

## Chronic pain: assessment and management

[C] Evidence review for pain management programmes

*NICE guideline*

*Intervention evidence review underpinning the research recommendation on pain management programmes in the NICE guideline*

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*Draft for Consultation*

*This evidence review was developed by  
the National Guideline Centre*



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# 1 Pain management programmes

## 1.1 Review question: What is the clinical and cost effectiveness of pain management programmes for the management of chronic pain?

### 1.2 Introduction

Pain management programmes (PMPs) are designed to help people better manage their chronic pain and everyday activities. They do not aim to cure pain. They are usually delivered as a group intervention by a multidisciplinary team of healthcare professionals who have specialist training in pain management. They are part of a package of care, that may also include optimisation of medication.

PMPs are usually offered on an outpatient basis over a period of weeks in a hospital or community setting. This format of programme delivery provides an opportunity for people to practise the taught activities in their everyday lives between sessions and then receive advice and feedback from the healthcare professional team when they next meet as a group. It also enables shared learning opportunities across members of the group. PMPs may be supplemented by online programme content, or the whole programme may be delivered online. PMPs are also delivered in a residential format over a period of weeks for people who may require more specialised input. These can be on a group or individual basis. The decision about what level of PMP is required for an individual is usually made by the healthcare professionals within a pain clinic and in the context of local, regional and national provision.

The content of a PMP typically includes education about pain and its impact on the individual as well as physical and psychological pain management approaches and often delivered by a multidisciplinary team. There is no standardised content for PMPs though there are guidelines from professional bodies about which broad topics a PMP should include and the recommended number of hours for a PMP. This means that the content and duration of PMPs varies widely and there is uncertainty regarding what constitutes an effective PMP. This evidence review will therefore look to determine the effectiveness of PMPs for people with chronic pain.

### 1.3 PICO table

For full details see the review protocol in appendix A.

**Table 1: PICO characteristics of review question**

<b>Population</b>	People, aged 16 years and over, with chronic pain Pain that persists or recurs for longer than 3 months.
<b>Intervention(s)</b>	Interventions: <ul style="list-style-type: none"><li>• Peer led pain management programmes</li><li>• Professional led or combination of professional and peer led pain management programmes</li></ul> Definition of a pain management programme: any intervention that has two or more components including a physical and a psychological component delivered by trained people, with some interaction/coordination between the two.

	Inpatient and outpatient pain management programmes will be compared separately with control, but not with each other.
<b>Comparison(s)</b>	<ul style="list-style-type: none"> <li>• Each other (peer led vs. professional led or combination of professional and peer led)</li> <li>• Standard care / waiting list</li> </ul>
<b>Outcomes</b>	<p>CRITICAL:</p> <ul style="list-style-type: none"> <li>• health related quality of life (including meaningful activity)</li> <li>• physical function</li> <li>• psychological distress (depression/ anxiety)</li> <li>• pain interference</li> <li>• pain self-efficacy.</li> </ul> <p>IMPORTANT:</p> <ul style="list-style-type: none"> <li>• use of healthcare services</li> <li>• sleep</li> <li>• discontinuation</li> <li>• pain reduction.</li> </ul> <p>Outcomes will be extracted at the longest time point up to 3 months and at the longest time point after 3 months.</p>
<b>Study design</b>	<p>Randomised controlled trials and systematic reviews of randomised controlled trials.</p> <p>Cross-over randomised controlled trials will be considered if no non-cross-over randomised controlled trial evidence is identified.</p>

## 1.4 Clinical evidence

### 1.4.1 Included studies

3 25 studies (30 papers) were included in the review;<sup>9, 24, 42, 68, 77, 106, 128, 158, 164, 186, 187, 204, 205, 236-</sup>  
4 238, 240, 244, 263, 280, 305-308, 318, 319, 337, 339, 347 these are summarised in Table 2 below. Evidence from  
5 these studies is summarised in the clinical evidence summary tables below (Table 3 and  
6 Table 4).

7 Twenty-four studies compared professional led pain management programmes with standard  
8 care or waiting list. One study compared peer led pain management programmes with  
9 standard care or waiting list. No evidence for a combination of professional and peer led  
10 programmes was identified.

11 See also the study selection flow chart in appendix C, study evidence tables in appendix D,  
12 forest plots in appendix E and GRADE tables in appendix F.

### 1.4.2 Excluded studies

14 Three Cochrane reviews relevant to this review question were identified. Foster 2007<sup>115</sup> was  
15 excluded because it included a different review population. Haines 2008<sup>155</sup> was excluded  
16 because the included interventions comprised education components of pain management  
17 only and therefore did not match the protocol definition of pain management programmes for  
18 this review. Theadom 2015<sup>323</sup> was also excluded because the included interventions were  
19 mind-body interventions such as cognitive behaviour therapy, biofeedback, mindfulness  
20 meditation, movement and relaxation therapies, which did not meet the protocol definition of  
21 a pain management programme for this review.

1 See the excluded studies list in Appendix I: Reasons for exclusion are briefly summarised to  
2 denote the element of the study that did not match the review protocol; therefore the words  
3 'incorrect' or 'inappropriate' are used in the context of this review and are not a reflection of  
4 the methodological validity of the studies themselves.

5

### 1.4.3 Summary of clinical studies included in the evidence review

2 Table 2: Summary of studies included in the evidence review

Study	Intervention and comparison	Details	Population	Outcomes	Comments
<b>Amris 2014<sup>9</sup></b>	<p><b>Intervention:</b> Professional-led pain management programme (n=96)</p> <p><b>Comparison:</b> Waiting list control group (n=95)</p>	<p><b>Pain management programme</b> (35 hours over 2 weeks, group based):</p> <ul style="list-style-type: none"> <li>• 3-hour counselling session</li> <li>• Educational sessions focused on information about chronic widespread pain and ways to manage pain.</li> <li>• Group discussions were focused on shared experiences of living with chronic pain and strategies to cope with this</li> <li>• Physical therapy included information about the principles of graded exercise and activity pacing, as well as supervised training sessions (aerobic, pool exercises, balance training, proprioception) and relaxation</li> <li>• Occupational therapy focused on pain-related interference and how to adapt to this.</li> <li>• Also included sessions led by psychologists (no further details), and a rheumatologist consultation.</li> </ul> <p>Led by: Psychologist, rheumatologist, nurse, occupational and physio therapists.</p> <p><b>Control:</b> Waiting list control. No further details</p>	<p>Chronic widespread pain</p> <p>Mean age 44 years</p> <p>Mean pain duration 10.5 years</p>	<p>At 6 months:</p> <ul style="list-style-type: none"> <li>• Quality of life</li> <li>• Psychological distress</li> <li>• Pain self-efficacy</li> <li>• Pain reduction</li> </ul>	<p>86% on pain medications as baseline (analgesics, NSAIDs, antidepressants, anticonvulsants)</p>
<b>Bourgault 2015<sup>42</sup></b>	<p><b>Intervention:</b> Professional led pain self-</p>	<p><b>PASSAGE program</b> (9 group sessions with 8 participants lasting 2.5 hours each) involving psycho-educational tools, CBT-related techniques (e.g. fixing</p>	<p>Fibromyalgia for at least 6 months</p> <p>Mean age 48 years</p>	<p>At 11 weeks and 6 months:</p> <ul style="list-style-type: none"> <li>• Quality of life</li> </ul>	

Study	Intervention and comparison	Details	Population	Outcomes	Comments
	<p>management group (n=29)</p> <p><b>Comparison:</b> Standard care (n=29)</p>	<p>realistic objectives, awareness of the impact of stress, awareness of control gain over symptoms) and patient-tailored exercises. Sessions included:</p> <ul style="list-style-type: none"> <li>• Personal outcome goals set</li> <li>• Sessions started with customized exercise routines (15 min)</li> <li>• Discussion re. experiences with tasks of the preceding week</li> <li>• Education covered FMS symptoms and their management</li> <li>• Self-management strategies, specific exercises, respiration techniques and relaxation which were practised</li> </ul> <p>Led by: two health care professionals who both acted as facilitators.</p> <p><b>Control group:</b> Able to do the Passage Program after study had finished.</p>	<p>Mean pain duration intervention group 15.66 (11.12) years, waiting list group 11.94 (8.23) years</p>	<ul style="list-style-type: none"> <li>• Psychological distress</li> <li>• Pain interference</li> <li>• Pain reduction</li> <li>• Sleep</li> <li>• Discontinuation</li> </ul>	
<b>Castel 2013<sup>68</sup></b>	<p><b>Intervention:</b> Professional led multidisciplinary programme (n=81)</p> <p><b>Comparison:</b> Conventional pharmacologic treatment (n=74)</p>	<p><b>Professional led multidisciplinary programme:</b> Total 24 sessions; 1 x hour of CBT and 1 x hour of physical, 2 days per week in groups of 8 patients.</p> <ul style="list-style-type: none"> <li>• CBT included information about FM, theory of pain perception, cognitive restructuring skills training, CBT for primary insomnia, assertiveness training, goal setting, activity pacing and pleasant activity scheduling training, life values, and relapse prevention.</li> <li>• Physical therapy treatment emphasized aerobic capacity, muscular strengthening</li> </ul>	<p>Women with fibromyalgia</p> <p>Mean age 48.9 (7) years</p> <p>Mean duration of pain 11.6 (9) years</p>	<p>At 3 and 15 months:</p> <ul style="list-style-type: none"> <li>• Quality of life</li> <li>• Psychological distress</li> <li>• Pain reduction</li> <li>• Sleep</li> <li>• Discontinuation</li> </ul>	<p>Both groups received conventional pharmacologic treatment.</p> <p>Inclusion criteria: between 3 and 8 years of schooling. Programme was designed for people with low educational levels.</p>

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		<p>and flexibility and alternated with sessions of hydrokinesiotherapy in a heated pool and kinesiotherapy in a gymnasium.</p> <ul style="list-style-type: none"> <li>• All sessions included overall aerobic work, coordination exercises, and flexibility exercises.</li> <li>• Difficulty of the exercises was individually tailored and progressively increased through the use of resistance media and a slow execution velocity.</li> <li>• Participants practiced Schultz autogenic training during sessions and given an audio CD to practice at home.</li> <li>• Physical therapy supplemented with an exercise routine between sessions and a scheduled daily march to facilitate the incorporation of the regular exercise into daily life.</li> </ul> <p><b>Conventional pharmacologic treatment:</b> Analgesics, antidepressants (tricyclics, selective serotonin reuptake inhibitors, and dual reuptake inhibitors), benzodiazepine, and nonbenzodiazepine hypnotics. Drug treatment adjusted as recommended by guidelines.</p>			<p>Hospital Anxiety and Depression scale reported as combined score for depression and anxiety – not validated so not included in the analysis</p>
<p><b>Corey 1996<sup>77</sup></b></p>	<p><b>Intervention:</b> Professional led functional restoration programme (n=100)</p> <p><b>Comparison:</b></p>	<p><b>Functional restoration programme:</b> Treatment sessions limited to 6.5 hours per day to a maximum of 35 days (average 32.9 days)</p> <ul style="list-style-type: none"> <li>• Focus on active physical therapy including stretching, strengthening and endurance building; work hardening; and education in posture and body mechanics.</li> </ul>	<p>Injured workers (work-related soft issue injury with no neurological involvement and disability longer than expected based on the nature of the</p>	<p>At 9-27 months (average 18 months):</p> <ul style="list-style-type: none"> <li>• Pain reduction</li> </ul>	

Study	Intervention and comparison	Details	Population	Outcomes	Comments
	Usual care (n=100)	<ul style="list-style-type: none"> <li>Group education and counselling addressed pain-related disability issues, attitudinal barriers to recovery, sleep disruption etc.</li> <li>Taught pain management strategies, stress management, problem solving techniques, relaxation and guided imagery techniques.</li> </ul> <p><b>Usual care:</b> discharged back to treating physician with a note of assessment findings and recommendations for proactive management.</p>	injury), referred from 3 to 6 months post injury (n=214)  Age: 18-60 years  Average duration of disability: 4.6 months		
Ersek 2008 <sup>106</sup>	<p><b>Intervention:</b> Professional led pain self-management group (n=133)</p> <p><b>Comparison:</b> Patient information booklet (n=123)</p>	<p><b>Pain self-management group:</b> 7 weekly 90 minute group sessions, incorporating basic education about persistent pain as well as training in and practice of pain self-management techniques, including:</p> <ul style="list-style-type: none"> <li>Progressive muscle relaxation;</li> <li>Selected range of motion, strengthening and balance exercises;</li> <li>Application of heat and cold.</li> <li>Presentations and discussion focused on; pacing activities,</li> <li>challenging negative thoughts,</li> <li>dealing with pain flare-ups and setbacks in pain management activities, and</li> <li>pain medicines and complementary therapies.</li> </ul> <p>Participants also received a syllabus, relaxation CD and 2 hot/cold gel packs. Participants developed personalised pain management plans, with the help of group facilitators to ensure they were specific and</p>	Older adults with chronic pain aged ≥65  Mean age 81.8 years  Duration of pain: at least 3 months	At 7 weeks and 12 months: <ul style="list-style-type: none"> <li>Physical function</li> <li>Psychological distress</li> <li>Pain interference</li> <li>Pain reduction</li> <li>Discontinuation</li> </ul>	All participants were residents in retirement facilities in the US, interventions were conducted in these locations.  Both groups had follow up phone calls at 12, 16, 22 and 30 weeks after the final session.  One year after initial enrolment, incentives were provided for completion of study measures to ensure high response rates (\$10 gift cards for post-treatment assessment and \$25 gift cards for 12 month assessment).

