Bilaga till rapport

Behandling och rehabilitering vid fibromyalgi, rapport 340 (2021)

Bilaga 3 Beskrivning av ingående studier

Innehåll

Studier inom behandling med läkemedel

Duloxetin jämfört med placebo

Arnold 2010

Author Year Country Ref #	Arnold 2010 USA, Puerto Rico [1]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial 48 research centers in the United States and Puerto Rico Adults w fibromyalgia according to ACR-90 and ≥ 4 on item "average pain" in BPI. Patients were included if they were judged to be reliable and had a level of understanding that allowed them to communicate intelligibly and provide informed consent. 12 (placebo-controlled phase) and 24 weeks (open-label active treatment phase).
Intervention 1 Participants (n) Drop-outs (n)	Duloxetine 60 -120 mg 1 week titration to steady dose (60 mg/day). Dose escalation week 4 and 8 if <50% pain reduction on BPI (up to 120 mg/day). Dose reduction to tolerance level if needed. 263 Completed intervention: 176/263 Participants included in analysis: 249/263
Comparison Participants (n) Drop-outs (n)	Placebo 267 Completed intervention: 187/267 Participants included in analysis: 258/267
Outcomes	SF-36 Subscales: 1) Mental components 2) Physical components, Brief Pain Inventory (BPI) 1) Severity 2) Interference, Beck Depression Inventory-II (BDI-11), Beck Anxiety Inventory (BAI), Multidimensional Fatigue Inventory (MFI) 1) Total score och 2) 4 subscales, Cognitive and Physical Functioning Questionnaire (CPFQ), Patient Global Assessment (PGI-I), Clinician Global Assessment (CGI-I)
Comments	

Arnold 2012

Author Year Country Ref #	Arnold 2012 United States, Mexico, Israel, and Argentina. [2]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial 29 outpatient research centers. Women and men ≥ 18 years of age with FM (ACR-90) and had a score ≥ 4 on the average pain severity item of the Brief Pain Inventory (BPI)-Modified Short Form. 12 weeks (end of treatment period).
Intervention 1	Duloxetine Duloxetine 30 mg/d (2 capsules: 1 placebo, 1 duloxetine 30 mg), taken orally.

Participants (n) Drop-outs (n)	155 Completed post-treatment: 121/155
Comparison Participants (n) Drop-outs (n)	Placebo Placebo (2 capsules: both placebo) taken orally. 153 Completed post-treatment: 110/153
Outcomes	FIQ - total score, SF-36 Subscales: 1) Mental components 2) Physical components, Brief Pain Inventory (BPI) Subscales: 1) Severity 2) Interference, Beck Depression Inventory (BDI), Beck Depression Inventory (BDI), Patient Global Assessment (PGI-I)
Comments	Of the 308 patients randomized, 306 (153 in each treatment group) were included in the primary efficacy analysis; 2 patients in the duloxetine 30 mg/d treatment group were lost to follow-up before the postbaseline BPI average pain severity was collected.

Murakami 2015

Author Year Country Ref #	Murakami 2015 Japan [3]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial 42 outpatient clinics and hospitals in Japan Fibromyalgia (ACR-1990), age 20-75 years, BPI average pain score of at least 4 at first 2 visits. 14 weeks (1 week of titration,12 weeks treatment at target dose and 1 weeks taper phase.
Intervention 1 Participants (n) Drop-outs (n)	Duloxetine 60 mg Administered orally, once per day. 60 mg. Escalation phase 20 mg/d for 1 week, 40 mg for 1 week. 196 Completed intervention: 166/196 Participants included in analysis: 191/196
Comparison Participants (n) Drop-outs (n)	Placebo Administered orally, once per day. 197 Completed intervention: 149/197 Participants included in analysis: 195/197
Outcomes	FIQ - total score och subscales, SF-36 8 subscales, Brief Pain Inventory (BPI) 1) Severity 2) Interference and 7 subscales, Beck Depression Inventory-II (BDI-11), Patient Global Assessment (PGI-I), Clinician Global Assessment (CGI-I)
Comments	

Pregabalin jämfört med placebo

Arnold 2008

Author Year Country Ref #	Arnold 2008 USA [4]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial 84 research centers Patients were identified by physician referral or advertisement for a fibromyalgia medication trial. Patients were aged ≥18 years and had met the 1990 ACR criteria for FM. Male or female (were non pregnant and nonlactating). Had a pain score of at least 40 mm on the 100-mm pain visual analog scale (VAS) at screening (visit 1) and random assignment (visit 2). Approximately 1 week after completion of the 14-week treatment phase.
Intervention 1 Participants (n) Drop-outs (n)	Pregabalin 600 mg/d Two equal doses given orally, 600 mg/day for 12 weeks 188 Completed study: 133/188
Intervention 2 Participants (n) Drop-outs (n)	Pregabalin 450 mg/d Two equal doses given orally, 450 mg/day for 12 weeks 190 Completed study: 125/190
Intervention 2 Participants (n) Drop-outs (n)	Pregabalin 300 mg/d Two equal doses given orally, 300 mg/day for 12 weeks 183 Completed study: 123/183
Comparison Participants (n) Drop-outs (n)	Placebo Twice daily for 12 weeks 184 Completed study: 125/184
Outcomes	FIQ - total score, SF-36 Subscales: 1) Mental components 2) Physical components 3) 8 subscales, NRS – intensity, Hospital Anxiety and Depression Score (HADS), MOS - Sleep Scale, Multidimensional Assessment of Fatigue (MAF), NRS - diary (quality of sleep), Patient global assessment (PGI) PGI-improvement
Comments	Of the 750 randomly assigned subjects, 745 took at least 1 dose of study medication and comprised the ITT population. Five randomly assigned subjects withdrew before initiation of study.

Ohta 2012

Author Year Country Ref #	Ohta 2012 Japan [5]
Study design Setting Recruitment Population	Randomized controlled trial Multicenter study performed in 44 sites in Japan. Patients were aged ≥18 years and had met the 1990 ACR criteria for FM.

Inclusion criteria	Patients also had a score of ≥40 mm on the 100 mm pain visual analogue scale (VAS) at Visit 2, and had assessed and documented their pain score on at least four of the past seven days prior to Visit 2 while recording an average pain score of ≥4 on the 11-point numeric rating scale.
Follow up	15 weeks from baseline (after 12 wks fixed dose treatment phase).
Intervention 1	Pregabalin 300 – 450 mg/d Maintenance dose set to either 300 or 450 mg/day at visit 5. 2 times daily (morning & evening).
Participants (n)	251
Drop-outs (n)	Received treatment: 250/251 Completed post-treatment: 207/251
Comparison	Placebo 2 times daily (morning & evening).
Participants (n)	250
Drop-outs (n)	Received treatment: 248/250 Completed post-treatment: 208/250
Outcomes	FIQ - total score and subscales, SF-36, VAS – intensity, MOS - Sleep Scale,
Comments	

Pauer 2011

Author	Pauer
Year	2011
Country	Global study performed in all parts of the world except Africa
Ref #	[6]
Study design	Randomized controlled trial
Setting	73 a study centers across Europe, North and South America, Australia, Asia.
Recruitment	
Population	Adults (18 years or over) w fibromyalgia according to ACR-90 and w at least moderate pain (≥ 4 on the 11-point NRS) or ≥ 40 mm on 100-mm VAS.
Inclusion criteria	
Follow up	End of treatment (14 weeks after treatment started).
Intervention 1	Pregabalin 600 mg/d Administered daily in 2 divided doses
Participants (n)	186
Drop-outs (n)	Completed study: 121/186
Intervention 2	Pregabalin 450 mg/d Administered daily in 2 divided doses
Participants (n)	182
Drop-outs (n)	Completed study: 133/182
Intervention 2	Pregabalin 300 mg/d Administered daily in 2 divided doses
Participants (n)	184
Drop-outs (n)	Completed study: 123/184
Comparison	Placebo Administered daily in 2 divided doses
Participants (n)	184
Drop-outs (n)	Completed study: 141/184
Outcomes	FIQ - total score, NRS – intensity, Subscales fr MOS - Sleep Scale: "sleep disturbance", NRS - diary – sleep quality, Patient global assessment (PGI) PGI-change
Comments	

Studier inom psykologisk behandling

KBT jämfört med väntelista eller sedvanlig vård

Alda 2011

Author Year Country Ref #	Alda 2011 Spain [7]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Primary health-care centers Patients were consecutively recruited by doctors working in primary carecentres until the required sample size was attained, with-out a quota of patients assigned from each center. Adult (18 to 65 years) with fibromyalgia according to ACR-90. Able to understand and read Spanish, had undergone no psychological treatment during the pre-ceding two years, were receiving no pharmacological treatment at that time or were willing to discontinue it for two weeks before the start of the study. End of treatment (9 weeks) and 6 months after start of treatment.
Intervention 1 Participants (n) Drop-outs (n)	CBT-pain 10 sessions during a period of 10 to 12 wks. Delivered in group. 57 Completed post-treatment: 56/57 Completed 6 month follow up: 49/57
Comparison Participants (n) Drop-outs (n)	Waitlist control 55 Completed post-treatment: 53/55 Completed 6 month follow up: 46/55
Outcomes	FIQ - total score, EQ-5D VAS, VAS – intensity, Hamilton Rating Scale for depression (HAM-D) 17-item version, Pain Catastrophising Scale (PCS) Total score plus 4 subscales
Comments	ITT population included participants with baseline and data from at least one follow-up assessment. We assumed to be participants with post treatment follow-up, as follow-up data should be available for at least this fraction of participants (CBT n= 56, waitlist n=53).

