑	⊕⊕○○
	Pain interference	↑	⊕⊕○○		
Psychological symptoms	Depression	↑	⊕⊕○○	↔	⊕○○○
	Anxiety	↔	⊕○○○	↑	⊕○○○
	Sleep Quality			↑	⊕⊕○○
	Fatigue	↑	⊕○○○	↔	⊕○○○
Mental and physical function	Cognitive och physical function	↔	⊕○○○		

FIQ = *Fibromyalgia Impact Questionnaire;* **QoL** = *Quality of Life*

** Results from the review: ↑ = Better effect; ↓ = Less effect; ↔ = No detectable effect (statistical test result of p >0.05 for a difference in effect between comparison groups).*

*** Evaluation of the strength of evidence of a result according to GRADE: ⊕⊕⊕⊕ = High; ⊕⊕⊕○ = Moderate; ⊕⊕○○ = Low; ⊕○○○ = Very low (meaning that the trustworthiness of the result is very low and can't be used to evaluate the true effect – even if a statistical test reached p <0.05).*

Psychological treatments

We evaluated the effects of *Cognitive Behavioral Therapy (CBT)*, *Acceptance and Commitment Therapy (ACT)* and *Mindfulness Based Stress Reduction (MBSR)*. The assessment of CBT, ACT, and MBSR included eight, two, and five studies respectively (Table 2).

Physical activity and Acupuncture

We evaluated the effects of *guided physical activity (physical activity under guidance from a physiotherapist or other therapist)* and of Acupuncture. The assessment of guided physical activity included nine studies, and the assessment of acupuncture included three studies (Table 3).

Psychoeducation

We evaluated the effects *multimodal psychoeducation* (psychoeducative interventions led by lecturers/therapists from several clinical professions). The assessment included four studies (Table 4).

Other treatments

In total, 19 studies were identified which were considered single studies of an intervention: other pharmacological treatments (*mirtazapin*, *gabapentin* and *pregabaline in combination with amitriptyline, venlafaxine or paroxetine*); psychological therapies (*CBT for insomnia* and *Emotional Written Exposure*), psychoeducative interventions, interventions for physical activity,

Table 2 Psychological therapies compared to treatment as usual or waiting list: effects after end of treatment.

Outcome		**CBT 3–6 months after end of treatment**		**ACT 3 months after end of treatment**		**MBSR 2–10 months after end of treatment**	
Fibromyalgia symptoms	FIQ	↔*	⊕○○○**	↑*	⊕○○○**	↑*	⊕○○○**
Quality of Life	Global QoL			↔	⊕○○○	↓	⊕○○○
	Mental QoL	↔	⊕○○○				
	Physical QoL	↔	⊕○○○				
Kroppsfunktioner							
Pain	Pain Intensity	↔	⊕○○○	↔	⊕○○○	↔	⊕○○○
	Pain Interference					↔	⊕○○○
Psychological symptoms	Depression	↔	⊕○○○	↑	⊕○○○	↔	⊕○○○
	Anxiety	↔	⊕○○○			↔	⊕○○○
	Stress/Distress					↑	⊕○○○
	Catastrophising	↔	⊕○○○	↔	⊕○○○	↑	⊕○○○
	Sleep problems	↑	⊕○○○	↔	⊕○○○	↔	⊕○○○
Activities and Participation							
Impairment	Physical					↔	⊕○○○
	Cognitive					↑	⊕○○○
Personal Factors							
Coping	Self efficacy	↑	⊕○○○				
	Coping with sleep	↓	⊕○○○				
	Acceptance	↑	⊕○○○	↑	⊕○○○		

FIQ = *Fibromyalgia Impact Questionnaire;* **QoL** = *Quality of Life*

** Results from the review:*
↑ = *Better effect;*
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Table 3 Guided Physical Activity compared to less active interventions for physical activity, treatment as usual or waiting list and Acupuncture compared to sham-treatment: effects after end of treatment.

Outcome		**Guided Physical Activity 3–12 months after end of treatment**		**Acupuncture 3–24 months after end of treatment**	
Fibromyalgia symptoms	FIQ	↑*	⊕○○○**	↑*	⊕○○○**
Quality of Life	Mental QoL			↔	⊕○○○
	Physical QoL			↔	⊕○○○
	Gobal change	↔	⊕○○○		
Body Functions					
Pain	Pain intensity	↔	⊕○○○	↔	⊕○○○
Psychological symptoms	Depression	↔	⊕○○○	↓	⊕○○○
	Anxiety	↔	⊕○○○		
	Stress/Distress	↔	⊕○○○		
	Sleep problems			↔	⊕○○○
	Fatigue	↔	⊕○○○	↔	⊕○○○
Activities and Participation					
Impairment	ADL	↔	⊕○○○		
Personal Factors					
Coping	Acceptance	↔	⊕○○○		

FIQ = *Fibromyalgia Impact Questionnaire;* **QoL** = *Quality of Life;* **ADL** = *Activity of Daily Life*

** Results from the review:*
↑ = *Better effect;*
↓ = *Less effect;*
↔ = *No detectable effect (statistical test result of p >0.05 for a difference in effect between comparison groups).*

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Table 4 Multimodal psychoeducation compared to treatment as usual: effects after end of treatment.