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		<p>realistic. They were encouraged to practice these in-between sessions.</p> <p>Led by: one of 3 leaders (2 nurses and 1 clinical psychologist)</p> <p><b>Educational book control condition (BOOK):</b> A copy of the Chronic Pain Workbook or Managing Your Pain Before It Manages You was given to participants. Both included self-management approaches to chronic pain. Facilitators phoned participants 1 and 4 weeks after receiving the book and, using a standard script, asked questions about current pain and functioning. No specific therapeutic component in the phone calls and facilitators did not help participants identify goals or develop a pain management plan.</p>			Pain interference on a 0-10 scale, assumed to be VAS
<b>Gatchel 2009<sup>128</sup></b>	<p><b>Intervention:</b> Professional led functional restoration (n=30)</p> <p><b>Comparison:</b> Standard treatment (standard anaesthesia pain clinic medical care) (n=36)</p>	<p><b>Functional restoration:</b> Interdisciplinary team approach consisting of 3 major components; physical therapy, occupational therapy, and psychosocial intervention.</p> <ul style="list-style-type: none"> <li>• An aggressive psychosocial and physical reconditioning program.</li> <li>• Not traditional passive physical treatment modalities.</li> <li>• Treatment initially guided by quantified measurements of function.</li> <li>• Psychosocial and return-to-work issues are simultaneously addressed by the psychology and occupational therapy components of the program.</li> </ul>	<p>Chronic pain in active duty military personnel</p> <p>Mean age: 36 years</p> <p>Duration of pain: &gt;3 months, also defined as time since injury, mean: 66 months (5.5 years)</p>	<p>At post treatment (duration not reported), 6 and 12 months:</p> <ul style="list-style-type: none"> <li>• Quality of life</li> <li>• Psychological distress</li> <li>• Physical function</li> <li>• Pain interference</li> <li>• Pain reduction</li> <li>• Use of healthcare services</li> <li>• Discontinuation</li> </ul>	<p>NB. Authors state that standard care is more than the usual medical care that most patients with chronic musculoskeletal pain conditions receive by their primary medical provider or primary care manager.</p> <p>Active treatment group also received standard care.</p>

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		<ul style="list-style-type: none"> <li>• Also receive standard treatment as necessary to manage their pain.</li> </ul> <p>Led by: a supervising nurse and physician team.</p> <p>Intervention duration not stated.</p> <p><b>Standard treatment:</b> Treatment similar to speciality pain treatment available at many larger military medical treatment facilities. Common treatments include:</p> <ul style="list-style-type: none"> <li>• Management of pain medications.</li> <li>• Proper use of antidepressant medications as appropriate.</li> <li>• Nerve blocks and steroid injections.</li> <li>• A basic exercise programme when appropriate.</li> </ul> <p>Led by: anesthesiologists with training in pain management or pain medicine.</p>			<p>Further details of the functional restoration programme published elsewhere.</p> <p>Results reported pre- and post-treatment and at 6 and 12 months follow-up. Duration of treatment not stated.</p>
<p><b>Hamnes 2012</b><sup>158</sup></p>	<p><b>Intervention:</b> Professional led inpatient self-management programme (n=75)</p> <p><b>Comparison:</b> Waiting list (n=72)</p>	<p><b>Professional led inpatient self-management programme</b></p> <p>1 week multidisciplinary programme based on a cognitive behavioural approach and focuses on enhancing self-efficacy and coping with the disease and daily life, including:</p> <ul style="list-style-type: none"> <li>• Setting goals</li> <li>• Swimming pool exercises</li> </ul>	<p>Fibromyalgia</p> <p>Age: 20-70 years (intervention 45.4 (9.4) years, control 49.7 (4) years)</p> <p>Duration of pain: intervention 7 (7.2) years, control 6.1 (6.5) years)</p>	<p>At 3 weeks:</p> <ul style="list-style-type: none"> <li>• Quality of life</li> <li>• Psychological distress</li> <li>• Pain self-efficacy</li> <li>• Discontinuation</li> </ul>	

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		<ul style="list-style-type: none"> <li>• Relaxation</li> <li>• Education on mechanisms of disease</li> <li>• Self-management techniques such as awareness of coping strategies, communication etc.</li> <li>• Stress management</li> <li>• Walking</li> <li>• Education and discussion on healthy eating</li> <li>• Group discussions</li> </ul> <p><b>Waiting list</b> did not receive any treatment at the hospital in the period from inclusion to participation in the SMP</p>			
<p><b>Heuts 2005<sup>164</sup></b></p>	<p><b>Intervention:</b> Professional led self-management programme (n=149)</p> <p><b>Comparison:</b> Usual care (n=148)</p>	<p><b>Self-management programme</b> 6 2 hour sessions</p> <ul style="list-style-type: none"> <li>• Goal setting, self-incentives and motivators to optimise activity level.</li> <li>• Discussion of rational use of medication.</li> <li>• Self-relaxation training, problem solving and self-diagnostic skills.</li> <li>• Moving and exercising (no further details provided).</li> <li>• Standardised training materials e.g. information sheets, handbook on OA and self-management.</li> </ul> <p>Led by: 2 physiotherapists</p> <p><b>Usual care</b></p>	<p>Osteoarthritis of the hip or knee</p> <p>Age: 40-60 years</p> <p>Duration of pain: not reported (joint disorder of at least 3 months)</p>	<p>At 3 months and 21 months:</p> <ul style="list-style-type: none"> <li>• Physical function</li> <li>• Pain self-efficacy</li> <li>• Pain reduction</li> <li>• Discontinuation</li> </ul>	<p>No information about the exercise component is given; however prerequisites for physiotherapists included having a room with facilities for exercise sessions.</p> <p>Pain measured by visual analogue scale is reported, however results are for knee and hip pain separately and unclear how many participants were in each group. Therefore, not included in the analysis.</p>

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		Care prescribed by a family physician or consulted specialist			
<b>Jensen 2001</b> <sup>186</sup>	<p><b>Intervention:</b> Professional led pain management programme (n=63)</p> <p><b>Comparison:</b> Usual care (n=48)</p>	<p><b>Professional led pain management programme</b> Combined physical therapy and CBT programmes for 40 hours per week.</p> <ul style="list-style-type: none"> <li>• individually tailored training</li> <li>• education with practical examples</li> <li>• goal setting, increasing exercise to improve muscular endurance</li> <li>• aerobic and pool training</li> <li>• relaxation</li> <li>• body awareness therapy</li> <li>• CBT component aimed to improve the subjects' ability to manage pain and resume normal level of activity</li> <li>• scheduled activities for approx 13-14 hours per week</li> <li>• activity planning</li> <li>• problem solving</li> <li>• cognitive coping techniques</li> <li>• activity pacing</li> <li>• training in how to break vicious circles</li> <li>• assertion training and the role of significant others</li> <li>• tailored homework assignments given at the end of each session</li> <li>• 6 x 90 minute booster sessions held over 1 year post-treatment.</li> </ul>	<p>Chronic non-specific spinal pain for at least 6 months</p> <p>Aged 18-60 years</p>	<p>At 4 weeks and 18 months:</p> <ul style="list-style-type: none"> <li>• Quality of life</li> </ul>	4 arm trial: CBT, physical therapy, CBT and physical therapy combined programme and usual care

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		<p>Led by physiotherapists, psychologists, physicians (all experienced in management of non-specific spinal pain).</p> <p><b>Usual care:</b> No treatment offered as part of research project. Normal routine of healthcare followed.</p>			
<b>Johansson 1998</b> <sup>187</sup>	<p><b>Intervention:</b> Professional led cognitive behavioural multidisciplinary pain management programme (n=21)</p> <p><b>Comparison:</b> Waiting list (n=21)</p>	<p><b>Pain management programme</b> 5 full days per week for 4 weeks and 2 day booster sessions after 2 months</p> <ul style="list-style-type: none"> <li>• Education on gate control theory of pain, activity in daily life, exercise and relaxation, overweight and sleep, time management and goals.</li> <li>• Goal setting regarding work, leisure, social pursuits and domestic duties, using graded activity training.</li> <li>• Exercise and individually tailored muscle training programmes including cycling, swimming and outdoor sports.</li> <li>• Pacing of activities relevant for workplace and leisure e.g. typing, cleaning, cooking etc.</li> <li>• Applied relaxation and cognitive techniques such as distraction, imagery and positive coping self-statements.</li> <li>• Social skills training on assertiveness and handling conflicts.</li> <li>• Drug reduction methods and planning of return to work.</li> </ul> <p>Led by: clinical psychologist, physiotherapist, occupational therapist, physical education</p>	<p>Chronic musculoskeletal pain</p> <p>Age: mean 43.5 (7.6) years</p> <p>Duration of pain: mean 11 (6.3) years</p>	<p>At 8 weeks:</p> <ul style="list-style-type: none"> <li>• Pain reduction</li> <li>• Pain interference</li> <li>• Discontinuation</li> </ul>	<p>Half of the patients lived at the hospital ward during the week due to long distances.</p>

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		<p>teacher, vocational counsellor, physician and a nurse.</p> <p><b>Waiting list:</b> no further details provided</p>			
<b>Kwok 2016</b> <sup>204</sup>	<p><b>Intervention:</b> Professional led arthritis self-management programme (n=19)</p> <p><b>Comparison:</b> waiting list control (n= 27)</p>	<p><b>Self-management programme</b> :(2-hourly interactive group sessions of 6-7, once a week for 6 weeks):</p> <ul style="list-style-type: none"> <li>• Patient-generated short term action plan (ASMP)</li> <li>• Interactive session including; lectures, group discussions, problem solving role plays and trying out skills introduced.</li> <li>• An overview of self-management principles,</li> <li>• Cognitive symptom management skills (distraction &amp; relaxation, managing depressive moods)</li> <li>• Skills for communicating with family members and health professionals,</li> <li>• Training in ADLs</li> <li>• Training in problem-solving skills and social skills</li> <li>• Counselling and therapy,</li> <li>• Social support</li> <li>• Exercise</li> <li>• Healthy eating.</li> </ul> <p>Led by: professional led, but further details not provided.</p> <p><b>Waiting list:</b> 6 week control period, followed by the post-control period assessment./ All received an identical programme to the</p>	<p>Chronic knee pain, aged &gt;60</p> <p>Mean age 71.5 years</p> <p>Duration of pain at least 3 months</p>	<p>At 7 weeks:</p> <ul style="list-style-type: none"> <li>• Health related quality of life</li> <li>• Physical function</li> <li>• Pain self-efficacy</li> <li>• Pain reduction</li> <li>• Discontinuation</li> </ul>	

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		participants in the control group, within one week after the assessment.			
<b>Laforest 2008</b> <sup>205</sup>	<p><b>Intervention:</b> Professional led self-management programme (n=65)</p> <p><b>Comparison:</b> Control group, no details provided (n=48)</p>	<p><b>I'm taking charge of my arthritis! Programme</b></p> <p>Weekly 1 hour individual home visits by a healthcare professional over 6 weeks</p> <ul style="list-style-type: none"> <li>• Life with arthritis – basic principles of management and intro to personal contract.</li> <li>• Physical exercises and relaxation techniques.</li> <li>• Managing pain and stiffness, including how to manage medication.</li> <li>• Positive thinking, managing emotions, easing loneliness and distraction techniques.</li> <li>• Managing energy – sleeping and eating well.</li> <li>• Building partnerships with health professionals.</li> </ul> <p>Led by: occupational therapists, physical therapists, social workers and kinesiologists.</p> <p><b>Control group</b> No details provided</p>	<p>Osteo- or rheumatoid arthritis</p> <p>Age: ≥50 years (average 78 years)</p> <p>Duration of pain: not reported.</p>	<p>At 8 weeks:</p> <ul style="list-style-type: none"> <li>• Physical function</li> <li>• Pain reduction</li> <li>• Discontinuation</li> </ul>	<p>Housebound an inclusion criterion</p> <p>Study reports physical function measured by WOMAC - average score on a 5 point scale was calculated, but online resources and other studies indicate that the physical function subscale should be 0-68. Unclear outcome. Therefore, not included in the analysis.</p>
<b>Martin 2012</b> <sup>236</sup> <b>Martin 2014</b> <sup>238</sup> <b>Martin 2014</b> <sup>237</sup>	<p><b>Intervention:</b> Professional led self-management programme (n=90)</p> <p><b>Comparison:</b> Standard</p>	<p><b>PMP</b> (2 sessions per week for 6 weeks):</p> <ul style="list-style-type: none"> <li>• Psychological component: CBT by qualified psychologist including cognitive, physiological and behavioural components aimed to identify and change negative thoughts, improve coping, and training on breathing and muscle relaxation. Training on assertiveness and communication skills was also given, as well as pacing of activities.</li> </ul>	<p>Fibromyalgia</p> <p>Mean age 50 years</p> <p>Pain duration 14 years</p>	<p>At 6 months:</p> <p>Quality of life</p> <p>Psychological distress</p>	