Castel 2012

Author Year Country Ref #	Castel 2012 Spain [8]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Not stated Not stated FM diagnosis (ACR-90). 18 – 65 years or older. End of treatment (week 14), 3, and 6 months post treatment.
Intervention 1	Multicomponent CBT 14 sessions, 12 in group and 2 individual sessions

Participants (n) Drop-outs (n)	34 Completed post-treatment: 31/34 Completed 3 month follow up: 32/34 Completed 6 month follow up: 26/34
Comparison Participants (n) Drop-outs (n)	Waitlist control 30 Completed post-treatment: 29/30 Completed 3 month follow up: 23/30 Completed 6 month follow up: 22/30
Outcomes	FIQ - total score, NRS – intensity, Coping Strategies Questionnaire (CSQ) Subscale: Pain catastrophizing, MOS - Sleep Scale Subscales: 1) Quantity of sleep 2) Sleep problems,
Comments	

Falcão 2008

Author Year Country Ref #	Falcão 2008 Brazil [9]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Research setting (University clinic), outpatients Patients were recruited from rheumatology outpatient clinics. Adult (18-65 years) women with fibromyalgia according to ACR. Patients had not received any kind of treatment for FM. End of treatment (10 weeks) and 3 months after end of treatment.
Intervention 1 Participants (n) Drop-outs (n)	CBT-pain Routine medical visits and CBT once a week for 10 weeks, in group. 30 Completed post-treatment: 25/30 Completed 3 month follow up: 25/30
Comparison Participants (n) Drop-outs (n)	Waitlist control Routine medical visits once a week for 10 weeks 30 Completed post-treatment: 26/30 Completed 3 month follow up: 26/30
Outcomes	FIQ - total score, SF-36 8 subskalor, VAS – intensity, Beck Depression Inventory (BDI), State-Trait Anxiety Inventory (STAI) – State,
Comments	9 of 60 excluded from analysis

Karlsson 2015

Author Year Country Ref #	Karlsson 2015 Sweden [10]
Study design Setting Recruitment Population	Randomized controlled trial Primary health-care centers Participants recruited via newspaper and local FM association Adult (18 to 64 years) with fibromyalgia according to ACR-90.

Inclusion criteria	Being Swedish speaking.
Follow up	6 and 12 months after start of treatment. Wait-list control group moved to open-label active treatment after 6 months and followed up at 18 months.
Intervention 1 Participants (n) Drop-outs (n)	CBT-pain 20 weekly sessions (3 hour per session) over 5 months. Three booster sessions over the next 6 months (total duration of the intervention: 11 months). Group delivery (5-7 women). Home assignments. 24 Completed 6 month follow up: 23/24 Completed 12 month follow up: 24/24
Comparison Participants (n) Drop-outs (n)	Waitlist control 24 Completed 6 month follow up: 24/24 Completed 12 month follow up: 22/24 (6 months after start of active treatment) Completed 18 month follow up: 22/24
Outcomes	West Haven-Yale Multidimensional Pain Inventory (MPI) Subscale: Pain severity Montgomery-Åsberg Depression Rating Scale – self-reported (MADR-S)
Comments	

McCrae 2019

Author Year Country Ref #	McCrae 2019 USA [11]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Research setting (University clinic), outpatients Participants were recruited from rheumatology and sleep clinics at the University of Florida and from the surrounding area through community advertisements. FM (ACR-90) with pain for at least 6 months and chronic insomnia. 18 years or older, willing to undergo randomization. Able to read and understand English. End of treatment (8 weeks) and 6 months after start of treatment.
Intervention 1 Participants (n) Drop-outs (n)	CBT-pain 8 individual sessions 37 Received intervention: 30/37 Completed post-treatment: 30/37 Completed 6 month follow up: 27/37
Comparison Participants (n) Drop-outs (n)	Waitlist control 37 Received intervention: 37/37 Completed post-treatment: 28/37 Completed 6 month follow up: 23/37
Outcomes	VAS – intensity, Beck Depression Inventory (BDI), Dysfunctional Beliefs and Attitudes about Sleep (DBAS) Total score (VAS 1-10), Pain Disability Index (PDI) Total score,
Comments	

Vallejo 2015

Author	Vallejo
Year	2015
Country	Spain
Ref #	[12]
Study design	Randomized controlled trial
Setting	Research setting (University clinic)
Recruitment	Patients at Rheumatology unit.
Population	18 years or older with fibromyalgia according to ACR-90.,
Inclusion criteria	Adequate reading comprehension and access to and ability to use a computer.
Follow up	There were 2 assessment points for the WL group (i.e., baseline and post-treatment) and 5 for the CBT group (i.e., baseline, post-treatment and 3 follow-up assessments at 3, 6, and 12 months).
Intervention 1	CBT 10 weekly sessions (120 minutes/session). Delivered in group. Homework assignments.
Participants (n)	20
Drop-outs (n)	Completed post-treatment: 20/20 Completed follow-up at 3, 6, and 12 months: 17/20
Intervention 2	iCBT A Web application with a 10-week session structure. Individual delivery.
Participants (n)	20
Drop-outs (n)	Completed post-treatment: 20/20 Completed follow-up at 3, 6, and 12 months: 16/20
Comparison	Waitlist control
Participants (n)	20
Drop-outs (n)	Completed post-treatment: 20/20
Outcomes	FIQ - total score Beck Depression Inventory (BDI), Hospital Anxiety and Depression Score (HADS) Total score, Pain Catastrophising Scale (PCS) 4 subscales, Chronic Pain Self-efficacy Scale (CPSS or CPSE) Total score och 3 subscales, Chronic Pain Coping Inventory (CPCI) Total score
Comments	

Woolfolk 2012

Author	Woolfolk
Year	2012
Country	USA
Ref #	[13]
Study design	Randomized controlled trial
Setting	Academic medical clinic.
Recruitment	Participants were referred to the study by their treating rheumatologists.
Population	Adult (18 to 64 years) with fibromyalgia according to ACR-90.
Inclusion criteria	
Follow up	End of treatment (3 months) and 9 months after start of treatment.
Intervention 1	Affective CBT (ACBT) + Treatment as usual 10 sessions over 3 months. Individual delivery.
Participants (n)	38
Drop-outs (n)	Completed post-treatment: 34/38 Completed 9 month follow up: 32/38
Comparison	Treatment as usual Content of TAU not given.
Participants (n)	38

Drop-outs (n)	Completed post-treatment: 35/38 Completed 9 month follow up: 32/38
Outcomes	SF-36 Subscale: physical function, VAS – intensity, Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI), Chronic Pain Self-efficacy Scale (CPSS eller CPSE) Total score
Comments	

KBT jämfört med annan intervention

Lumley 2017

Author Year Country Ref #	Lumley 2017 USA [14]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Flyers sent to rheumatologists, advertisements in the community, announcements to FM patient associations, and informational workshops. FM as defined by the 1990 or 2011 criteria of the American College of Rheumatology (ACR) Post treatment (2 weeks after last session) och 6 months post treatment.
Intervention 1 Participants (n) Drop-outs (n)	Emotional Awareness and Expression Therapy Eight, 90-minute, weekly sessions. 79 Post treatment assessment: 74/79 6 months follow up: 70/79
Intervention 2 Participants (n) Drop-outs (n)	CBT Eight, 90-minute, weekly sessions. 75 Post treatment assessment: 69/75 6 months follow up: 66/75
Comparison Participants (n) Drop-outs (n)	Fibromyalgia Education Eight, 90-minute, weekly sessions. 76 Post treatment assessment: 73/76 6 months follow up: 72/76
Outcomes	FIQ-R Total score and subscales, SF-12 Subscale: Physical functioning, CES-D, The Generalized Anxiety Disorder (GAD-7) Total score, Pittsburgh Sleep Quality Index (PSQI) Total score and subscales, Patient reported outcomes measurement information system (PROMIS) Fatigue short form Multiple Ability Self-Report Questionnaire (MASQ) Total score
Comments	