Outcome		**Psychoeducation 6–12 months after end of treatment**	
Fibromyalgia symptoms	FIQ	↑*	⊕○○○**
Body Functions			
Pain	Pain intensity	↑	⊕○○○
	Pain interference	↑	⊕○○○
Psychological symptoms	Depression	↔	⊕○○○
	Anxiety	↔	⊕○○○
	Stress/Distress	↔	⊕○○○
	Catastrophising	↑	⊕○○○
Activities and Participation			
Impairment	ADL	↑	⊕○○○

** Results from the review:*
↑ = *Better effect;*
↓ = *Less effect;*
↔ = *No detectable effect (statistical test result of p >0.05 for a difference in effect between comparison groups).*

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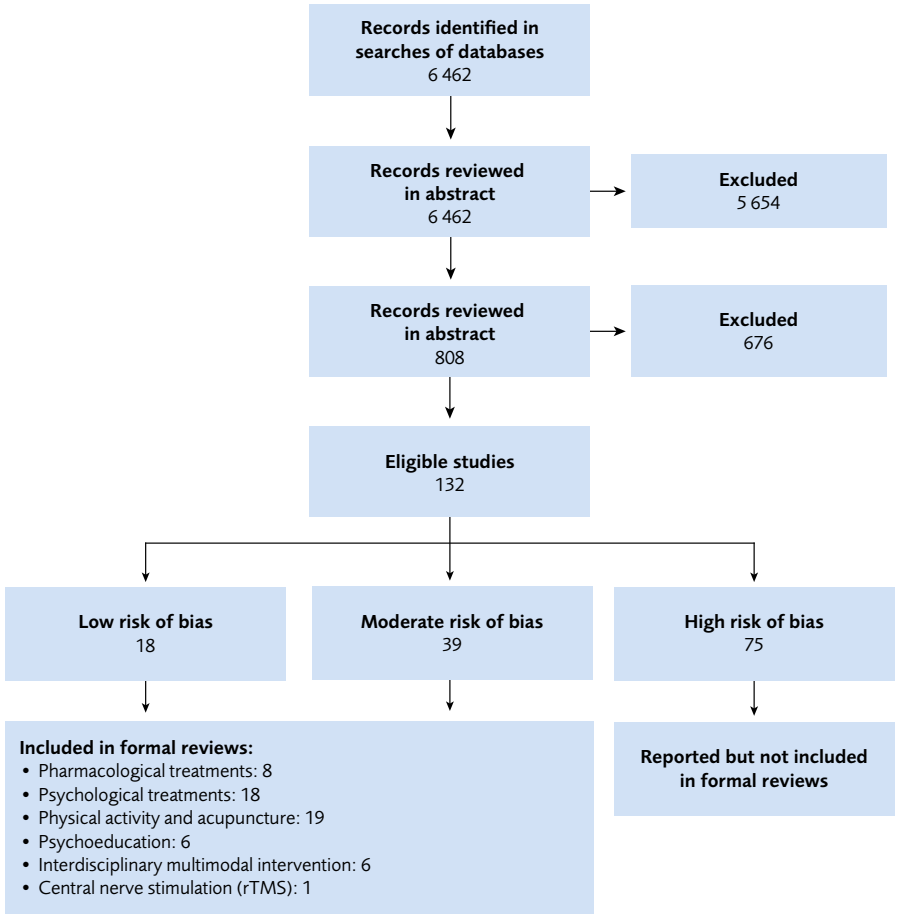

Figure 1 Flow chart.

manual therapy (*myofascial release*) and nerve stimulation of the brain (*rTMS*). The studies are listed in the report but not included in the assessments.

Conflicts of Interest

In accordance with SBU's requirements, the experts and scientific reviewers participating in this project have submitted statements about conflicts of interest. These documents are available at SBU's secretariat. SBU has determined that the conditions described in the submissions are compatible with SBU's requirements for objectivity and impartiality.

Appendices at www.sbu.se/340e

- Search strategies
- Tools for evaluation of risk of bias
- Characteristics of included studies
- Excluded articles
- Risk of bias

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