Study	Intervention and comparison	Details	Population	Outcomes	Comments
	pharmacologic care (n=90)	<ul style="list-style-type: none"> <li>• Group sessions (12 people or less): practical exercises and other activities on the topic of the day covered, practical breathing and relaxation exercises, explanation of tasks to do at home.</li> <li>• Physiotherapy: Warming and stretching exercises with a regular exercise programme given.</li> <li>• Educational component: characteristics of fibromyalgia and its nature, course, appropriate organisation of day-to-day life, physician-patient relationship.</li> <li>• Pharmacological treatment (same as control).</li> </ul> <p>Led by: Physician, clinical psychologist and a physiotherapist experienced in chronic pain management.</p> <p><b>Comparison:</b> Medication included amitriptyline, maximum dose of 75mg/24h), an analgesic (paracetamol, maximum dose of 4gr/24h), and an opioid central analgesic (tramadol, maximum dose of 400mg/24h).</p>			
<b>McBeth 2012<sup>240</sup>, Beasley 2015<sup>24</sup></b>	<p><b>Intervention:</b> Professional led widespread chronic pain management (n=112)</p> <p><b>Comparison:</b> treatment as usual (n=109)</p>	<p><b>MUSICIAN trial:</b> Telephone delivered CBT: Following an initial assessment (45-60 minutes): 7 weekly sessions (each 30-45 minutes long), and 1 session 3 months and 1 session 6 months after randomization. Patients defined their own goals and programme was tailored accordingly. Patients received a self-management CBT manual, "Managing Chronic Widespread Pain."</p>	<p>Chronic fibromyalgia for which a doctor had been consulted within the past year</p> <p>Mean age, 56 (13) years</p>	<p>At 9 months:</p> <ul style="list-style-type: none"> <li>• Quality of life</li> <li>• Sleep</li> </ul>	4 armed trial: telephone CBT, exercise, combined intervention, treatment as usual

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		<p>Exercise module: Following an induction session, patients were offered 6 fitness instructor-led monthly appointments. Exercise intensity increased until exercise levels were sufficient to achieve 40% to 85% of heart rate reserve. Exercises were negotiated with instructor rather than being prescribed. Instructors received 1 day training and communicated with CBT staff.</p> <p>Led by: 4 therapists accredited by the British Association for Behaviour and Cognitive Psychotherapies</p> <p><b>Comparison:</b> Treatment as usual</p>	Duration of pain not reported		
<b>Mehlsen 2017<sup>244</sup></b>	<p><b>Intervention:</b> Stanford chronic pain self-management programme (peer led) (n=216)</p> <p><b>Comparison:</b> treatment as usual (n=208)</p>	<p><b>Chronic pain self-management programme:</b> 6, 2 ½ hour weekly workshops focusing on how to manage pain in daily life, groups of 8-16. A manual is followed to deliver the process. Themes encompass:</p> <ul style="list-style-type: none"> <li>• Managing feelings such as frustration, anger and depression;</li> <li>• Managing fatigue, social isolation and poor sleep quality;</li> <li>• Improving and maintaining strength, flexibility and endurance; correct use of medication;</li> <li>• Effective communication;</li> <li>• Nutrition;</li> <li>• Pacing and evaluation of new treatment possibilities.</li> </ul>	<p>Any chronic pain aetiology</p> <p>Mean age, 54.5 years, range 25-93 years</p> <p>Duration of pain: at least 3 months, mean 8.85 years, range 0-50 years</p>	<p>At 6 weeks and 5 months:</p> <ul style="list-style-type: none"> <li>• Physical function</li> <li>• Psychological distress</li> <li>• Pain reduction</li> <li>• Pain self-efficacy</li> <li>• Healthcare resource use</li> </ul>	<p>Recruitment from municipal health support centres in Denmark. Courses delivered within these centres.</p> <p>Workshop leaders receive 4 days of intensive, structured training overseen by master trainers who are certified to educate workshop leaders.</p> <p>Study also reported pain self-efficacy measured by a self-</p>

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		<p>Includes lectures and exercises in light physical activity, visualisation, relaxation and communication. Instruction focus on how to implement these exercises at home and implementing action plans which they perform on a weekly basis.</p> <p>Led by: Lay led, facilitated by 2 workshop leaders of whom at least 1 also suffers from a long-term pain condition, the other may suffer from a pain condition, other long-term condition or be a close relative to a person with a long-term condition.</p> <p><b>Treatment as usual:</b> no restriction in terms of access to usual treatment or new interventions. Could not join pain management programmes in their municipality until 5 months after the first session of the course. After this time they could sign up, but were not automatically offered participation.</p>			efficacy scale 'inspired by the Arthritis Self-Efficacy Scale'. Not validated, so not included in the analysis.
Miller 2020 248	<p><b>Intervention:</b> Professional led pain management programme (n=50)</p> <p><b>Comparison:</b> Waiting list control (n=52)</p>	<p><b>COMMENCE (chronic pain self-management support with pain science education and exercise)</b> (1 1.5 h group session and 1 30-45 min 1:1 session per week for 6 weeks):</p> <ul style="list-style-type: none"> <li>education about self-management (strategies included progressive goal setting, activity scheduling, thought monitoring, relaxation, sleep education, reflection, self-monitoring, graded activity and exercise)</li> </ul>	<p>Chronic non-cancer pain</p> <p>Mean age (SD): intervention group 53.4 (13.5), wait list group 52.2 (11.7) years</p> <p>Duration of pain (median (IQR)): intervention group 120 (59-201), wait</p>	<p>At 7 and 18 weeks:</p> <ul style="list-style-type: none"> <li>Physical function</li> <li>Psychological distress</li> <li>Pain reduction</li> <li>Pain interference</li> <li>Pain self-efficacy</li> <li>Healthcare resource use</li> </ul>	

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		<ul style="list-style-type: none"> <li>• education about pain science (function of nervous system, other systems involved in pain, neuroplasticity, etc.)</li> <li>• education about cognitive behavioural principles to support behaviour change</li> <li>• 1:1 visits to support implementation of self-management plans and development of an exercise program tailored to participants' goals and abilities</li> <li>• 3 types of exercises encouraged: frequent pain-free movement, exercises that simulate functional tasks needed to perform goals, and regular aerobic exercise</li> <li>• also completed a program workbook and encouraged to continue self-management plans beyond the intervention</li> </ul> <p>Led by: a single trained physiotherapist</p> <p><b>Control group:</b> Waiting list - usual care most often included medication management, advice to stay active and referral to a specialist where appropriate</p>	<p>list group 120 (37-228) months</p>		
<p><b>Nicholas 2013</b><sup>263</sup></p>	<p><b>Intervention:</b> Professional led pain management programme (n=49)</p> <p><b>Comparison:</b> Waiting list control (n=39)</p>	<p><b>Pain management programme</b> (8 2h sessions, over 4 weeks):</p> <ul style="list-style-type: none"> <li>• Self-management reading texts</li> <li>• Psychological sessions (coping strategies, goals of management, sleep management)</li> <li>• Exercise sessions (relaxation, stretching, functional exercises)</li> </ul>	<p>Chronic pain conditions (non-cancer pain for more than 6 months)</p> <p>Mean age 73.9 years.</p> <p>Mean pain duration 6 years</p>	<p>At 4 weeks:</p> <ul style="list-style-type: none"> <li>• Physical functioning</li> <li>• Psychological distress</li> <li>• Pain self-efficacy</li> <li>• Pain reduction</li> <li>• Discontinuation</li> </ul>	

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		<ul style="list-style-type: none"> <li>Education: discussions of mechanisms of chronic pain</li> </ul> <p>Led by: Psychologist and physiotherapist</p> <p>Control group: no further details</p>			
<b>Peters 1990</b> <sup>280</sup>	<p><b>Intervention:</b> Professional led inpatient and outpatient pain management programmes (n=62)</p> <p><b>Comparison:</b> Control group (received standard medical treatment but unable to participate in pain-management programme) (n=23)</p>	<p><b>Inpatient programme</b> (4 weeks):</p> <ul style="list-style-type: none"> <li>CBT with education on pain and strategies to reduce the impact of pain, and relaxation strategies</li> <li>Exercise component (speed walking, swimming, stationary cycling) and biomechanics education</li> <li>Medication management with reduction if appropriate</li> <li>Staff support</li> </ul> <p>Led by: Multidisciplinary team (psychiatrist, medical and nursing staff, psychologist, occupational therapists, physiotherapist, vocational rehabilitation officer)</p> <p><b>Outpatient programme:</b> 9 weekly sessions, maximum of 10 patients to each programme: education (no further details) practical advice on increasing exercise medication management relaxation training</p> <p>Led by: Occupational therapists with contributions from a psychiatrist, rheumatologist, physiotherapist and nursing staff.</p>	<p>Non-malignant pain of more than 6 months duration</p> <p>Mean age not stated</p> <p>Majority of participants had pain for 1 year or more</p>	<p>At 4-9 weeks:</p> <ul style="list-style-type: none"> <li>Psychological distress</li> <li>Pain reduction</li> <li>Discontinuation</li> </ul>	

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		Control group: Standard medical treatment through the outpatient pain clinic if required			
<b>Smeets 2006</b> , <sup>306</sup> <b>Smeets 2006</b> <sup>307</sup> & <b>Smeets 2008</b> <sup>305</sup>	<b>Intervention:</b> Combined active physical treatment and cognitive behavioural treatment (n=61)  <b>Comparison:</b> Waiting list (n=51)	<b>Combined active physical treatment and cognitive behavioural treatment</b> 19 sessions with a total duration of 11 hours <ul style="list-style-type: none"> <li>Active physical treatment including 30 minutes of aerobic bicycle training and 75 minutes of strength and endurance training 3 times per week for 10 weeks, supervised by physiotherapists.</li> <li>CBT consisting of operant behavioural graded activity techniques and problem solving training.</li> <li>Graded activity started with 3 group sessions followed by a maximum of 17 30 minute individual sessions; daily performance graphically registered in a personal diary and discussed regularly.</li> <li>Problem solving training – 10 1.5 hour sessions, max 4 patients. Course book with additional information, session summaries and homework.</li> <li>Integration of APT, GA and PST; e.g. patients told that parallel increase in fitness expected to facilitate graded activity and therapists delivering APT periodically asked patients to present performance graphs.</li> </ul> <p>Led by: physiotherapists, psychologist and social worker.</p> <p>Waiting list</p>	Chronic low back pain  Age: 18-65 years (average 42 years)  Duration of pain: Intervention 56.2 (70.6) months, control 44.7 (72.1) months	At 10 weeks: <ul style="list-style-type: none"> <li>Physical function</li> <li>Psychological distress</li> <li>Pain reduction</li> <li>Discontinuation</li> </ul>	4 armed trial: active physical treatment, CBT, combined treatment, waiting list  Study also reports use of healthcare services, but unclear outcome so not extracted (percentages and unclear total numbers)

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		Patients requested to wait 10 weeks after which they were offered individual rehabilitation. Not allowed to participate in diagnostic or therapeutic procedures during this time.			
<b>Smith 2019</b> <sup>308</sup>	<p><b>Intervention:</b> Reboot Online (n=45)</p> <p><b>Comparison:</b> Usual care (n=46)</p>	<p><b>Professional led online pain management programme</b> 8 online sessions over 16 weeks.</p> <ul style="list-style-type: none"> <li>• Illustrated story of a fictional character, who learns to self-manage her chronic pain using a multidisciplinary approach.</li> <li>• Educational video content incorporated specialist information from pain medicine, rehabilitation medicine, psychiatry, anaesthetics, rheumatology, and radiology; in addition to allied health disciplines.</li> <li>• Core physiotherapy and psychotherapy modules embedded in each lesson and combined with a graded exercise program focusing on activity and exercise reactivation within pacing and goal-setting. This was coupled with evidence-based CBT skills including thought challenging, activity planning, problem solving, effective communication and flare-up management.</li> <li>• Access to downloadable lesson homework summaries, 'Extra information and resources' (PDFS), 'Expert videos' from a wide range of pain management specialists and audio-recordings including 15-30 minute relaxation files.</li> <li>• DVD demonstrating a graded Tai Chi program with instructions from a physiotherapist.</li> </ul>	<p>Chronic pain</p> <p>Age: Mean (SD): 45 (13.86) years</p> <p>Duration of pain: 59% had pain for &gt;5 years</p>	<p>At 28 weeks:</p> <ul style="list-style-type: none"> <li>• Psychological distress</li> <li>• Pain interference</li> <li>• Pain self-efficacy</li> <li>• Pain reduction</li> </ul>	

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		<ul style="list-style-type: none"> <li>Graded exercise component whereby a physiotherapist narrated a series of videos of an actor performing an exercise and the patient was instructed to repeat the exercise then move on to the next step within gradual pacing guidelines. The patient was asked to select their own cardiovascular exercise (e.g. swimming, walking), again increasing with gradual pacing.</li> <li>Regular automatic and manual email communication to notify them that a lesson was available and encourage completion.</li> </ul> <p><b>Usual care</b> Continued with treatments already commenced at intake assessment and permitted to engage in any new interventions for chronic pain management during the study.</p>			
<b>Tavafian 2007</b> <sup>318</sup>	<p><b>Intervention:</b> Professional led back school programme (n=50)</p> <p><b>Comparison:</b> Clinic (n=52)</p>	<p><b>Professional led back school programme</b> 4-day, 5-session programme</p> <ul style="list-style-type: none"> <li>Assessment of knowledge, perceptions and beliefs concerning health, non-healthy behaviors and approaches and motivation to changing non-healthy behaviour.</li> <li>Psychological evaluations and focus on individual coping skills, anger management and relaxation.</li> <li>Back school classes, including anatomy and physiology of the spine</li> <li>Instruction in the natural history of spinal conditions, lifestyle factors that accelerate chronic low back pain and techniques for preventing further injury.</li> </ul>	<p>Women with chronic back pain</p> <p>Age: ≥18 years (intervention 42.9 (10.7) years, clinic 44.7 (10.8) years)</p> <p>Duration of pain: intervention 8.9 (3.2) months, clinic 9.2 (3.2) months</p>	<p>At 3 months:</p> <ul style="list-style-type: none"> <li>Quality of life</li> <li>Discontinuation</li> </ul>	