ACT jämfört med väntelista eller sedvanlig vård

Luciano 2014

Author	Luciano
Year	2014
Country	Spain
Ref #	[15]
Study design	Randomized controlled trial
Setting	Primary health care centers.
Recruitment	Patients recruited from primary health care centers
Population	Adult (18-56 years) patients with fibromyalgia according to ACR 1990.
Inclusion criteria	Could speak and read Spanish fluently, with no pharmacological treatment (or agreed to discontinue use to participate in the study) and no previous psychological treatment during the previous year.
Follow up	End of treatment (3 months) and 6 months after start of treatment
Intervention 1	GACT (Group Acceptance and Commitment Therapy) Eight 2 1/2 hour long structured sessions. Delivered in group. Home exercises assigned (15 to 30 minutes/day).
Participants (n)	51
Drop-outs (n)	Completed post-treatment: 46/51 Completed 6 month follow up: 45/51
Comparison	Waitlist No active treatment
Participants (n)	53
Drop-outs (n)	Completed post-treatment: 50/53 Completed 6 month follow up: 47/53
Outcomes	FIQ Total score, EQ-5D, VAS – intensity, Hospital Anxiety and Depression Score (HADS) Subscales: 1) Depression 2) Anxiety, Pain Catastrophising Scale (PCS) Total score, The Chronic Pain Acceptance Questionnaire (CPAQ) Total score
Comments	

Simister 2018

Author	Simister
Year	2018
Country	Canada
Ref #	[16]
Study design	Randomized controlled trial
Setting	Web-based intervention
Recruitment	Recruitment via local clinics, patient organisations and advertisement.

Population	Age 18 years and older, formal diagnosis of FM, and self-reported pain intensity rating of at least 4of 10 on the basis ofa0to10rating scale (0 representing no pain).
Inclusion criteria	Participants were also screened using the diagnostic criteria according to Wolfe to ensure they met criteria for FM.
Follow up	End of treatment (2 months) and 5 months after start of treatment
Intervention 1	Online ACT-program plus Treatment as usual Distance delivery (internet-online) to be completed within 2 months. ACT consisted of 7 modules patients were encouraged to complete 1/wk. Individual delivery. Home assignments.
Participants (n)	33
Drop-outs (n)	Completed post-treatment: 27/33 Completed 6 month follow up: 25/33
Comparison	Treatment as usual Continued current treatment regime.
Participants (n)	34
Drop-outs (n)	Completed post-treatment: 31/34 Completed 6 month follow up: 25/34
Outcomes	FIQ-R Total score, McGill Pain questionnaire (MPG) Short form (SF-MPQ), CES-D Depression, Pittsburgh Sleep Quality Index (PSQI), CPAQ-R Total score
Comments	

MBSR jämfört med väntelista eller sedvanlig vård

Cejudo 2019

Author	Cejudo
Year	2019
Country	Spain
Ref #	[17]
Study design	Randomized controlled trial
Setting	Not stated
Recruitment	Volunteers from the Association of Relatives and Affected by Fibromyalgia of the province of Ciudad Real.
Population	Adult (>18 years) women with fibromyalgia (ACR).
Inclusion criteria	commit to the daily practice of mindfulness, and not be currently receiving mindfulness training
Follow up	End of treatment (20 weeks), and 6 months post-treatment.
Intervention 1	MBI (Mindfulness based intervention) 1-hour group session once per week for 20 weeks.
Participants (n)	59
Drop-outs (n)	Follow up at 20 weeks (end of treatment): 53/59 Follow up at 6 months post treatment: 52/59
Comparison	Wait list The treatment of the Control Group was focused on psychoeducation and included information on common symptoms in FM and advice on self-care.
Participants (n)	58
Drop-outs (n)	Follow up at 20 weeks (end of treatment): 51/58 Follow up at 6 months post treatment: 49/58
Outcomes	Satisfaction w life Scale (SWLS) - går att väga samman med EQ-5D
Comments	

Schmidt 2011

Author	Schmidt
Year	2011
Country	Germany
Ref #	[18]
Study design	Randomized controlled trial
Setting	University hospital.
Recruitment	Patient recruitment through patient self-help groups, media and medical practitioners at a pain clinic located within a university hospital.
Population	Women 18–70 years of age who currently had fibromyalgia (ACR).
Inclusion criteria	Command of the German language and motivation to participate.
Follow up	End of treatment (8 wks). Weeks three and seven after end of treatment.
Intervention 1	Mindfulness based stress reduction (MBSR) 8 wks duration. 7 (2.5 hr long) sessions and 1 all-day session on a weekend. Delivered in groups of 12.
Participants (n)	59
Drop-outs (n)	Received intervention: 53/59 Follow up at 3 weeks post treatment: 45/59 Follow up at 7 weeks post treatment: 47/59
Intervention 2	Active control 8 wks duration. Delivered similar to MBSR in time. Delivered in groups.
Participants (n)	59
Drop-outs (n)	Received intervention: 56/59

	Follow up at 3 weeks post treatment: 51/59 Follow up at 7 weeks post treatment: 49/59
Comparison Participants (n) Drop-outs (n)	Wait list 59 Follow up at 3 weeks post treatment: 52/59 Follow up at73 weeks post treatment: 56/59
Outcomes	FIQ - total score, Quality of Life Profile for the Chronically ill (PLC) Total score, Pain Perception Scale (PPS) Subscales (sensory and affective pain), CES-D, State Trait Anxiety Inventory (STAI) Subscale: Trait, Pittsburgh Sleep Quality Index (PSQI) Total score, Giessen Complaint Questionnaire (GCQ)
Comments	

Sephton 2007

Author Year Country Ref #	Sephton 2007 USA [19]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial University Patients recruited through notices in newspapers and TV. Adult (>18 years) women with fibromyalgia (ACR). Able to attend a group that met weekly. 8 wks (end of treatment), and 2 months post-treatment.
Intervention 1 Participants (n) Drop-outs (n)	Mindfulness-based stress reduction MBSR) 8 weekly 2.5 hour long sessions. Group delivery. Home assignments (ca 30-45 minutes/day encouraged). 51 Received intervention: 42/51 Follow up at 2 months post treatment: 41/51 Participants included in analysis: 51/51
Comparison Participants (n) Drop-outs (n)	Wait list 40 Follow up at 2 months post treatment: 27/40 Participants included in analysis: 39/40
Outcomes	Beck Depression Inventory (BDI) Total score and cognitive and somatic subscales
Comments	

Perez-Aranda 2019

Author Year Country Ref #	Perez-Aranda 2019 Spain [20]
Study design Setting Recruitment Population Inclusion criteria	Randomized controlled trial Rheumatology Clinic Recruitment from a rheumatology clinic. Patients 18–65 years of age who currently have fibromyalgia (ACR). Able to understand Spanish language and provided informed consent to participate.

Follow up	2 months (end of treatment) and 12 months (10 months after end of treatment)
Intervention 1 Participants (n) Drop-outs (n)	Mindfulness-based stress reduction (MBSR) + TAU Treatment period: 8 wks. Two-hour long sessions, 1 per week plus a half day (6 h) long retreat. Delivered in group (ca 15 patients/group). 75 Follow up at end of treatment: 68/75 Follow up at 2 months post treatment: 44/75
Comparison Participants (n) Drop-outs (n)	TAU (Wait list) No active treatment 75 Follow up at end of treatment: 68/75 Follow up at 2 months post treatment: 43/75
Outcomes	FIQ-R - total score (100) EQ-5D-5L and EQ-VAS, Hospital Anxiety and Depression Score (HADS) Subscale: Depression Perceived Stress Scale (PSS 10) Total score Pain Catastrophising Scale (PCS) Total score Multidimensional Inventory of Subjective Cognitive Impairment (MISCI) PGI-C Förändring PSI-C Item: function
Comments	

MBSR jämfört med annan intervention

VanGordon 2017

Author	VanGordon
Year	2017
Country	UK
Ref #	[21]
Study design	Randomized controlled trial
Setting	Multiple sites. Separate training rooms utilized by a meditation centre and GP surgery
Recruitment	Talks at FMS self-help groups, posters in GP surgeries, and emails sent to members of FMS support groups.
Population	Male and female aged between 18 and 65 years, being able to read and write using the English language with a current diagnosis of FMS (as confirmed by a letter from a general practitioner [GP], rheumatologist, or hospital pain consultant).
Inclusion criteria	Not currently undergoing formal psychotherapy, no changes in psychopharmacology type or dosage 1-month prior to intervention (although stable prescription medication was permitted), and not currently practicing mindfulness or meditation.
Follow up	8 wks and 6 months
Intervention 1	Meditation Awareness training 8 (2 hr long) workshops over 8 wks. Delivered in group.
Participants (n)	74
Drop-outs (n)	Completed post intervention assessment: 54/74 Completed 6 months follow-up assessment: 45/74
Intervention 2	Cognitive behavioural theory for groups 8 (2 hr long) workshops over 8 wks. Delivered in group.
Participants (n)	74
Drop-outs (n)	Completed post intervention assessment: 52/74 Completed 6 months follow-up assessment: 40/74
Outcomes	FIQ-R - total score, McGill Pain questionnaire (MPQ), Short Form (SF-MPQ), Depression, Anxiety, and Stress Scale (DASS), NRS - Sleep quality,
Comments	

Psykoedukativa insatser jämfört med väntelista eller sedvanlig vård

Barrenengoa-Cuadra 2021

Author	Barrenengoa-Cuadra
Year	2021
Country	Spain
Ref #	[22]
Study design	Randomized controlled trial
Setting	Primary care setting.
Recruitment	Databases of patients with FM included in the waiting lists for appointments in five primary health care centres.
Population	Male and female patients aged 18 years or older who had been previously diagnosed with FM by their attending physician in any health care setting.
Inclusion criteria	
Follow up	After treatment (1 month) and follow-up visits at 6 and 12 months.
Intervention 1	Intervention group The intervention consisted of six 2-hr weekly classes aught by a multidisciplinary team of two or three experienced therapists trained in teaching educational interventions to patients with FM, followed by a seventh reinforcement class a month later
Participants (n)	70
Drop-outs (n)	Completed 1 month follow up: 70/70 Completed 12 month follow up:68/70
Comparison	Treatment as usual The usual treatment for patients with FM is mainly pharmacological and adjusted to the symptomatic profile of each individual patient, mostly including antidepressants, antiepileptics and opioid and nonopioid analgesics-.
Participants (n)	70
Drop-outs (n)	Completed 1 month follow up: 69/70 Completed 12 month follow up: 67/70
Outcomes	FIQ - total score, Brief Pain Inventory: 1) BPI - subscale: severity 2) BPI - subscale: interference, HADS: depression, HADS – anxiety, Pain Catastrophising Scale (PCS), Healthy Assessment Questionnaire (HAQ)
Comments	

Luciano 2011

Author	Luciano
Year	2011
Country	Spain
Ref #	[23, 24]
Study design	Randomized controlled trial
Setting	general practices
Recruitment	Patients recruited through general practitioners office
Population	Patients aged between 18 and 75 years contactable by telephone, and who met the diagnostic criteria of FM established by the ACR.
Inclusion criteria	
Follow up	At end of treatment (2 months.)
Intervention 1	Psychoeducational program + TAU

	Nine 2-hour sessions delivered over a 2-month period (1 afternoon session per week). 5 educative sessions and 4 autogenic training sessions.
Participants (n)	108
Drop-outs (n)	Followed up at post-treatment: 92/108
Comparison	Treatment as Usual In general practice, the treatment provided is mainly pharmacologic and is adjusted to the symptomatic profile of the patient. In addition, counselling about aerobic exercise adjusted to patients' physical limitations is usually provided.
Participants (n)	108
Drop-outs (n)	Followed up at post-treatment: 93/108
Outcomes	FIQ - total score and FIQ - 7 subscales,
Comments	

Musekamp 2019

Author	Musekamp
Year	2019
Country	Germany
Ref #	[25]
Study design	Randomized controlled trial
Setting	Inpatient rehabilitation centres.
Recruitment	Patients recruited through fliers, advertisements and presentations at fibromyalgia support groups
Population	Eligible for participation were adult patients with FMS (ICD-10: M79.7), evaluated by the physicians at admission.
Inclusion criteria	
Follow up	At end of treatment (6 weeks post randomization), follow up at 6 and 12 months.
Intervention 1	Intervention Group Six sessions of 90 min each plus one optional preparing session. Topics were diagnosis and treatment of FMS, coping strategies for pain and stress and promotion of physical activity.
Participants (n)	295
Drop-outs (n)	Received allocated intervention: 281 Folloup up end of treatment: 252/281 Follow up at 6 months: 224/281 Follow up at 12 months: 201/281
Comparison	Treatment as utual Information about FMS and coping with pain. In contrast to the intervention condition, usual care education did not consider the updated evdence on FMS and was less self-management oriented.
Participants (n)	316
Drop-outs (n)	Received allocated intervention: 302 Folloup up end of treatment: 265/302 Follow up at 6 months: 244/302 Follow up at 12 months: 222/302
Outcomes	FIQ - health impairment, Patient Health Questionnaire (PHQ) HQ 4, subscales: 1) Depression, 2) Anxiety
Comments	

Studier inom fysisk aktivitet och manuella behandlingar

Guidad fysisk aktivitet jämfört med väntelista, sedvanlig behandling eller annan minimal intervention

Baptista 2012

Author	Baptista
Year	2012
Country	Brazil
Ref #	[26]
Study design	Randomized controlled trial
Setting	Not stated
Recruitment	Patients were selected from the Rheumatology outpatient clinic
Population	Diagnosis of fibromyalgia based on the criteria of the American College of Rheumatology (1); female gender; age between 18 and 65 years.
Inclusion criteria	
Follow up	At 16 weeks (T16) and 32 weeks (T32) following the initial evaluation.
Intervention 1	Dance One-hour belly dance classes twice a week for 16 weeks. Maximum of eight students per class.
Participants (n)	40
Drop-outs (n)	Completed 16 weeks follow up: 39/40 Completed 32 weeks follow up: 38/40
Comparison	Control
Participants (n)	40
Drop-outs (n)	Completed 16 weeks follow up: 39/40 Completed 32 weeks follow up: 37/40
Outcomes	FIQ - total score, SF-36 8 subscales, VAS – intensity, Beck Depression Inventory-II (BDI-II), State-Trait Anxiety Inventory (STAI) "Part 1 and 2" - state and trait.
Comments	

Carson 2010

Author	Carson
Year	2010
Country	USA
Ref #	[27, 28]
Study design	Randomized controlled trial
Setting	Exercise studio at university school of nursing.
Recruitment	The participants were all patients referred to a university tertiary care center.
Population	Diagnosis of FM (ACR-90) for at least 1 year, female, stable pharmacologic and/or non-pharmacologic treatment for FM for at least 3 months.
Inclusion criteria	
Follow up	Post treatment (8 weeks) and after 3 months (only intervention group).
Intervention 1	Yoga of awareness Eight once-per-week 120 min group classes (7–12 patients per group). 40 min stretching, 25 min mindfulness, 10 min breathing techniques, 20 min how to apply yoga for coping, 25 min group discussions.
Participants (n)	25
Drop-outs (n)	Received treatment: 22/25 Follow up post treatment: 22/25

	Follow up 3 months post treatment: 21/25
Comparison Participants (n) Drop-outs (n)	Wait list Routine medical care for FM. After the post-treatment assessment, these patients were invited to participate in the yoga program. 28 Follow up post treatment: 26/28
Outcomes	FIQ-R - total score and 9 Subscales, Diary: Pain, Diary: Emotional distress, Diary: Fatigue, PGI-I Overall improvement, The Chronic Pain Acceptance Questionnaire (CPAQ) Total score och subscales: 1) Activity engagement 2) Pain willingness, Coping Strategies Questionnaire (CSQ) Subscale: 1) Pain catastrophizing Vanderbilt Multidimensional Pain Coping Inventory (VMPCI) 10 subscales - adaptive resp maladaptive coping
Comments	

DaCosta 2005

Author Year Country Ref #	DaCosta 2005 Canada [29]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Not stated. From hospital or community rheumatologists, directly or through letters of invitation and through newspaper advertisements. Adult women w fibromyalgia 12 wks (post-treatment), 6 and 12 months from study entry.
Intervention 1 Participants (n) Drop-outs (n)	Home based exercise program The patient met with a phsyiotherapist for 4 sessions over the 12 wks for help and instruction on aerobic exercise. Patients were provided w a heart rate monitor and were asked to complete an FM symptom measure and to record exercise activity weekly during the 12-week intervention phase and monthly thereafter. 39 Completed Baseline questionnaires: 39/39 Completed post intervention (3 months): 33/39 Completed 6 months follow up: 33/39 Completed 12 months follow up: 28/39
Comparison Participants (n) Drop-outs (n)	Treatment as usual Participants were asked to complete an FM symptom measure and to record exercise activity weekly during the 12-week intervention phase and monthly thereafter. 41 Completed Baseline questionnaires: 40/41 Completed post intervention (3 months): 36/41 Completed 6 months follow up: 36/41 Completed 12 months follow up: 33/41
Outcomes	FIQ - total score, VAS – intensity 1 Upper body 2) Lower body The Symptom Checklist-90—Revised (SCL-90-R)
Comments	