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		<ul style="list-style-type: none"> <li>• Instruction in lumbar stabilization, body mechanics and prevention techniques.</li> <li>• Weight-bearing exercise and optimal aerobic fitness programme.</li> </ul> <p>Led by: PhD level educator, clinical psychologist, rheumatologist, physical therapist.</p> <p><b>Clinic</b> Received only medication under the supervision of a leading physician</p> <p>Medication for both groups was the same (Acetaminophen, NSAID, and Chlordiazepoxide)</p>			
<b>Tavafian 2011</b> <sup>319</sup>	<p><b>Intervention:</b> Professional-led PMP (n=97)</p> <p><b>Comparison:</b> Oral drug treatment only (both groups received oral drug treatment) (n=100)</p>	<p><b>Group based rehabilitation programme</b> (5 classes over 1 week followed by 1 month of motivational conversations)</p> <p>Covered biological and psychosocial aspects of pain. Classes were in anatomy, physiology, lifestyle, pain prevention techniques, posture, stretching, strengthening, risk factors, coping with stress and threatening events, emotional regulation strategies and CBT. A core leader took questions to any experts who were not in attendance.</p> <p>Led by staff from different specialities.</p>	<p>Low back Pain &gt;90 days</p> <p>Mean age 49</p>	<p>At 3 and 6 months:</p> <ul style="list-style-type: none"> <li>• Quality of life</li> <li>• Physical functioning</li> <li>• Pain reduction</li> <li>• Discontinuation</li> </ul>	Delivered in Iran
<b>van Eijk-Hustings 2013</b> <sup>337</sup>	<p><b>Intervention:</b> Professional led multidisciplinary</p>	<p><b>Professional led multidisciplinary programme</b> 1 year programme</p>	<p>Fibromyalgia</p> <p>Age 18-65 years (intervention 41.6</p>	<p>At 12 weeks and 21 months:</p> <ul style="list-style-type: none"> <li>• Quality of life</li> </ul>	3 arm trial including an aerobic exercise group (n=47)

Study	Intervention and comparison	Details	Population	Outcomes	Comments
	<p>programme (n=108)</p> <p><b>Comparison:</b> Usual care (n=48)</p>	<p>Phase 1 – 12 weeks course 3 half days per week with 2 therapy sessions of 1.5 hr duration per day:</p> <ul style="list-style-type: none"> <li>• Socioterapy (twice a week, based on transactional analysis and aiming to increase social behaviour strategies and social support).</li> <li>• Physiotherapy (twice a week, based on graded activity and comprising aerobic exercise, strength training, relaxation etc.).</li> <li>• Psychotherapy (once a week, consisting of information about FM and pain mechanisms and using methods of core qualities, rational emotive therapy and transactional analysis).</li> <li>• Creative arts therapy (once a week, allowing expression of feeling through visual arts).</li> </ul> <p>Phase 2 – aftercare programme consisting of 5 meetings over 9 months:</p> <ul style="list-style-type: none"> <li>• repeat the key messages about coping in order to preserve the behavioural change achieved in phase 1.</li> <li>• maximum of 7 individual therapy sessions with one of the therapists could be scheduled if considered necessary.</li> </ul> <p><b>Usual care</b></p> <p>At least individualised education about FM and lifestyle advice by a rheumatologist or a specialised rheumatology nurse within one or two consultations, but could also include a diversity of other treatments such as physiotherapy or social support from the rheumatology nurse.</p>	<p>(8.8) years, control 42.9 (11) years)</p> <p>Duration of pain: 7.1 (6.8) years, 7.1 (6.4) years)</p>	<ul style="list-style-type: none"> <li>• Physical functioning</li> <li>• Psychological distress</li> <li>• Sleep</li> <li>• Pain reduction</li> <li>• Use of healthcare services</li> <li>• Discontinuation</li> </ul>	

Study	Intervention and comparison	Details	Population	Outcomes	Comments
van Koulil 2010 <sup>339</sup>	<p><b>Intervention:</b> Professional led tailored treatment programme (n=68)</p> <p><b>Comparator:</b> Waiting list (n=90)</p>	<p><b>Tailored treatment:</b> 16 sessions over 10 weeks of CBT and exercise training in groups of 8, tailored to individual's specific cognitive-behavioural pattern. 1 booster session was held 3 months after treatment completion.</p> <ul style="list-style-type: none"> <li>• Each session started with 2 hours of CBT followed by 2 hours of exercise training.</li> <li>• The participant's partner (or other significant relation) attended 3<sup>rd</sup>, 9<sup>th</sup> and 15<sup>th</sup> session.</li> <li>• Pain persistence and pain avoidance groups differed slightly, but for both CBT was aimed at diminishing the daily perceived cognitive, behavioural, emotional and social consequences of pain and accompanying symptoms.</li> <li>• Exercise training was aimed at increasing physical fitness and flexibility. Each session consisted of relaxation training, aerobic exercises and hydrotherapy or anaerobic exercises.</li> <li>• Participants received consolidating homework assignments to perform exercises at home, work on individual goals and reading texts for 1.5 hours a day.</li> </ul> <p>Led by: CBT by cognitive-behavioural therapists (a psychotherapist and a social worker) and exercise by physiotherapists.</p> <p><b>Waiting list:</b> no further detail provided.</p>	<p>Fibromyalgia with high risk profile of heightening psychological distress</p> <p>Mean age 41.7 years</p> <p>Duration of pain: not stated</p>	<p>At 10 weeks 6 months:</p> <ul style="list-style-type: none"> <li>• Quality of life</li> <li>• Psychological distress</li> <li>• Discontinuation</li> </ul>	<p>Outpatient setting</p> <p>Recruitment included identifying people at high risk of psychological distress, and then assigning to a pain-avoidance or pain-persistence group and then cluster randomised. These groups have been combined for analysis in this review.</p> <p>Study also reports physical function, assessed using a combination of 3 subscales from other assessment measures. This is not extracted here due to not being a validated measure.</p>

Study	Intervention and comparison	Details	Population	Outcomes	Comments
<b>Williams 1996</b> <sup>347</sup>	<p><b>Intervention 1:</b> Professional led inpatient cognitive behavioural pain management programme (n=43)</p> <p><b>Intervention 2:</b> Professional led outpatient cognitive behavioural pain management programme (n=45)</p> <p><b>Comparison:</b> Waiting list (n=33)</p>	<p><b>Professional led inpatient cognitive behavioural pain management programme</b> 4.5 days per week for 4 weeks, returning home at weekends</p> <ul style="list-style-type: none"> <li>• Exercise and stretch increasing gradually on a quota system.</li> <li>• Goal setting covering work, leisure, social pursuits and domestic duties.</li> <li>• Pacing of activities – regular schedule of activities and breaks increasing on the quota system.</li> <li>• Education covering concepts of chronic and acute pain, medical/surgical treatments, disuse, sleep etc.</li> <li>• Cognitive and behavioural sessions on problem solving and cognitive techniques.</li> <li>• Drug reduction aiming for nil by discharge.</li> <li>• Relaxation technique.</li> <li>• Sleep hygiene techniques.</li> <li>• Relapse prevention using ‘setback plans’.</li> <li>• Family involvement by inviting spouses to attend part of the programme.</li> <li>• Teaching supported by a manual given to patients at the end.</li> </ul> <p><b>Professional led outpatient cognitive behavioural pain management programme</b> 3.5 hours per week for 8 weeks Programme components were the same as the inpatient programme.</p>	<p>Chronic pain</p> <p>Age: average 50 years</p> <p>Duration of pain: inpatient group 100 (80) months outpatient group 93(85) months waiting list group 87 (80) months</p>	<p>At 8 weeks:</p> <ul style="list-style-type: none"> <li>• Physical function</li> <li>• Psychological distress</li> <li>• Pain self-efficacy</li> <li>• Pain reduction</li> <li>• Discontinuation</li> </ul>	

Study	Intervention and comparison	Details	Population	Outcomes	Comments
		<p>Led by: unit staffed by a consultant anaesthetist, 2 clinical psychologists, a physiotherapist, an occupational therapist and a senior nurse.</p> <p><b>Waiting list</b> No new treatments initiated during the study programme period and then entered the programme as non-randomised patients</p>			

1 **1.4.4 Quality assessment of clinical studies included in the evidence review**

2 **Table 3: Clinical evidence summary: Professional led pain or combination of professional and peer led management programmes**  
3 **vs. standard care/waiting list**

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Professionally led pain management programme (95% CI)
Quality of life SF36 Physical component final values (high is good outcome) ≤12 weeks. Scale from: 0 to 100.	46 (1 study) 7 weeks	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	The mean quality of life in the control groups was 38.04	The mean quality of life in the intervention groups was 6.02 higher (2.09 to 9.95 higher)
Quality of life SF12 Physical component final values (high is good outcome) ≤12 weeks. Scale from: 0 to 100.	43 (1 study) 11 weeks	⊕⊖⊖⊖ VERY LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean quality of life in the control groups was 29.41	The mean quality of life in the intervention groups was 1.14 higher (4.63 lower to 6.91 higher)
Quality of life SF36 Mental component final values (high is good outcome) ≤12 weeks. Scale from: 0 to 100.	46 (1 study) 7 weeks	⊕⊖⊖⊖ VERY LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean quality of life in the control groups was 51.24	The mean quality of life in the intervention groups was 3.81 higher (3.02 lower to 10.64 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Professionally led pain management programme (95% CI)
Quality of life SF12 Mental component final values (high is good outcome) ≤12 weeks. Scale from: 0 to 100.	43 (1 study) 11 weeks	⊕⊕⊕⊕ VERY LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean quality of life in the control groups was 39.07	The mean quality of life in the intervention groups was 1.67 higher (4.23 lower to 7.57 higher)
Quality of life SF36 Physical component change scores (high is good outcome) >12 weeks. Scale from: 0 to 100.	170 (1 study) 6 months	⊕⊕⊕⊕ MODERATE <sup>1</sup> due to risk of bias, imprecision	-	The mean change in quality of life in the control groups was 0.78	The mean change in quality of life in the intervention groups was 0.57 higher (0.94 lower to 2.08 higher)
Quality of life SF12 Physical component final values (high is good outcome) >12 weeks. Scale from: 0 to 100.	43 (1 study) 6 months	⊕⊕⊕⊕ VERY LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean quality of life in the control groups was 28.65	The mean quality of life in the intervention groups was 1.84 higher (3.24 lower to 6.92 higher)
Quality of life SF36 Mental component change scores (high is good outcome) >12 weeks. Scale from: 0 to 100.	170 (1 study) 6 months	⊕⊕⊕⊕ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean change in quality of life in the control groups was 1.15	The mean change in quality of life in the intervention groups was 1.14 higher (1.48 lower to 3.76 higher)
Quality of life SF12 Mental component final values (high is good outcome) >12 weeks. Scale from: 0 to 100.	43 (1 study) 6 months	⊕⊕⊕⊕ VERY LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean quality of life in the control groups was 37.59	The mean quality of life in the intervention groups was 3.16 higher (2.93 lower to 9.25 higher)
Quality of life SF36 Physical function final values (high is good outcome) ≤12 weeks. Scale from: 0 to 100.	390 (3 studies) 1-3 months	⊕⊕⊕⊕ VERY LOW <sup>1,2,3</sup> due to risk of bias, inconsistency, imprecision	-	The mean quality of life in the control groups was 57.84	The mean quality of life in the intervention groups was 10.37 higher (2.70 lower to 23.44 higher)
Quality of life SF36 Physical role final values (high is good outcome) ≤12 weeks. Scale from: 0 to 100.	391 (3 studies) 1-3 months	⊕⊕⊕⊕ VERY LOW <sup>1,3</sup>	-	The mean quality of life in the control	The mean quality of life in the intervention groups was