Fontaine 2010

Author Year Country	Fonataine 2010 USA

Ref #	[30, 31]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Participants were recruited from the Arthritis Center and Rheumatology clinics, by advertisements in the Arthritis newsletter, newspaper advertisements, and via clinical trial recruitment websites. Adults aged 18 years or older who met American College of Rheumatology diagnostic criteria for FM. At enrolment, participants were not meeting the US Surgeon General's 1996 recommendation for physical activity for the previous six months (that is, not engaging in either moderate-intensity physical activity for ≥ 30 minutes on ≥ five days per week or vigorous physical activity ≥ three times per week for ≥ 20 minutes each time during the previous month). Post intervention (12 weeks), 6 months and 12 months.
Intervention 1 Participants (n) Drop-outs (n)	Lifestyle physical activity Sex 60-minute group sessions over 12 weeks. First week prescribed 15 minutes, above usual level, of accumulated moderate-intensity LPA five to seven days a week and asked to increase the daily duration of LPA by five minutes each week. 46 Completed intervention: 40/46 Completed 6 and 12 months follow up: 30/46
Intervention 2 Participants (n) Drop-outs (n)	Fibromyalgia education Three 90- 120-minute meetings once per month for 12 weeks. Education, Q&A, Social support. n. The final session of FME presented information on exercise and physical activity, but no specific recommendations or prescription concerning exercise was given. 38 Completed intervention: 33/38 Completed 6 and 12 months follow up: 23/38
Comparison	Not applicable
Outcomes	FIQ - total score, VAS – intensity, CES-D, Fatigue Severity Scale (FSS),
Comments	For 6- and 12-months n analyzed = 53.

Haak 2008

Author Year Country Ref #	Haak 2008 Sweden [32]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial The subjects were recruited from the local press, Patient's Association for Fibromyalgia, national care centres (primary care, physiotherapists, family doctors) and the Swedish National Insurance Scheme. Female, at least 18 years old with fibromyalgia diagnosis since at least 6 months Post treatment. 4 months follow up (only intervention)
Intervention 1 Participants (n) Drop-outs (n)	Qigong 9 group sessions during 7 weeks for a total of 11.5 hours 29 Follow up post treatment: 28/29 Follow up 4 months post treatment: 28/29
Comparison	Wait list Waiting list for 7 weeks, thereafter qigong 9 group sessions during 7 weeks for a total of 11.5 hours.

Participants (n) Drop-outs (n)	28 Follow up post treatment: 28/28
Outcomes	The World Health Organization Quality of Life BREF (WHOQOL-BREF) Total score och subscales: 1) Psychological health, 2) Physical health, Diary 1) pain intensity 2) Inconvenience due to pain 3) Ability to control, Visual Numerological Scale (VNS), Beck Depression Inventory (BDI), State-Trait Anxiety Inventory (STAI) – state, Diary: Sleep quality, Visual Numerological Scale (VNS), Diary: 1) Restoration after sleep, 2) Energy level, 3) Ability to concentrate, Visual Numerological Scale (VNS)
Comments	

Mannerkorpi 2010

Author Year Country Ref #	Mannerkorpi 2010 Sweden [33]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Newspaper advertisements, at health care centres or from participation in an earlier study. Women aged 20 to 60 years with fibromyalgia, defined by the ACR 1990 criteria [2]:a history of long-lasting generalized pain and pain in at least 11 of 18 tender points examined by manual palpation. Ablility to manage a bicycle test at 50 watts or more, and interest in exercising outdoors twice a week for 15 weeks. 16 weeks (post 15-week intervention) and 6 months.
Intervention 1 Participants (n) Drop-outs (n)	Nordic walking group Supervised exercise sessions twice a week for 15 weeks. The target was to achieve 20 minutes of moderate-to-high intensity exercise. 34 Received intervention: 29/34 Post treatment analysis: 29/34 Long time follow up analysis:28/34
Intervention 2 Participants (n) Drop-outs (n)	Low intensive walking group Supervised exercise sessions once a week for 15 weeks. Walked at a low intensity level. 33 Received intervention: 28/33 Post treatment analysis: 29/33 Long time follow up analysis:26/33
Comparison	Not applicable.
Outcomes	FIQ - total score Subscale: pain, Multidimensional Fatigue Inventory (MFI) Subscales: 1) General fatigue 2) Physical fatigue 3) Reduced activity 4) Redcuced motivation 5) Mental fatigue
Comments	

Paulucci 2016

Author Year Country Ref #	Paolucci 2016 Italy [34]
Study design Setting	 At a physical medicine and rehabilitation unit.

Recruitment	
Population	FM (ACR 1990 and 2010), diagnosis established by the patient's rheumatologist. Age 18-60 years. A score of >5 on the visual analog scale (VAS), in the last three months.
Inclusion criteria	Tenderness of at least 2 of the 4 tender points on the back; and baseline condition of sedentary lifestyle with no or irregular physical activity.
Follow up	At 5 weeks and 12 weeks following the initial evaluation.
Intervention 1 Participants (n) Drop-outs (n)	Physical Exercises 21 Follow up 5 weeks:19/21 Follow up 12 weeks: 18/21
Intervention 2 Participants (n) Drop-outs (n)	Perceptual surfaces 20 Follow up 5 weeks:19/20 Follow up 12 weeks: 18/20
Comparison Participants (n) Drop-outs (n)	Control group 21 Follow up 5 weeks:20/21 Follow up 12 weeks: 18/21
Outcomes	FIQ - total score and The Fibromyalgia Assessment Status (FAS) - total score, Health Assessment Questionnaire (HAQ) - total score
Comments	

Fysioterapeutisk behandling – Guidad fysisk aktivitet jämfört med annan intervention

Altan 2009

Author Year Country Ref #	Altan 2009 Turkey [35]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial. Physical medicine and rehabilitation department. Patients at rheumatology clinic. Women who had a diagnosis of fibromyalgia syndrome (FMS) according to the ACR. End of treatment (12 weeks) and 12 weeks after end of treatment (24 weeks).
Intervention 1 Participants (n) Drop-outs (n)	Pilates exercise program 1 hour 3 times a week for 12 weeks. The exercise program follows the basic principles of the Pilates method. 25 Completed treatment, 12 weeks: 25/25 Follow up 24 weeks: Not stated
Comparison Participants (n) Drop-outs (n)	Control group Home exercise/relaxation program and instructions to do this 1 hour 3 times a week for 12 weeks. 25 Completed treatment, 12 weeks: 25/25 Follow up 24 weeks: Not stated
Outcomes	FIQ - total score, Nottingham Health Profile (NHP): Subscales combined in a summated score, VAS – intensity past wk,
Comments	

Calandre 2009

Author Year Country Ref #	Calandre 2009 Spain [36]
Study design Setting Recruitment Population Inclusion criteria Follow up	Radomized controlled trial Patients at pain unit or rehabilitation at university hospital. Patients were included if they were aged 18 years or older, had a diagnosis of fibromyalgia according to the current ACR criteria, and provided written informed consent to participate. End of treatment (6 weeks), 1 month and 3 months post treatment.
Intervention 1 Participants (n) Drop-outs (n)	Tai Chi 18 physiotherapy sessions of 60 minutes of duration performed 3 times a week during 6 weeks. Training was done in a pool with water heated at 36ºC of temperature. Patients were taught the 16 movements of Tai Chi. 42 Completed trial (6 weeks): 32/42 1 month follow up: 30/42 3 month follow up: 29/42
Intervention 2	Stretching

	18 physiotherapy sessions of 60 minutes of duration performed 3 times a week during 6 weeks. Training was done in a pool with water heated at 36ºC of temperature. Stretching was done with facilitating objects.
Participants (n) Drop-outs (n)	39 Completed trial (6 weeks): 34/39 1 month follow up: 32/39 3 month follow up: 28/39
Outcomes	FIQ - total score Subscales: 7 subscales, SF-36 Subscales: 1) Physical components 2) Mental components, Beck Depression Inventory (BDI) Total score and subscales: 1) Affective component 2) Somatic component, State-Trait Anxiety Inventory (STAI) Subscales: 1) State 2) Trait, Pittsburgh Sleep Quality Index (PSQI) - total score Subscales (7 subscales),
Comments	

Kayo 2012

Author Year Country Ref #	Kayo 2012 Brazil [37]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Patients at a Rheumatology Services at a Specialty Outpatient Clinic 30–55 years of age, diagnosed with fibromyalgia according ACR 1990 criteria. Women who agreed to participate in an exercise program 3 times per week for 16 weeks, and to discontinue medication for Fibromyalgia 4 weeks before the start of the study (washout period), and who had at least 4 years of schooling. End of treatment (16 weeks) and follow up 12 weeks after treatment ended (28 weeks).
Intervention 1 Participants (n) Drop-outs (n)	Walking program Physical activity, walking, for about 60 min, 3 times per week for 16 weeks. 30 Completed treatment (16 weeks): 28/30 Follow up (28 weeks): 23/30
Intervention 2 Participants (n) Drop-outs (n)	Muscle-strengthening exercises Physical activity, 11 free active exercises, for about 60 min, 3 times per week for 16 weeks. 30 Completed treatment (16 weeks): 23/30 Follow up (28 weeks): 22/30
Comparison Participants (n) Drop-outs (n)	Control Group 30 Completed treatment (16 weeks): 28/30 Follow up (28 weeks): 23/30
Outcomes	FIQ - total score, SF-36 Subscale: Bodily pain, VAS – intensity,
Comments	

Richards 2002

Author	Richards
Year	2002
Country	UK
Ref #	[38]
Study design	Randomised controlled trial
Setting	Group based classes took place at a "healthy living centre."
Recruitment	Hospital rheumatology outpatients
Population	Men and women aged 18-70 years who had fibromyalgia according to ACR1990 and were able to give informed consent
Inclusion criteria	
Follow up	End of treatment (3 months), follow up at 6 months and 12 months.
Intervention 1	Exercise 1-hour long classes of up to 18 individuals twice weekly for 12 weeks. Individualised aerobic exercise programme, mostly walking on treadmills and cycling on exercise bicycles.
Participants (n)	69
Drop-outs (n)	End of treatment (3 months): 57/69 Follow up 6 months: Not stated Follow up 12 months: Not stated
Comparison	Relaxation 1-hour long classes of up to 18 individuals twice weekly for 12 weeks. Upper and lower limb stretches and relaxation techniques.
Participants (n)	67
Drop-outs (n)	End of treatment (3 months): 55/67 Follow up 6 months: Not stated Follow up 12 months: Not stated
Outcomes	FIQ - total score,
Comments	Analysed data on an intention to treat basis. Any missing follow up data was replaced with the last know value even if this was the baseline value.

Wang 2010

Author	Wang
Year	2010
Country	United States
Ref #	[39]
Study design	Randomized controlled trial
Setting	Tertiary care academic hospital.
Recruitment	Not stated.
Population	21 years of age or older and fulfilled the ACR 1990 diagnostic criteria for fibromyalgia.
Inclusion criteria	
Follow up	End of treatment (12 weeks) and follow up 24 weeks.
Intervention 1	Tai chi 60 minutes each and took place twice a week for 12 weeks, classical Yang style of tai chi.
Participants (n)	33
Drop-outs (n)	Completed 12 weeks evaluation: 32/33 Completed 24 weeks evaluation: 30/32
Comparison	Control intervention 60 minutes each and took place twice a week for 12 weeks, wellness education and stretching.
Participants (n)	33
Drop-outs (n)	Completed 12 weeks evaluation: 29/33 Completed 24 weeks evaluation: 29/33

Outcomes	FIQ - total score, SF-36 Subscales: 1) Physical components 2) Mental components, "Patient's global assessment", CES-D, Pittsburgh Sleep Quality Index (PSQI) - total score, Chronic Pain Self-efficacy Scale (CPSS) - total score,
Comments	

Wang 2018

Author Year Country Ref #	Wang 2018 United States [40]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized comparative trial Urban tertiary care academic hospital Advertisements and enrolment through clinic. 21 years or older and fulfilled the ACR 1990 and 2010 preliminary diagnostic criteria for fibromyalgia 12, 24, and 52 weeks.
Intervention 1 Participants (n) Drop-outs (n)	Tai chi 1 session* 12 weeks. Each session 60 min. Warm-up and a review of tai chi principles, meditative movements, breathing techniques, and various relaxation methods. 39 Completed week 12: 29/39 Completed week 24: 28/39 Completed week 52: 25/39
Intervention 2 Participants (n) Drop-outs (n)	Tai chi 2 session * 12 weeks. Each session 60 min. Warm-up and a review of tai chi principles, meditative movements, breathing techniques, and various relaxation methods. 37 Completed week 12: 31/37 Completed week 24: 30/37 Completed week 52: 26/37
Intervention 3 Participants (n) Drop-outs (n)	Tai chi 1 session * 24 weeks. Each session 60 min. Warm-up and a review of tai chi principles, meditative movements, breathing techniques, and various relaxation methods. 39 Completed week 12: 36/39 Completed week 24: 34/39 Completed week 52: 29/39
Intervention 4 Participants (n) Drop-outs (n)	Tai chi 2 session * 24 weeks. Each session 60 min. Warm-up and a review of tai chi principles, meditative movements, breathing techniques, and various relaxation methods. 36 Completed week 12: 29/36 Completed week 24: 32/36 Completed week 52: 25/36
Intervention 5 Participants (n) Drop-outs (n)	Aearobic exercise 2 session * 24 weeks. Each session 60 min. Active warm-up including low intensity movements and dynamic stretching; choreographed aerobic training, progressing gradually from low to moderate intensity; and a cool-down involving low intensity movements, and dynamic and static stretching. 75 Completed week 12: 58/75 Completed week 24: 57/75 Completed week 52: 53/75
Outcomes	FiQ-R - total score,

	SF-36 Subscales: 1) Physical components 2) Mental components, Beck Depression Inventory-II (BDI-II), Hospital Anxiety and Depression Scale (HADS) Subscale: Depression, Hospital Anxiety and Depression Scale (HADS) Subscale: Anxiety, Pittsburgh Sleep Quality Index (PSQI) - total score, Health Assessment Questionnaire (HAQ) - total score, Patient's global assessment, Arthritis Self-Efficacy Scale (ASES) - total score, Coping Strategies Questionnaire (CSQ) - total score
Comments	

Akupunktur

Assefi 2005

Author	Assefi
Year	2005
Country	USA
Ref #	[41]
Study design	Randomized controlled trial
Setting	8 private acupuncture practices
Recruitment	
Population	Adults 18 years of age or older. Fibromyalgia diagnosed by a physician. Pre-randomization global pain score of 4 or greater on a visual analogue scale.
Inclusion criteria	
Follow up	After 1, 4, 8, and 12 weeks of acupuncture treatment; and 3 and 6 months after completion of treatment
Intervention 1	Directed acupuncture for fibromyalgia twice weekly for 12 weeks (24 treatments)
Participants (n)	25
Drop-outs (n)	Completed study: 23/25
Comparison 1	Sham acupuncture for unrelated condition (control 1) twice weekly for 12 weeks (24 treatments)
Participants (n)	24
Drop-outs (n)	Completed study: 22/24
Comparison 2	Sham needling (control 2) twice weekly for 12 weeks (24 treatments)
Participants (n)	24
Drop-outs (n)	Completed study: 22/24
Comparison 3	Simulated acupuncture (control 3) twice weekly for 12 weeks (24 treatments)
Participants (n)	23
Drop-outs (n)	Completed study: 19/23
Outcomes	SF-36 Subscales: 1) Physical components 2) Mental components, VAS – intensity, VAS: 1) Fatigue 2) sleep quality
Comments	Completed study means completed Approximately participant drop out 13%, but not clearly stated in article.

Targino 2008

Author	Targino
Year	2008
Country	Brazil
Ref #	[42]
Study design	Randomized controlled trial
Setting	Not stated.
Recruitment	By physicians from hospital.
Population	Female. Diagnosed according to the 1990 American College of Rheumatology (ACR) criteria. 20 to 70 years. VAS >4.
Inclusion criteria	Use antidepressant medicine.
Follow up	Post treatment (3 months after baseline). 6, 12 and 24 months after baseline.
Intervention 1	Acupuncture + standard care

	Twenty 20-minute sessions twice weekly for 10 weeks. Acupuncture points employed were: Ex-HN-3 and bilateral LR3, LI4, PC6, GB34 and SP6 points. Chi sensation was sought. 12.5–75 mg of tricyclic antidepressants per day, oral instruction to walk for 30 min twice a week, to perform mental relaxation exercises for another 30 min. They were also told to perform twice-weekly stretching exercises.
Participants (n) Drop-outs (n)	34 Follow up 3 months: 34/34 Follow up 6 months: 34/34 Follow up 12 months: 34/34 Follow up 24 months: 32/34
Comparison	Standard care 12.5–75 mg of tricyclic antidepressants per day, oral instruction to walk for 30 min twice a week, to perform mental relaxation exercises for another 30 min. They were also told to perform twice-weekly stretching exercises.
Participants (n) Drop-outs (n)	24 Follow up 3 months: 24/24 Follow up 6 months: 24/24 Follow up 12 months: 24/24 Follow up 24 months: 23/24
Outcomes	SF-36 Subscales: 8 subscales, VAS – intensity,
Comments	