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Professionally led pain management programme (95% CI)
		due to risk of bias, inconsistency		groups was 30.33	21.51 higher (3.64 to 39.37 higher)
Quality of life SF36 Bodily pain final values (high is good outcome) ≤12 weeks. Scale from: 0 to 100.	391 (3 studies) 1-3 months	⊕⊕⊕⊕ VERY LOW <sup>1,2,3</sup> due to risk of bias, inconsistency, imprecision	-	The mean quality of life in the control groups was 47.23	The mean quality of life in the intervention groups was 8.41 higher (2.27 to 14.55 higher)
Quality of life SF36 General health final values (high is good outcome) ≤12 weeks . Scale from: 0 to 100.	390 (3 studies) 1-3 months	⊕⊕⊕⊕ VERY LOW <sup>1,2,3</sup> due to risk of bias, inconsistency, imprecision	-	The mean quality of life in the control groups was 51.22	The mean quality of life in the intervention groups was 5.54 higher (3.93 lower to 15.02 higher)
Quality of life SF36 Vitality final values (high is good outcome) ≤12 weeks. Scale from: 0 to 100.	391 (3 studies) 1-3 months	⊕⊕⊕⊕ VERY LOW <sup>1,2,3</sup> due to risk of bias, inconsistency, imprecision	-	The mean quality of life in the control groups was 50.4	The mean quality of life in the intervention groups was 7.34 higher (0.02 to 14.66 higher)
Quality of life SF36 Social functioning final values (high is good outcome) ≤12 weeks. Scale from: 0 to 100.	391 (3 studies) 1-3 months	⊕⊕⊕⊕ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean quality of life in the control groups was 60.43	The mean quality of life in the intervention groups was 9.4 higher (2.37 to 16.42 higher)
Quality of life SF36 Emotional role final values (high is good outcome) ≤12 weeks. Scale from: 0 to 100.	391 (3 studies) 1-3 months	⊕⊕⊕⊕ VERY LOW <sup>1,2,3</sup> due to risk of bias, inconsistency, imprecision	-	The mean quality of life in the control groups was 42.27	The mean quality of life in the intervention groups was 16.74 higher (3.37 lower to 36.86 higher)
Quality of life SF36 Mental health final values (high is good outcome) ≤12 weeks. Scale from: 0 to 100.	391 (3 studies) 1-3 months	⊕⊕⊕⊕ VERY LOW <sup>1,2,3</sup> due to risk of bias,	-	The mean quality of life in the control groups was 58.87	The mean quality of life in the intervention groups was 8.52 higher (1.23 lower to 18.26 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Professionally led pain management programme (95% CI)
		inconsistency, imprecision			
Quality of life SF36 Physical function final values (high is good outcome) >12 weeks. Scale from: 0 to 100.	299 (2 studies) 6-19 months	⊕⊕⊖⊖ LOW <sup>1,3</sup> due to risk of bias, inconsistency	-	The mean quality of life in the control groups was 60.25	The mean quality of life in the intervention groups was 10.52 higher (5.74 to 15.31 higher)
Quality of life SF36 Physical role final values (high is good outcome) >12 weeks. Scale from: 0 to 100.	299 (2 studies) 6-19 months	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	The mean quality of life in the control groups was 32.45	The mean quality of life in the intervention groups was 18.63 higher (10.15 to 27.10 higher)
Quality of life SF36 Bodily pain final values (high is good outcome) >12 weeks. Scale from: 0 to 100.	299 (2 studies) 6-19 months	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	The mean quality of life in the control groups was 45.62	The mean quality of life in the intervention groups was 11.85 higher (6.71 to 16.99 higher)
Quality of life SF36 General health final values (high is good outcome) >12 weeks. Scale from: 0 to 100.	299 (2 studies) 6-19 months	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	The mean quality of life in the control groups was 49.95	The mean quality of life in the intervention groups was 7.46 higher (2.28 to 12.63 higher)
Quality of life SF36 Vitality final values (high is good outcome) >12 weeks. Scale from: 0 to 100.	299 (2 studies) 6-19 months	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	The mean quality of life in the control groups was 46.6	The mean quality of life in the intervention groups was 7.47 higher (2.27 to 12.67 higher)
Quality of life SF36 Social functioning final values (high is good outcome) >12 weeks. Scale from: 0 to 100.	299 (2 studies) 6-19 months	⊕⊕⊖⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean quality of life in the control groups was 66.1	The mean quality of life in the intervention groups was 7.59 higher (1.69 to 13.48 higher)
Quality of life SF36 Emotional role final values (high is good outcome) >12 weeks. Scale from: 0 to 100.	299 (2 studies) 6-19 months	⊕⊕⊖⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean quality of life in the control groups was 50.35	The mean quality of life in the intervention groups was 10.52 higher (0.03 to 21 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Professionally led pain management programme (95% CI)
Quality of life SF36 Mental health final values (high is good outcome) >12 weeks. Scale from: 0 to 100.	299 (2 studies) 6-19 months	⊕⊕⊖⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean quality of life in the control groups was 60.15	The mean quality of life in the intervention groups was 5.34 higher (0.01 lower to 10.68 higher)
Quality of life FIQ final values (high is poor outcome) ≤12 weeks. Scale from: 0 to 100.	298 (2 studies) 10-12 weeks	⊕⊕⊖⊖ LOW <sup>1</sup> due to risk of bias	-	The mean quality of life in the control groups was 62.2	The mean quality of life in the intervention groups was 14.28 lower (18.01 to 10.55 lower)
Quality of life FIQ final values (high is poor outcome) >12 weeks. Scale from: 0 to 100.	401 (3 studies) 6-13 months	⊕⊕⊖⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean quality of life in the control groups was 68.1	The mean quality of life in the intervention groups was 9.71 lower (13.09 to 6.33 lower)
Quality of life EQ-5D final values (high is good outcome) ≤12 weeks. Scale from: 0 to 1.	156 (1 study) 3 months	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias,	-	The mean quality of life in the control groups was 0.5	The mean quality of life in the intervention groups was 0.01 higher (0.11 lower to 0.09 higher)
Quality of life EQ-5D final values (high is good outcome) >12 weeks. Scale from: 0 to 1.	329 (2 studies) 9-21 months	⊕⊕⊖⊖ LOW <sup>1</sup> due to risk of bias	-	The mean quality of life in the control groups was 0.58	The mean quality of life in the intervention groups was 0.05 higher (0.01 lower to 0.11 higher)
Quality of life EQ-5D VAS (high is good outcome), final values ≤12 weeks. Scale from: 0 to 100.	156 (1 study) 3 months	⊕⊕⊖⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean quality of life in the control groups was 48.3	The mean quality of life in the intervention groups was 5.7 higher (1.1 lower to 12.5 higher)
Quality of life EQ-5D VAS (high is good outcome), final values >12 weeks. Scale from: 0 to 100.	115 (1 study) 21 months	⊕⊕⊖⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean quality of life in the control groups was 51.9	The mean quality of life in the intervention groups was 5.4 higher (2.48 lower to 13.28 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Professionally led pain management programme (95% CI)
Quality of life (inpatient PMP) FIQ (high is poor outcome) final values ≤12 weeks. Scale from: 0 to 100.	118 (1 study) 4 weeks	⊕⊕⊕⊖ LOW <sup>1</sup> due to risk of bias	-	The mean quality of life in the control groups was 61	The mean quality of life in the intervention groups was 5.1 lower (65.61 lower to 55.41 higher)
Physical function Roland Morris Disability Questionnaire (high is poor outcome), final values ≤12 weeks. Scale from: 0 to 24.	518 (3 studies) 7-12 weeks	⊕⊕⊕⊖ LOW <sup>1</sup> due to risk of bias	-	The mean physical function in the control groups was 11.48	The mean physical function in the intervention groups was 1.41 lower (2.3 to 0.52 lower)
Physical function Western Ontario and McMaster Universities Osteoarthritis Index (high is poor outcome) change scores ≤12 weeks. Scale from: 0 to 68.	197 (1 study) 3 months	⊕⊖⊖⊖ VERY LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean physical function in the control groups was 0.53	The mean physical function in the intervention groups was 2.99 lower (5.68 to 0.3 lower)
Physical function FIQ physical function subscale final values (high is poor outcome) ≤12 weeks. Scale from: 0 to 10.	156 (1 study) 3 months	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	The mean physical function in the control groups was 4	The mean physical function in the intervention groups was 0.1 lower (0.81 lower to 0.61 higher)
Physical function 6 minute walk test final values and change scores ≤12 weeks	118 (2 studies) 7-8 weeks	⊕⊖⊖⊖ VERY LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean physical function in the control groups was 306.06 metres	The mean physical function in the intervention groups was 45.2 higher (7.92 to 82.48 higher)
Physical function 10 minute walk test final values and change scores ≤12 weeks	61 (1 study) 8 weeks	⊕⊕⊕⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean physical function in the control groups was 482 metres	The mean physical function in the intervention groups was 49 higher (69.52 lower to 167.52 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Professionally led pain management programme (95% CI)
Physical function Short musculoskeletal function assessment – dysfunction index final values (high is poor outcome) ≤12 weeks. Scale from: 34-170.	92 (1 study) 7 weeks	⊕⊕⊖⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean physical function in the control groups was 44.1	The mean physical function in the intervention groups was 8.9 lower (15.3 to 2.5 lower)
Physical function Roland Morris Disability Questionnaire final values (high is poor outcome) >12 weeks. Scale from: 0 to 24.	405 (2 studies) 6-12 months	⊕⊕⊖⊖ LOW <sup>1</sup> due to risk of bias	-	The mean physical function in the control groups was 10.35	The mean physical function in the intervention groups was 0.99 lower (2.09 lower to 0.10 higher)
Physical function Western Ontario and McMaster Universities Osteoarthritis Index final values (high is poor outcome) >12 weeks. Scale from: 0 to 68.	207 (1 study) 21 months	⊕⊖⊖⊖ VERY LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean physical function in the control groups was 35.1	The mean physical function in the intervention groups was 5 lower (9.7 to 0.3 lower)
Physical function FIQ physical function subscale final values (high is poor outcome) >12 weeks. Scale from: 0 to 10.	156 (1 study) 21 months	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	The mean physical function in the control groups was 3.9	The mean physical function in the intervention groups was 0.3 lower (1.01 lower to 0.41 higher)
Physical function Short musculoskeletal function assessment – dysfunction index final values (high is poor outcome) >12 weeks. Scale from: 34-170.	80 (1 study) 18 weeks	⊕⊕⊖⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean physical function in the control groups was 43.2	The mean physical function in the intervention groups was 8 lower (14.7 to 1.3 lower)
Physical function (inpatient PMP) 10 minute walk test, final values ≤12 weeks	69 (1 study) 8 weeks	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	The mean physical function in the control groups was 482 metres	The mean physical function in the intervention groups was 188 higher (94.76 to 281.24 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Professionally led pain management programme (95% CI)
Psychological distress Depression Anxiety Stress Scale change scores (high is poor outcome) ≤ 12 weeks. Scale from: 0 to 42.	88 (1 study) 8 weeks	⊕⊕⊖⊖ LOW <sup>1</sup> due to risk of bias	-	The mean change in psychological distress in the control groups was -0.6	The mean change in psychological distress in the intervention groups was 0.88 higher (2.94 lower to 4.7 higher)
Psychological distress BDI (0-63), Geriatric Depression Scale (0-30), Patient health questionnaire depression (0-27) and FIQ depression subscale (0-10), high is poor outcome, final values ≤12 weeks	718 (7 studies) 7-12 weeks	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	-	The mean psychological distress in the intervention groups was 0.11 standard deviations lower (0.26 lower to 0.04 higher)
Psychological distress FIQ anxiety subscale 0-10, Impact of Rheumatic Diseases on General Health and Lifestyle anxiety scale 10-40 and State-Trait Anxiety Inventory 20-80 (high is poor outcome), final values ≤12 weeks	359 (3 studies) 8-12 weeks	⊕⊖⊖⊖ VERY LOW <sup>1,2,3</sup> due to risk of bias, inconsistency, imprecision	-	-	The mean psychological distress in the intervention groups was 0.32 standard deviations lower (0.68 lower to 0.03 higher)
Psychological distress Geriatric Depression Scale 0-30, BDI 0-63, HADS depression 0-21, FIQ depression subscale 0-10, Patient health questionnaire depression 0-27 (high is poor outcome), final values >12 weeks	606 (5 studies) 4.5-21 months	⊕⊕⊖⊖ LOW <sup>1</sup> due to risk of bias	-	-	The mean psychological distress in the intervention groups was 0.05 standard deviations lower (0.21 lower to 0.11 higher)
Psychological distress HADS anxiety 0-21, FIQ anxiety subscale 0-10 and Impact of Rheumatic Diseases on Health and Lifestyle anxiety scale 10-40 (high is poor outcome) final values >12 weeks	398 (3 studies) 6-21 months	⊕⊖⊖⊖ VERY LOW <sup>1,2,3</sup> due to risk of bias, inconsistency, imprecision	-	-	The mean psychological distress in the intervention groups was 0.34 standard deviations lower (0.88 lower to 0.2 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Professionally led pain management programme (95% CI)
Psychological distress GAD-10 anxiety change scores (high is poor outcome) >12 weeks. Scale from: 0 to 10.	183 (1 study) 6 months	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	The mean change in psychological distress in the control groups was -0.54	The mean change in psychological distress in the intervention groups was 0.24 lower (1.98 lower to 1.5 higher)
Psychological distress Kessler-10 psychological distress scale final values (high is poor outcome) >12 weeks. Scale from 10 to 50.	80 (1 study) 28 weeks	⊕⊖⊖⊖ VERY LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean psychological distress in the control groups was 19.95	The mean psychological distress in the intervention groups was 1.83 higher (1.18 lower to 4.84 higher)
Psychological distress (inpatient PMP) General Health Questionnaire (high is poor outcome) final values ≤12 weeks. Scale from: 0 to 60.	118 (1 study) 4 weeks	⊕⊕⊖⊖ LOW <sup>1</sup> due to risk of bias	-	The mean psychological distress in the control groups was 24.6	The mean psychological distress in the intervention groups was 0.4 higher (23.06 lower to 23.86 higher)
Psychological distress (inpatient PMP) BDI (high is poor outcome) final values ≤12 weeks. Scale from: 0 to 63.	114 (2 studies) 4-8 weeks	⊕⊖⊖⊖ VERY LOW <sup>1,2,3</sup> due to risk of bias, inconsistency, imprecision	-	The mean psychological distress in the control groups was 14.19	The mean psychological distress in the intervention groups was 3.72 lower (12.48 lower to 5.04 higher)
Psychological distress (inpatient PMP) State-Trait Anxiety Inventory (high is poor outcome), final values ≤12 weeks. Scale from: 20 to 80.	69 (1 study) 8 weeks	⊕⊕⊖⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean psychological distress in the control groups was 45	The mean psychological distress in the intervention groups was 8.2 lower (14.17 to 2.23 lower)
Pain interference BPI interference scale 0-10 and PROMIS pain interference 8-40 final values (high is poor outcome) ≤12 weeks.	359 (3 studies) 7-11 weeks	⊕⊕⊖⊖ LOW <sup>1</sup> due to risk of bias	-	-	The mean pain interference in the intervention groups was 0.1 standard deviations