Vas 2016

Author Year Country Ref #	Vas 2016 Spain [43]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Three primary care centers Referred by general practitioner. Adults (17 years of age or more) w a diagnosis in Fibromyalgia according to ACR criteria. End of treatment (10 weeks), 6 months and 12 months.
Intervention 1 Participants (n) Drop-outs (n)	Acupuncture Individualised treatment based on diagnostics using Traditional Chinese Medicine. 82 Follow up 10 weeks:78/82 Follow up 6 months: 75/82 Follow up 12 months: 73/82
Comparison Participants (n) Drop-outs (n)	Sham intervention Simulated acupuncture on dorsal and lumbar regions. 82 Follow up 10 weeks:81/82 Follow up 6 months: 80/82 Follow up 12 months: 80/82
Outcomes	FIQ - total score, SF-36 (SF-12) Subscales: 1) Mental components, 2) Physical components, VAS – intensity, Hamilton Rating Scale for depression (HAM-D)
Comments	

Behandlingar som undersökts i enbart en studie

Studier inom behandling med läkemedel

Arnold 2007

Author Year Country Ref #	Arnold 2007 USA [44]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial 3 outpatient research centres Patients were identified by physician referral or response to an advertisement for a fibromyalgia medication trial. Female or male patients, 18 year or older and met ACR90 diagnostic criteria Patients were required to score ≥4 onthe average pain severity item of the Brief Pain Inventory (BPI) at screening and randomization. Exclusion criteria (selected): Patients with other rheumatic or medical disorders that contributed to the symptoms of fibromyalgia were excluded. Patients patients who, in the opinion of the investigator, were treatment refractory, patients prior treatment with gabapentin or pregabalin Post treatment (12 weeks of treatment phase).
Intervention 1 Participants (n) Drop-outs (n)	Gabapentin titrated up to 2,400 mg/day during first 6 weeks of treatment phase. The dose was reduced to 1,200 mg/day for patients who could not tolerate target dose. 75 18/75
Comparison Participants (n) Drop-outs (n)	Placebo 75 13/72
Outcomes	BPI, pain severity and pain interference scores FIQ total score (range 0–80) Clinical Global Impression of Severity (range 1–7) MOS sleep measure MADRAS SF-36 (8 subscales) Adverse events
Comments	Study medication dose was stable for the last 4 weeks of the therapy phase.

Miki 2016

Author Year Country Ref #	Miki 2016 Japan [45]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Tertiary care hospitals Not stated Male or female patients aged between 20 and 64 years who met the ACR90 diagnostic criteria for FM Post treatment (12 weeks).
Intervention 1 Participants (n)	Mirtazapine 215

Drop-outs (n)	Analyzed: 211/215 Lost to follow up: 3/215 Discontinued intervention: 23/215
Comparison Participants (n) Drop-outs (n)	Placebo 215 Analyzed: 211/215 Lost to follow up: 2/215 Discontinued intervention: 23/215
Outcomes	SF-36 Subscales: 1) Mental components 2) Physical components 3) Role/ social components 4) 8 subscales NRS - Intensity
Comments	

Ramzy 2017

Author Year Country Ref #	Ramzy 2017 Egypt [46]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Not stated Not stated Subjects included 75 adult women (> 18 and < 70 years of age) who were previously diagnosed with fibromyalgia according to the standard 2010 criteria of the ACR3 (Appendix 1) and who were available for the entire 6 months of the study protocol. bimonthly for 6 consecutive months
Intervention 1 Participants (n) Drop-outs (n)	Amitriptyline Pregabalin 75 mg/dag och Amitriptylin 25 mg/dag 24 End of study: 24/24
Intervention 2 Participants (n) Drop-outs (n)	Venlafaxine Pregabalin 75 mg/dag och Venlafaxin 75 mg/dag 25 End of study: 25/25
Intervention 3 Participants (n) Drop-outs (n)	Paroxetine Pregabalin 75 mg/dag och Paroxetin 25 mg/dag 26 End of study: 26/26
Outcomes	Somatic Symptoms Scale-8 (SSS-8) Subscale: severity, CES-D
Comments	

Studier inom psykologisk behandling

Broderick 2005

Author Year Country Ref #	Broderick 2005 [47]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial. Notices in local newspapers and an academic hospital and by contacting patients in laboratory database. Women older than 21 years of age with a Fibromyalgia diagnosis by a physician. End of treatment (3 weeks), follow up at 4 months and 10 months.
Intervention 1 Participants (n) Drop-outs (n)	Emotional Disclosure Three 20-minute writing sessions in the laboratory with approximately 1-week intervals. Retelling of an important current or past traumatic event with emotional expression and cognitive reappraisal. 31 Post treatment: 29/31 4 months follow up: 28/31 10 months follow up: 26/31
Intervention 2 Participants (n) Drop-outs (n)	Neutral writing Three 20-minute writing sessions in the laboratory with approximately 1-week intervals. Write about day-to-day activities in relation to the time invested. 32 Post treatment: 26/32 4 months follow up: 26/32 10 months follow up: 26/32
Comparison Participants (n) Drop-outs (n)	Treatment as usual 29 Post treatment: 29/29 4 months follow up: 29/29 10 months follow up: 28/29
Outcomes	FIQ Subscale: Physical function, The Quality of Life Scale (QoL) Total score, Brief Pain Inventory (BPI) Subscale: Interference, McGill Pain questionnaire (MPQ) Total score and subscales, Beck Depression Inventory-II (BDI-II), Anxiety Trait and State (STAI), MOS - Sleep Scale Subscales: 1) Energy 2) Fatigue.
Comments	

Martinez 2014

Author Year Country Ref #	Martinez 2014 Spain [48]
Study design Setting Recruitment Population	Randomized controlled trial At a university hospital rheumatology unit Patients were recruited from the Rheumatology Service and Pain Unit Women aged 25 – 60, diagnosed with FM (ACR 1990) since more than 6 months.

Inclusion criteria	Being stable as regards the intake of analgesics, antidepressants or other drugs at least 1 month before ethe study, and meeting the diagnostic criteria for insomnia.
Follow up	Post treatment, at 3 and 6 months after intervention.
Intervention 1 Participants (n) Drop-outs (n)	CBT - insomnia 32 Completed treatment: 30/32 Follow up post treatment: 30/32 Follow up at 3 months: 29/32 Follow up at 6 months: 27/32
Intervention 2 Participants (n) Drop-outs (n)	Sleep hygiene 32 Completed treatment: 29/32 Follow up post treatment: 27/32 Follow up at 3 months: 22/32 Follow up at 6 months: 20/32
Comparison Participants (n) Drop-outs (n)	Not included
Outcomes	FIQ - total score, SF-36 Mental component summary, McGill Pain questionnaire (MPQ), MPQ-SF (short form), The Symptom Checklist-90 (SCL-90) Subscales: 1) Depression 2) Anxiety, Pittsburgh Sleep Quality Index (PSQI) Total score and subscales, Multidimensional Pain Inventory (MPI) Subscale: fatigue, Pain catastrophizing scale (PCS) Total score, Chronic Pain Self-efficacy Scale (CPSS) Total score
Comments	

Scheidt 2013

Author Year Country Ref #	Scheidt 2013 Germany [49]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controll trial University medical center. Via patient self-help groups, news media and referrals from the Department of Rheumatology. Women, 18–70 years of age, who currently suffered from fibromyalgia as (ACR). 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 Post treatment (25 weeks) and 12 months postintervention.
Intervention 1 Participants (n) Drop-outs (n)	Adapted form of short-term psychodynamic psychotherapy 25 weekly 1-hour sessions of psychodynamic psychotherapy 24 Received intervention: 23/24 Post treatment: 20/24 4 months follow up: 18/24 Intention to treat: 23
Comparison Participants (n) Drop-outs (n)	Treatment as usual Four 10-15-minute contacts during a 6-months period. 23 Post treatment: 20/23 4 months follow up: 17/23 Intention to treat: 23

Outcomes	FIQ Total score, SF-36 Subscales: 1) Physical function 2) Mental health, Hospital Anxiety and Depression Score (HADS) Subscales: 1) Depression 2) Anxiety, The Symptom Checklist-90 (SCL-90) SCL-27 (short form), Pain Disability Index (PDI) Total score,
Comments	