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Professionally led pain management programme (95% CI)
					lower (0.3 lower to 0.11 higher)
Pain interference BPI interference scale 0-10 and PROMIS pain interference 8-40 final values (high is poor outcome) >12 weeks.	420 (4 studies) 4.5-12 months	⊕⊕⊕⊖ LOW <sup>1</sup> due to risk of bias	-	-	The mean pain interference in the intervention groups was 0.06 standard deviations lower (0.26 lower to 0.13 higher)
Pain interference (inpatient PMP) VAS (high is poor outcome) final values ≤12 weeks. Scale from: 0 to 100.	36 (1 study) 8 weeks	⊕⊖⊖⊖ VERY LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean pain interference in the control groups was 48.2	The mean pain interference in the intervention groups was 0.6 lower (14.23 lower to 13.03 higher)
Self-efficacy Pain Self-Efficacy Questionnaire final values and change scores (high is good outcome) ≤12 weeks. Scale from: 0 to 60.	271 (4 studies) 7-8 weeks	⊕⊕⊕⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean self-efficacy in the control groups was 32.26	The mean self-efficacy in the intervention groups was 6.11 higher (4.61 to 7.61 higher)
Self-efficacy Arthritis Self-Efficacy Scale change scores (high is good outcome) ≤12 weeks	192 (1 study) 3 months	⊕⊕⊕⊖ LOW <sup>1</sup> due to risk of bias	-	The mean self-efficacy in the control groups was 0.03	The mean self-efficacy in the intervention groups was 0.04 higher (0.13 lower to 0.21 higher)
Self-efficacy Pain Self-Efficacy Questionnaire final values and change scores (high is good outcome) >12 weeks. Scale from: 0 to 60.	330 (3 studies) 4.5-7 months	⊕⊖⊖⊖ VERY LOW <sup>1,2,3</sup> due to risk of bias, inconsistency, imprecision	-	The mean self-efficacy in the control groups was 29.73	The mean self-efficacy in the intervention groups was 4.49 higher (0.66 to 8.32 higher)
Self-efficacy Arthritis Self Efficacy Scale final values (high is good outcome) >12 weeks	195 (1 study) 21 months	⊕⊕⊕⊖ LOW <sup>1</sup> due to risk of bias	-	The mean self-efficacy in the control groups was 3.7	The mean self-efficacy in the intervention groups was 0.2 higher (0.04 lower to 0.44 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Professionally led pain management programme (95% CI)
Self-efficacy (inpatient PMP) Pain Self-Efficacy Questionnaire (high is good outcome), final values ≤12 weeks. Scale from: 0 to 60.	69 (1 study) 8 weeks	⊕⊕⊖⊖ LOW <sup>1</sup> due to risk of bias	-	The mean self-efficacy in the control groups was 26.7	The mean self-efficacy in the intervention groups was 12.4 higher (7.07 to 17.73 higher)
Self-efficacy (inpatient PMP) Arthritis Self-Efficacy Scale pain subscale (high is good outcome) final values ≤12 weeks. Scale from: 10 to 100.	118 (1 study) 4 weeks	⊕⊕⊖⊖ LOW <sup>1</sup> due to risk of bias	-	The mean self-efficacy in the control groups was 52.3	The mean self-efficacy in the intervention groups was 2.5 higher (53.7 lower to 58.7 higher)
Pain reduction NRS and VAS final values and change scores (high is poor outcome) ≤12 weeks. Scale from: 0 to 10.	1035 (10 studies) 7-12 weeks	⊕⊕⊖⊖ LOW <sup>1</sup> due to risk of bias	-	The mean pain score in the control groups was 6.2	The mean pain score in the intervention groups was 0.49 lower (0.74 to 0.24 lower)
Pain reduction NRS and VAS final values and change scores (high is poor outcome) >12 weeks. Scale from: 0 to 10.	1039 (8 studies) 4.5-27 months	⊕⊖⊖⊖ VERY LOW <sup>1,3</sup> due to risk of bias, inconsistency	-	The mean pain score in the control groups was 5.81	The mean pain score in the intervention groups was 0.2 lower (0.59 lower to 0.19 higher)
Pain reduction (inpatient PMP) VAS (high is bad outcome) final values ≤12 weeks. Scale from: 0 to 10.	150 (3 studies) 4-8 weeks	⊕⊕⊖⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean pain score in the control groups was 5.81	The mean pain score in the intervention groups was 0.69 lower (1.41 lower to 0.04 higher)
Sleep Chronic Pain Sleep Index (0-10, high is good outcome), MOS Sleep scale (12-71, high is good outcome) and FIQ unrefreshed sleep subscale (0-10, high is poor outcome, scale inverted for analysis), final values ≤12 weeks	354 (3 studies) 11-12 weeks	⊕⊖⊖⊖ VERY LOW <sup>1,2,3</sup> due to risk of bias, inconsistency, imprecision	-	-	The mean sleep in the intervention groups was 0.47 standard deviations higher (0.56 lower to 1.5 higher)
Sleep Chronic Pain Sleep Index (0-10, high is good outcome), MOS Sleep scale (12-71, high is good	554 (4 studies) 6-21 months	⊕⊖⊖⊖ VERY LOW <sup>1,2,3</sup> due to risk of bias,	-	-	The mean sleep in the intervention groups was 0.43 standard deviations

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Professionally led pain management programme (95% CI)
outcome), Sleep Scale (0-20, high is poor outcome, scale inverted for analysis) and FIQ unrefreshed sleep subscale (0-10, high is poor outcome, scale inverted for analysis), final values >12 weeks		inconsistency, imprecision			higher (0.12 to 0.74 higher)
Use of healthcare services Mean number of GP contacts within previous 2 months ≤12 weeks	156 (1 study) 3 months	⊕⊕⊖⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean use of healthcare services in the control groups was 0.5	The mean use of healthcare services in the intervention groups was 0.5 higher (0.21 lower to 1.21 higher)
Use of healthcare services Mean number of medical specialist contacts within previous 2 months ≤12 weeks	156 (1 study) 3 months	⊕⊕⊖⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean use of healthcare services in the control groups was 0.2	The mean use of healthcare services in the intervention groups was 0.1 lower (0.38 lower to 0.18 higher)
Use of healthcare services Mean number of physiotherapist contacts within previous 2 months ≤12 weeks	156 (1 study) 3 months	⊕⊕⊖⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean use of healthcare services in the control groups was 3.4	The mean use of healthcare services in the intervention groups was 1.2 lower (2.89 lower to 0.49 higher)
Use of healthcare services Mean number of other paramedical professional contacts within previous 2 months ≤12 weeks	156 (1 study) 3 months	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	The mean use of healthcare services in the control groups was 0.8	The mean use of healthcare services in the intervention groups was 0 higher (0.98 lower to 0.98 higher)
Use of healthcare services Mean number of GP contacts within previous 2 months >12 weeks	156 (1 study) 21 months	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	The mean use of healthcare services in the control groups was 0.7	The mean use of healthcare services in the intervention groups was 0.2 higher (0.51 lower to 0.91 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Professionally led pain management programme (95% CI)
Use of healthcare services Mean number of medical specialist contacts within previous 2 months >12 weeks	156 (1 study) 21 months	⊕⊕⊖⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean use of healthcare services in the control groups was 0.2	The mean use of healthcare services in the intervention groups was 0.1 higher (0.18 lower to 0.38 higher)
Use of healthcare services Mean number of physiotherapist contacts within previous 2 months >12 weeks	156 (1 study) 21 months	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	The mean use of healthcare services in the control groups was 2.8	The mean use of healthcare services in the intervention groups was 0.2 lower (1.89 lower to 1.49 higher)
Use of healthcare services Mean number of other paramedical professional contacts within previous 2 months >12 weeks	156 (1 study) 21 months	⊕⊕⊖⊖ LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean use of healthcare services in the control groups was 0.2	The mean use of healthcare services in the intervention groups was 0.8 higher (0.18 lower to 1.78 higher)
Use of healthcare services Mean number of MD and/or ED visits for pain care >12 weeks	24 (1 study) 12 months	⊕⊖⊖⊖ VERY LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean use of healthcare services in the control groups was 23.1	The mean use of healthcare services in the intervention groups was 18 lower (50.16 lower to 14.16 higher)
Use of healthcare services Mean number of primary care visits during the previous week >12 weeks	80 (1 study) 18 weeks	⊕⊕⊖⊖ LOW <sup>1</sup> due to risk of bias	-	The mean use of healthcare services in the control groups was 3.2	The mean use of healthcare services in the intervention groups was 0.27 lower (1.26 lower to 0.72 higher)
Use of healthcare services Mean number of emergency department visits during the previous week >12 weeks	80 (1 study) 18 weeks	⊕⊕⊖⊖ LOW <sup>1</sup> due to risk of bias	-	The mean use of healthcare services in the control groups was 0.2	The mean use of healthcare services in the intervention groups was 0.02 higher

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Professionally led pain management programme (95% CI)
					(0.23 lower to 0.27 higher)
Use of healthcare services Mean number of specialist appointment visits during the previous week >12 weeks	80 (1 study) 18 weeks	⊕⊕⊕⊕ VERY LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean use of healthcare services in the control groups was 0.5	The mean use of healthcare services in the intervention groups was 0.26 lower (0.56 lower to 0.04 higher)
Use of healthcare services Mean number of diagnostic imaging visits during the previous week >12 weeks	80 (1 study) 18 weeks	⊕⊕⊕⊕ VERY LOW <sup>1,2</sup> due to risk of bias, imprecision	-	The mean use of healthcare services in the control groups was 0.5	The mean use of healthcare services in the intervention groups was 0.18 lower (0.51 lower to 0.15 higher)
Discontinuation Discontinuation	1822 (13 studies) 7-12 weeks	⊕⊕⊕⊕ VERY LOW <sup>1,2,3,4</sup> due to risk of bias, inconsistency, indirectness, imprecision	RR 1.35 (0.78 to 2.34)	61 per 1000	21 more per 1000 (from 13 fewer to 82 more)
Discontinuation (inpatient PMP) Discontinuation for any reason	321 (4 studies) 4-8 weeks	⊕⊕⊕⊕ VERY LOW <sup>1,2,4</sup> due to risk of bias, indirectness, imprecision	RR 1.07 (0.65 to 1.76)	131 per 1000	9 more per 1000 (from 46 fewer to 100 more)
<p>1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias</p> <p>2 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs</p> <p>3 Downgraded by 1 or 2 increments because heterogeneity, I<sup>2</sup>=50%, p=0.04, unexplained by subgroup analysis</p> <p>4 Downgraded by 1 or 2 increments because the majority of the evidence had indirect outcomes</p>					

1 **Table 4: Clinical evidence summary: Peer led pain management programmes vs. standard care/waiting list**

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Usual care	Risk difference with Peer-led pain management programmes (95% CI)
Physical function Roland Morris Disability Questionnaire final values (high is bad outcome) ≤12 weeks. Scale from: 0 to 24.	399 (1 study) 6 weeks	⊕⊕⊕⊖ MODERATE1 due to risk of bias	-	The mean physical function in the control groups was 14.8	The mean physical function in the intervention groups was 1.2 lower (2.07 to 0.33 lower)
Physical function Roland Morris Disability Questionnaire final values (high is bad outcome) >12 weeks. Scale from: 0 to 24.	391 (1 study) 5 months	⊕⊕⊕⊖ MODERATE1 due to risk of bias	-	The mean physical function in the control groups was 14.2	The mean physical function in the intervention groups was 0.5 lower (1.41 lower to 0.41 higher)
Psychological distress Pain catastrophising scale (high is bad outcome) final values ≤12 weeks. Scale from: 0 to 52.	399 (1 study) 6 weeks	⊕⊕⊕⊖ MODERATE1 due to risk of bias	-	The mean psychological distress in the control groups was 23.7	The mean psychological distress in the intervention groups was 1.6 lower (3.69 lower to 0.49 higher)
Psychological distress Pain catastrophising scale (high is bad outcome) final values >12 weeks. Scale from: 0 to 52.	391 (1 study) 5 months	⊕⊕⊕⊖ MODERATE1 due to risk of bias	-	The mean psychological distress in the control groups was 22.4	The mean psychological distress in the intervention groups was 1.1 lower (3.24 lower to 1.04 higher)
Self-efficacy Arthritis Self Efficacy Scale (high is good outcome) final values ≤12 weeks. Scale from: 5 to 50.	399 (1 study) 6 weeks	⊕⊕⊖⊖ LOW1,2 due to risk of bias, imprecision	-	The mean self-efficacy in the control groups was 23.8	The mean self-efficacy in the intervention groups was 2.7 lower (4.5 to 0.9 lower)
Self-efficacy Arthritis Self Efficacy Scale (high is good outcome) final values >12 weeks. Scale from: 5 to 50.	391 (1 study) 5 months	⊕⊕⊖⊖ LOW1,2 due to risk of bias, imprecision	-	The mean self-efficacy in the control groups was 23.5	The mean self-efficacy in the intervention groups was 3.4 lower (5.39 to 1.41 lower)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Usual care	Risk difference with Peer-led pain management programmes (95% CI)
Pain reduction VAS (high is poor outcome) final values ≤12 weeks. Scale from: 0 to 10.	399 (1 study) 6 weeks	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	The mean pain reduction in the control groups was 53.9	The mean pain reduction in the intervention groups was 0.4 higher (2.66 lower to 3.46 higher)
Pain reduction VAS (high is poor outcome) final values >12 weeks. Scale from: 0 to 10.	391 (1 study) 5 months	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	The mean pain reduction in the control groups was 53.7	The mean pain reduction in the intervention groups was 2 lower (5.8 lower to 1.8 higher)
Use of healthcare services Total healthcare costs in Euros	410 (1 study) 5 months	⊕⊕⊕⊖ MODERATE <sup>1</sup> due to risk of bias	-	The mean use of healthcare services in the control groups was 2135 Euros	The mean use of healthcare services in the intervention groups was 96 higher (551.65 lower to 743.65 higher)
1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias 2 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs					

- 1
- 2 See appendix F for full GRADE tables.
- 3

## 1.5 Economic evidence

### 1.5.1 Included studies

3 One health economic study was identified with the relevant comparison and has been  
4 included in this review.<sup>24, 171, 173, 209, 240</sup> This is summarised in the health economic evidence  
5 profile below (Note that **Table 5** includes only the relevant comparisons for this review,  
6 although the evidence table in Appendix H: includes all comparators in the study.  
7 **Table 5**) and the health economic evidence tables in appendix H.

### 1.5.2 Excluded studies

9 Three additional health economic studies were identified as relevant to this question, but  
10 were selectively excluded as the committee judged that other available evidence was of  
11 greater applicability and methodological quality.<sup>240, 336, 337</sup> These are listed in appendix I, with  
12 reasons for exclusion given.

13 See also the health economic study selection flow chart in appendix G.

14

**1.5.3 Summary of studies included in the economic evidence review**

2 Note that **Table 5** includes only the relevant comparisons for this review, although the evidence table in Appendix H: includes all comparators  
3 in the study.

4 **Table 5: Health economic evidence profile: pain management programs vs. usual care**

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental QALYs	Cost effectiveness	Uncertainty
Beasley , 2015 [UK]	Directly applicable <sup>(a)</sup>	Potentially serious limitations <sup>(b)</sup>	<ul style="list-style-type: none"> <li>• Within-trial analysis (same paper).</li> <li>• Cost-utility analysis (QALYs).</li> <li>• Population: &gt; over 25 years with chronic widespread pain according to the definition in the American College of Rheumatology (ACR) 1990 criteria for fibromyalgia, for which they have consulted their general practitioner in the previous year.</li> <li>• 6 month interventions.</li> <li>• Follow-up: 30 months (24 months post treatment).</li> </ul> <p>Comparators:</p> <ul style="list-style-type: none"> <li>• Treatment as usual.</li> <li>• Combined telephone-delivered cognitive behavioural therapy (TCBT) and exercise therapy: initial assessment (45-60 mins) followed by 7 weekly sessions (30-45 mins each), 1 session at three months, and 1 session at 6 months after randomisation.</li> </ul>	<p><b>Complete case analysis:</b> £1,778</p> <p><b>Multiple imputation analysis:</b> £1,453</p>	<p><b>Complete case analysis:</b> 0.047</p> <p><b>Multiple imputation analysis:</b> 0.096</p>	<p><b>Complete case analysis:</b> £37,830 per QALY gained</p> <p><b>Multiple imputation analysis:</b> £15,135 per QALY gained</p>	Used non-parametric bootstrapping.

5 Abbreviations: ICER: incremental cost-effectiveness ratio; QALY: quality-adjusted life years; RCT: randomised controlled trial  
6 (a) UK NHS study, used EQ-5D. Participation in study based on self-reported symptoms and recruited through primary care, may not necessarily be representative of general  
7 population with chronic widespread pain caused by fibromyalgia.

- 1 (b) *Treatment as usual not defined, usual care provided by GP was not restricted and may not be the same across all participants in that group. Within-study analysis which*
- 2 *may not reflect full body of evidence. The imputed results are also quite different to the complete case data results, leading to a change in conclusion on cost*
- 3 *effectiveness. It is hard to know which results should be used without knowing the details of the imputations and the nature of the missing data*
- 4 .

## 1.6 Evidence statements

### 1.6.1 Clinical evidence statements

#### 3 Quality of life

4 Moderate to very low quality evidence from 6 studies with a total of 735 participants showed  
5 a clinically important benefit of professional-led outpatient pain management programmes,  
6 but moderate to very low quality evidence from 2 studies with a total of 199 participants  
7 showed no clinically important difference between professional-led outpatient pain  
8 management programmes and usual care at up to 3 months. Moderate to very low quality  
9 evidence from 7 studies with a total of 1029 participants showed a clinically important benefit  
10 of professional-led outpatient pain management programmes, but moderate to very low  
11 quality evidence from 3 studies with a total of 328 participants showed no clinically important  
12 difference between professional-led outpatient pain management programmes and usual  
13 care beyond 3 months. Low quality evidence from one study with a total of 118 participants  
14 showed no clinically important difference between professional-led inpatient pain  
15 management programmes and usual care at up to 3 months.

#### 16 Physical function

17 Moderate to very low quality evidence from 9 studies with a total of 1142 participants showed  
18 no clinically important difference between professional-led outpatient pain management  
19 programmes and usual care at time points up to 3 months. Moderate to very low quality  
20 evidence from 5 studies with a total of 848 participants showed no clinically important  
21 difference between or professional-led outpatient pain management programmes and usual  
22 care after 3 months. Moderate quality evidence from one study with a total of 69 participants  
23 showed a clinically important benefit of professional-led inpatient pain management  
24 programmes before 3 months. Moderate quality evidence from one study with a total of 399  
25 participants showed no clinically important difference between peer-led pain management  
26 programmes and usual care at follow up before or after 3 months.

#### 27 Psychological distress

28 Moderate to very low quality evidence from 9 studies with a total of 948 participants showed  
29 no clinically important difference between professional-led outpatient pain management  
30 programmes and usual care at time points up to 3 months. Moderate to very low quality  
31 evidence from 8 studies with a total of 1003 participants showed no clinically important  
32 difference between or professional-led outpatient pain management programmes and usual  
33 care after 3 months. Low to very low quality evidence from 2 studies with a total of 114  
34 participants showed a clinically important benefit of professional-led inpatient pain  
35 management programmes before 3 months, but low quality evidence from one study with a  
36 total of 118 participants showed no clinically important difference between professional-led  
37 inpatient pain management programmes and usual care. Moderate quality evidence from  
38 one study with a total of 399 participants showed no clinically important difference between  
39 peer-led pain management programmes and usual care at follow up time points before or  
40 after 3 months.

#### 41 Pain interference

42 Low quality evidence from 3 studies with a total of 359 participants showed no clinically  
43 important difference between professional-led outpatient pain management programmes and  
44 usual care at time points up to 3 months. Low quality evidence from 4 studies with a total of  
45 420 participants showed no clinically important difference between or professional-led  
46 outpatient pain management programmes and usual care at time points after 3 months. Very  
47 low quality evidence from one study with a total of 36 participants showed no clinically

1 important difference between professional-led inpatient pain management programmes and  
2 usual care at time points up to 3 months.

### 3 **Self-efficacy**

4 Low quality evidence from 4 studies with a total of 271 participants showed a clinically  
5 important benefit of professional-led outpatient pain management programmes at time points  
6 up to 3 months, but low quality evidence from one study with a total of 192 participants  
7 showed no clinically important difference between professional-led outpatient pain  
8 management programmes and usual care at time points up to 3 months. Low to very low  
9 quality evidence from 4 studies with a total of 525 participants showed no clinically important  
10 difference between or professional-led outpatient pain management programmes and usual  
11 care at time points after 3 months. Low quality evidence from one study with a total of 69  
12 participants showed a clinically important benefit of professional-led inpatient pain  
13 management programmes at time points up to 3 months, but low quality evidence from one  
14 study with a total of 118 participants showed no clinically important difference between  
15 professional-led inpatient pain management programmes and usual care. Low quality  
16 evidence from one study with a total of 399 participants showed no clinically important  
17 difference between peer-led pain management programmes and usual care at follow up time  
18 points before or after 3 months.

### 19 **Pain reduction**

20 Low quality evidence from 10 studies with a total of 1035 participants showed no clinically  
21 important difference between professional-led outpatient pain management programmes and  
22 usual care at time points up to 3 months. Very low quality evidence from 8 studies with a total  
23 of 1039 participants showed no clinically important difference between professional-led  
24 outpatient pain management programmes and usual care at time points after 3 months. Low  
25 quality evidence from 3 studies with a total of 150 participants showed no clinically important  
26 difference between professional-led inpatient pain management programmes and usual care  
27 at time points after 3 months. Moderate quality evidence from one study with a total of 399  
28 participants showed no clinically important difference between peer-led pain management  
29 programmes and usual care at follow up time points before or after 3 months.

### 30 **Sleep**

31 Very low quality evidence from 3 studies with a total of 354 participants showed no clinically  
32 important difference between professional-led outpatient pain management programmes and  
33 usual care at time points up to 3 months. Very low quality evidence from 4 studies with a total  
34 of 554 participants showed no clinically important difference between professional-led  
35 outpatient pain management programmes and usual care at time points after 3 months.

### 36 **Use of healthcare services**

37 Moderate to low quality evidence from one study with a total of 156 participants showed no  
38 clinically important difference between professional-led outpatient pain management  
39 programmes and usual care at time points up to 3 months. Moderate to very low quality  
40 evidence from 2 studies with a total of 236 participants showed no clinically important  
41 difference between professional-led outpatient pain management programmes and usual  
42 care at time points after 3 months. Moderate quality evidence from one study with a total of  
43 410 participants showed no clinically important difference between peer-led pain  
44 management programmes and usual care at time points after 3 months.

### 45 **Discontinuation**

46 Very low quality evidence from 13 studies with a total of 1822 participants showed more trial  
47 discontinuations from the professional-led outpatient pain management programmes arms  
48 than the usual care arms. Very low quality evidence from 4 studies with a total of 321

1 participants showed no clinically important difference between professional-led inpatient pain  
2 management programmes and usual care.

### **1.6.2 Health economic evidence statements**

- 4 • One cost-utility analysis found that a pain management programme:
  - 5 ○ was not cost effective compared to usual care for the management of chronic pain in
  - 6 the complete case analysis (ICER: £37,830 per QALY gained).
  - 7 ○ was cost effective compared to usual care for the management of chronic pain in the
  - 8 multiple imputation analysis (ICER: £15,135 per QALY gained).
  - 9 This analysis was assessed as directly applicable, with potentially serious limitations.

## **1.7 The committee's discussion of the evidence**

### **1.7.1 Interpreting the evidence**

#### **1.7.1.1 The outcomes that matter most**

13 The committee considered health-related quality of life, physical function, psychological  
14 distress, pain interference and pain self-efficacy to be critical outcomes for decision-making.  
15 Use of healthcare services, sleep, discontinuation and pain reduction were also considered  
16 to be important outcomes. The critical and important outcomes agreed by the committee  
17 were adapted by consensus from relevant core outcome sets registered under the Core  
18 Outcome Measures in Effectiveness Trials (COMET) Initiative. This included the Initiative on  
19 Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)  
20 recommendations.

21 Pain reduction was considered to be a critical outcome for some other reviews included in  
22 this guideline; however the committee considered that the primary aim of pain management  
23 programmes is to reduce the impact of pain on quality of life, not to reduce pain severity.

24 Evidence was identified for all critical and important outcomes.

#### **1.7.1.2 The quality of the evidence**

26 Evidence from 25 randomised controlled trials was identified for this review. The vast  
27 majority of the evidence (24 studies) compared professional led pain management  
28 programmes with usual care or waiting list. No evidence comparing a combination of  
29 professional and peer led programmes with usual care, or comparing professional-led with  
30 peer-led pain management programmes, was identified.

31 The quality of the evidence ranged from moderate to very low. The main reasons for  
32 downgrading were risk of bias, inconsistency and imprecision. There was a lack of blinding in  
33 the studies due to the nature of the interventions. This, combined with the mostly subjective  
34 outcomes, resulted in a high risk of performance bias. There was substantial variation in the  
35 quality and completeness of descriptions of the interventions and comparators between the  
36 studies, which may be a possible reason for the inconsistency observed for some outcomes.  
37 Some studies were of small sample size, which increased the uncertainty around the point  
38 estimates.