Studier inom psykoedukativa interventioner

Hammond 2006

Author Year Country Ref #	Hammond 2006 United Kingdom [50]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Community leisure centres. From a rheumatology outpatient department at one district general hospital. Adults (>18 years) with fibromyalgia according to ACR 1990 criteria. 4 and 8 months.
Intervention 1 Participants (n) Drop-outs (n)	Patient Education Weekly education classes in groups over 10 weeks. Comprehensive education program based on social cognitive theory and self-management CBT approach. Education about medical and psychological aspects of fibromyalgia and physical exercises given in 2-hour sessions. 71 Received intervention: 71/71 Assessment at 4 months: 53/71 Assessment at 8 months: 52/71
Comparison Participants (n) Drop-outs (n)	Relaxation Booklet on fibromyalgia and 1 hour classes in relaxation. Classes once a week for 10 weeks. 62 Received intervention: 62/62 Assessment at 4 months: 51/62 Assessment at 8 months: 49/62
Outcomes	FIQ - total score and FIQ - 8 sub scales, SF-36, MOS Sleep Scale (SP-12), Arthritis Self-Efficacy Scale (ASES)
Comments	

Hsu 2010

Author Year Country Ref #	Hsu 2010 USA [51]
Study design Setting Recruitment Population Inclusion criteria	Randomized controlled trial Patients recruited through fliers, advertisements and presentations at fibromyalgia support groups Adult (18 years or more) women w fibromyalgia (according ACR 1990 criteria)

Follow up	At end of treatment (6 weeks post randomization) and 6 months.
Intervention 1 Participants (n) Drop-outs (n)	Affective self awareness Three weekly 2-hour manual-based group sessions conducted by a physician. Four components: education on a psychophysiological model of pain, written emotional disclosure on stress, affective awareness techniques and re-engagement in in activities. 24 Completed 6 week follow up: 21/24 Completed 6 month follow up: 21/24
Comparison Participants (n) Drop-outs (n)	Wait list 21 Completed 6 week follow up: 21/21 Completed 6 month follow up: 21/21
Outcomes	SF-36, Brief Pain Inventory (BPI), MOS Sleep Scale, Multidimensional Fatigue Inventory (MFI), Beliefs about Pain Control Questionnaire (BPCQ)
Comments	

Stuifberger 2010

Author Year Country Ref #	Stuifberger 2010 United States [52]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Primary care setting. Notices in local newspapers and websites, fliers in physician offices, community sites and support groups. Female 20–75 years of age, having physician-diagnosed fibromyalgia syndrome for at least six months, and willing to participate. At 2, 5 and 8 months after baseline.
Intervention 1 Participants (n) Drop-outs (n)	Intervention group Designed to engage women with fibromyalgia syndrome in assessing their present health behaviours, setting meaningful goals for change and addressing the barriers, resources and skills necessary to change those behaviours. 123 Received intervention: 98/123 (Analysed with RM ANOVA) Follow up at 2 months: 88/123 Follow up at 5 months: 87/123 Follow up at 8 months: 84/123
Comparison Participants (n) Drop-outs (n)	Treatment as usual Participants randomly assigned to the attention-control group received eight classroom sessions on topics related to disease management that were carefully scripted so that content did not overlap with that presented in the intervention classes. 111 Received intervention: 89/111 (Analysed with RM ANOVA) Follow up at 2 months: 83/111 Follow up at 5 months: 83/111 Follow up at 8 months: 81/111
Outcomes	FIQ - total score, SF-36: 1) Mental components 2) Physical components The Health Promoting Lifestyle Profile II (HPLP-II) Total score plus 6 subscales.
Comments	

Studier inom fysisk aktivitet och manuella behandlingar

Ang 2013

Author Year Country Ref #	Ang 2013 USA [53]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial. Telephone-delivered intervention Referred from specialty or primary care clinics. Between 18 and 65 years old, American College of Rheumatology classification criteria for FM. Average Brief Pain Inventory (BPI) pain severity score Z4; FIQ-PI score Z2; and on stable doses of medications for FM for more than 4 weeks. Post Treatment, at 3 and 6 months post treatment.
Intervention 1 Participants (n) Drop-outs (n)	Exercise based motivational interviewing Participants received 6 telephone calls over a 12-week period 107 Post intervention, week 12: 97/107 3 months follow up: 95/107 6 months follow up: 97/107
Comparison Participants (n) Drop-outs (n)	Edcucation control Participants received 6 telephone calls over a 12-week period 109 Post intervention, week 12: 102/109 3 months follow up: 98/109 6 months follow up: 101/109
Outcomes	FIQ Subscale: 1) Physical impairment, PHQ-8. Depression,
Comments	

Castro-Sánchez 2011a

Author Year Country Ref #	Castro-Sánchez 2011 Spain [54]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Patients diagnosed with FMS (ACR) who belong to a Fibromyalgia Association. FMS diagnosis, age from 18 to 65 years (working age range), no regular physical activity, and agreement to attend evening therapy sessions. Agreement to attend evening therapy sessions, limitation of usual activities due to pain on at least 1 day in the previous 30 days, and/or moderate or worse average pain level (≤4 on 10-point scale). End of treatment (20 weeks), 1 months and 6 months.
Intervention 1 Participants (n) Drop-outs (n)	Massage Myofascial release therapy Massage-myofascial release therapy during a weekly 90-minute session for 20 weeks. Aimed to release myofascial restrictions at the sites of the 18 painful points. 32 Analyzed: 30/32
Comparison	Sham

	Weekly 30-minute session of disconnected magnetotherapy for 20 weeks. With the patient in prone position, magnotherapy was applied on the cervical area (15 min) and lumbar area (15 min).
Participants (n) Drop-outs (n)	32 Analyzed: 29/32
Outcomes	SF-36 Subscales: 8 subscales, Pittsburgh Sleep Quality Index (PSQI) Subscales: 1) Sleep quality, , 2) Sleep latency, 3) Sleep duration, 4) Sleep efficiency, 5) Sleep disturbance, 6) Daily dysfunction
Comments	

Castro-Sánchez 2011b

Author Year Country Ref #	Castro-Sánchez 2011 Spain [55]
Study design Setting Recruitment Population Inclusion criteria Follow up	Randomized controlled trial Age 40–65 years, patients diagnosed with fibromyalgia syndrome by physicians. Agreement to attend evening therapy sessions, limitation of usual activities due to pain on at least 1 day in the previous 30 days, and/or moderate or worse average pain level (≤4 on 10-point scale). End of treatment (20 weeks), 6 months and 12 months.
Intervention 1 Participants (n) Drop-outs (n)	Myofascial release therapy Twice-weekly for 20 weeks, 1-hour session of 10 myofascial release modalities. 47 Analyzed: 45/47
Comparison Participants (n) Drop-outs (n)	Sham Short-wave and ultrasound treatment for 30 minutes twice-weekly for 20 weeks. 47 Analyzed: 41/47
Outcomes	FIQ - total score and 5 subscales: 1) N Days feeling good, 2) Pain, 3) Fatigue, 4) Tiredness walking, 5) Stiffness, VAS – intensity, McGill Pain Questionnaire (MPG) Subscales: 1) Sensory, 2) Affective, 3) Sensory and affective subscales combined, Clinician Global Impression (CGI) 1) Severity, 2) Improvement
Comments	

Annan behandling

Mhalla 2011

Author	Mhalla
Year	2011
Country	Not stated.
Ref #	[56]
Study design	Randomized controlled trial
Setting	Not stated.
Recruitment	Not stated.
Population	Female patients of at least 18 years of age, who fulfilled ACR-90 cirteria, pain intensity ≥4 (BPI).
Inclusion criteria	Patients with inflammatory rheumatic disease, autoimmune disease, or painful disorders that might confound assessment of FM pain or current primary psychiatric condition or substance abuse were not included. Patients with contraindication for TMS such as seizures, brain trauma, brain surgery och intracranial hypertension, neurological disorders, pacemaker or other metallic implants were excluded. Stable medication for pain and sleep disorders for at least one month before enrolment and throughout the study.
Follow up	Throughout treatment, at end of treatment and 4 weeks after end of treatment.
Intervention 1	Repetitive transcranial magnetic stimulation (rTMS). A total of 14 sessions over 21 weeks, consisting of an ‘‘induction phase’’ with one session per day for 5 days was followed by a ‘‘maintenance phase’’ consisting of one weekly session for 3 weeks, and 3 monthly sessions thereafter.
Participants (n)	20
Drop-outs (n)	3/20
Comparison	Sham
Participants (n)	20
Drop-outs (n)	5/20
Outcomes	Pain intensity SF-McGill questionnaire (sensory and affective dimensions of pain) Brief Pain Inventory (BPI) – interference Fibromyalgia Impact Questionnaire (FIQ) total score Hospital Anxiety and Depression Scale (HAD), anxienty and depression Beck Depression Inventory (BDI) Pain Catastrophizing Scale (PCS) Negative effects
Comments	

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