#### **1.7.1.3 Benefits and harms**

##### ***Professional-led pain management programmes***

41 The committee noted that the most frequent benefit observed was for quality of life, although  
42 there was some imprecision around many of the effect estimates. When observed, the

1 benefits were not consistent between studies. There were no consistent benefits observed in  
2 any of the other critical or important outcomes, with the majority demonstrating no clear  
3 difference from usual care or waiting list control. The committee discussed potential reasons  
4 that benefits might be seen in the overall quality of life measures, but not in other outcomes,  
5 and considered this may be because there were small effects in individual domains which  
6 when grouped together show a benefit that is not demonstrated when considered alone.  
7 They discussed further that the populations in the studies where benefit was observed from  
8 the evidence were chronic knee, back and spinal pain, where the programmes may be more  
9 targeted than for widespread pain conditions.

10 There was less evidence for inpatient pain management programmes than outpatient  
11 programmes. Overall, the evidence for inpatient programmes showed a benefit across more  
12 of the outcomes when compared with usual care than outpatient programmes compared with  
13 usual care. The committee considered that this may be because in general, inpatient  
14 programmes are of higher intensity. However, evidence showed no difference between  
15 inpatient programmes and usual care in quality of life, pain interference, pain reduction or  
16 discontinuation and evidence for psychological distress and pain self-efficacy was conflicting.  
17 The committee considered that the evidence was insufficient to make a recommendation for  
18 inpatient pain management programmes.

### 19 ***Peer-led pain management programmes***

20 Only one study was identified relevant to the review protocol for this intervention. This was a  
21 relatively large study, however no difference was observed in any of the reported outcomes:  
22 physical function, psychological distress, self-efficacy, pain reduction or use of healthcare  
23 services, when compared with usual care.

### 24 ***Overall***

25 The committee noted the diversity of the interventions, in terms of the intensity, duration,  
26 components, structure and aims of the programmes. For example, it was highlighted that  
27 while some interventions included distraction from pain techniques, others used mindfulness  
28 techniques, which can be considered contrasting approaches. The committee discussed the  
29 difficulty in determining what the effective components and characteristics of a pain  
30 management programme might be, and consequently the difficulty in defining what an  
31 effective pain management programme might consist of. The committee noted that some of  
32 the interventions included in pain management programmes such as supervised exercise  
33 and ACT/CBT are recommended in this guideline as single interventions for chronic primary  
34 pain. The committee discussed that it may be expected that combination of these single  
35 interventions within a pain management programme would result in aggregated benefits or at  
36 least equal benefits to those shown from the interventions delivered individually. However,  
37 this was not reflected in the evidence for pain management programmes. The committee  
38 discussed possible reasons for this which might include that the interventions might not be  
39 delivered in programmes in the same way or with the same intensity compared to when  
40 delivered individually, or may be more tailored to the individual when delivered in isolation.  
41 The committee were also aware that people recommended for programmes may have  
42 already tried single interventions and so might be a different subgroup of the population,  
43 even though they have the same diagnosis. It was agreed that the evidence reviewed was  
44 too inconsistent; where benefits were observed they were only small, there was uncertainty  
45 around them and they were shown for specific conditions, therefore the committee could not  
46 make a positive recommendation for pain management programmes.

47 There was insufficient evidence to make a recommendation against the use of pain  
48 management programmes. The only evidence of harm was for discontinuation in the  
49 professional-led programmes; however the committee considered the very low quality of the  
50 evidence, taking into account the uncertainty and the indirectness of the outcome. The  
51 committee considered that some types of pain management programmes may be beneficial  
52 to people with chronic pain and therefore may also have a prospect of being cost-effective,

1 but that the evidence did not allow conclusions to be drawn regarding which types these  
2 were. The committee were therefore cautious about making a recommendation against the  
3 use of pain management programmes, as they did not wish to remove the option of having  
4 any potentially beneficial services.

5 The committee discussed whether a research recommendation might be of benefit to  
6 determine a model for an effective pain management programme for chronic pain. It was  
7 agreed that further research was required to determine the characteristics of a clinically  
8 effective pain management programme to help inform future guidance.

### **1.7.2 Cost effectiveness and resource use**

10 The economic evidence review identified one relevant study comparing a pain management  
11 programme to usual care for people with chronic widespread pain. The programme  
12 examined by this study consisted of a combination of telephone-delivered cognitive  
13 behavioural therapy (TCBT) delivered by accredited therapists, and exercise therapy  
14 delivered by fitness instructors who completed a 1-day training session on exercise  
15 prescription. The base case used a complete case analysis approach and the incremental  
16 cost-effectiveness ratio (ICER) was calculated to be £37,830, and hence would not be  
17 considered cost effective under the NICE cost-effectiveness threshold. The ICER calculated  
18 using multiple imputation was £15,135, and is considered cost effective. The difference was  
19 because the imputed data led to a slightly lower incremental cost, and an incremental QALY  
20 around twice as large. There was a large amount of missing data that was imputed. This  
21 study was assessed as being partially applicable with minor limitations. The committee  
22 expressed concern over the disparity between the two ICERs, as it is difficult to tell which is a  
23 more accurate reflection of the true cost effectiveness of the programme without knowing the  
24 nature of the missing data from the original study. Therefore the committee view was that  
25 cost effectiveness of pain management programmes remained uncertain. It was also noted  
26 that the paper does not specifically indicate the level of interaction between therapists  
27 delivering TCBT and fitness instructors delivering the exercise component. The study was  
28 rated as directly applicable as it was a UK study from the NHS perspective using the EQ-5D,  
29 but with potentially serious limitations because of methodological limitations such as the fact  
30 that the imputed outcomes led to a different conclusion to the complete case data, and the  
31 economic evaluation was based on a single RCT. Participation in the study was also based  
32 on self-reported symptoms.

33 The committee noted that pain management programmes tend to be very expensive in  
34 general because of the multiple intervention components involved and therefore are very  
35 staff intensive. Where benefit was identified, this was in specific groups (chronic knee, back  
36 and spinal pain). Additionally, studies included in the clinical review differed in many ways  
37 such as in their components that made up a pain management programme, and the duration,  
38 intensity, and delivery style of the components, and therefore it was difficult to determine  
39 what the effective characteristics of a pain management programme are. Given this, the  
40 committee agreed to make a research recommendation to identify the optimal characteristics  
41 of a clinically and cost effective pain management programme.

### **1.7.3 Other factors the committee took into account**

43 The committee noted that the evidence was based predominantly on older adults, however  
44 as recommendations could not be made based on the evidence identified, whether this was  
45 relevant to younger people with chronic pain was not discussed.

46

47

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# 1 Appendices

## 2 Appendix A: Review protocols

### 4 Review protocol for pain management programmes

ID	Field	Content
0.	PROSPERO registration number	Not registered.
1.	Review title	What is the clinical and cost effectiveness of pain management programmes for the management of chronic pain?
2.	Review question	What is the clinical and cost effectiveness of pain management programmes for the management of chronic pain?
3.	Objective	To determine the clinical and cost effectiveness of pain management programmes for the management of chronic pain.
4.	Searches	<p>The following databases will be searched:</p> <ul style="list-style-type: none"> <li>• Cochrane Central Register of Controlled Trials (CENTRAL)</li> <li>• Cochrane Database of Systematic Reviews (CDSR)</li> <li>• Embase</li> <li>• MEDLINE</li> <li>• CINAHL, Current Nursing and Allied Health Literature</li> </ul> <p>Searches will be restricted by:</p>

		<ul style="list-style-type: none"> <li>English language</li> <li>Human studies</li> <li>Letters and comments are excluded.</li> </ul> <p>Other searches:</p> <ul style="list-style-type: none"> <li>Inclusion lists of relevant systematic reviews will be checked by the reviewer.</li> </ul> <p>The searches may be re-run 6 weeks before final committee meeting and further studies retrieved for inclusion if relevant.</p> <p>The full search strategies will be published in the final review.</p>
5.	Condition or domain being studied	Pain that persists or recurs for longer than 3 months.
6.	Population	Inclusion: People, aged 16 years and over, with chronic pain.
7.	Intervention/Exposure/Test	<p>Interventions:</p> <ul style="list-style-type: none"> <li>Peer led pain management programmes</li> <li>Professional led or combination of professional and peer led pain management programmes</li> </ul> <p>Definition of a pain management programme: any intervention that has two or more components including a physical and a psychological component delivered by trained people, with some interaction/coordination between the two.</p> <p>Inpatient and outpatient pain management programmes will be compared separately with control, but not with each other.</p>
8.	Comparator/Reference standard/Confounding factors	Comparators:

		<ul style="list-style-type: none"> <li>• each other (peer led vs. professional led or combination of professional and peer led)</li> <li>• standard care (GP appointments)/waiting list</li> </ul>
9.	Types of study to be included	<p>Randomised controlled trials and systematic reviews of randomised controlled trials</p> <p>Cross-over randomised controlled trials will be considered if no non-cross-over randomised controlled trial evidence is identified.</p>
10.	Other exclusion criteria	Non-English language studies
11.	Context	<p>A clear understanding of the evidence for the effectiveness of chronic pain treatments:</p> <ul style="list-style-type: none"> <li>• improves the confidence of healthcare professionals in their conversations about pain, and</li> <li>• helps healthcare professionals and patients to have realistic expectations about outcomes of treatment.</li> </ul>
12.	Primary outcomes (critical outcomes)	<ul style="list-style-type: none"> <li>• health related quality of life (including meaningful activity)</li> <li>• physical function (5 minute walk, sit to stand, Roland Morris Disability Questionnaire, Oswestry Disability Index, Canadian Occupational Performance Measure)</li> <li>• psychological distress (depression/ anxiety) (preferably Hospital Anxiety and Depression Scale)</li> <li>• pain interference (brief pain inventory interference subscale)</li> <li>• pain self-efficacy (pain self-efficacy questionnaire)</li> </ul> <p>Outcomes will be extracted at the longest time point up to 3 months and at the longest time point after 3 months</p>
13.	Secondary outcomes (important outcomes)	<ul style="list-style-type: none"> <li>• use of healthcare services</li> <li>• sleep</li> <li>• discontinuation</li> <li>• pain reduction (any validated scale)</li> </ul>

		Outcomes will be extracted at the longest time point up to 3 months and at the longest time point after 3 months.	
14.	Data extraction (selection and coding)	<p>EndNote will be used for reference management, sifting, citations and bibliographies. All references identified by the searches and from other sources will be screened for inclusion. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above.</p> <p>EviBASE will be used for data extraction.</p> <p>Study investigators may be contacted for missing data where time and resources allow.</p>	
15.	Risk of bias (quality) assessment	Risk of bias will be assessed using the Cochrane Risk of Bias (2.0) tool. Disagreements between the review authors over the risk of bias in particular studies will be resolved by discussion, with involvement of a third review author where necessary.	
16.	Strategy for data synthesis	Pairwise meta-analyses will be performed using Cochrane Review Manager (RevMan5). GRADEpro will be used to assess the quality of evidence for each outcome, taking into account individual study quality and the meta-analysis results. The 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) will be appraised for each outcome.	
17.	Analysis of sub-groups	<p>Proposed sensitivity/subgroup analysis to be explored where there is heterogeneity:</p> <ul style="list-style-type: none"> <li>• cognitive impairment</li> <li>• learning difficulties</li> <li>• first language not English</li> <li>• sensory impairment</li> <li>• homeless</li> <li>• people aged 16-18 years</li> </ul>	
18.	Type and method of review	<input checked="" type="checkbox"/>	Intervention
		<input type="checkbox"/>	Diagnostic
		<input type="checkbox"/>	Prognostic

		<input type="checkbox"/>	Qualitative
		<input type="checkbox"/>	Epidemiologic
		<input type="checkbox"/>	Service Delivery
		<input type="checkbox"/>	Other (please specify)
19.	Language	English	
20.	Country	England	
21.	Anticipated or actual start date	NA – not registered on PROSPERO	
22.	Anticipated completion date	19/08/2020	
23.	Named contact	<p>5a. Named contact National Guideline Centre</p> <p>5b Named contact e-mail Chronicpain@nice.org.uk</p> <p>5e Organisational affiliation of the review National Institute for Health and Care Excellence (NICE) and the National Guideline Centre</p>	
24.	Review team members	<p>From the National Guideline Centre: Serena Carville, Guideline Lead Maria Smyth, Senior Systematic Reviewer Rebecca Boffa, Senior Systematic Reviewer Margaret Constanti, Senior Health Economist</p>	

		Joseph Runicles, Information Specialist Katie Broomfield, Project Manager
25.	Funding sources/sponsor	This systematic review is being completed by the National Guideline Centre which receives funding from NICE.
26.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
27.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of <a href="#">Developing NICE guidelines: the manual</a> . Members of the guideline committee are available on the NICE website: <a href="https://www.nice.org.uk/guidance/indevelopment/gid-ng10069">https://www.nice.org.uk/guidance/indevelopment/gid-ng10069</a>
28.	Other registration details	NA
29.	Reference/URL for published protocol	NA
30.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: <ul style="list-style-type: none"> <li>• notifying registered stakeholders of publication</li> <li>• publicising the guideline through NICE's newsletter and alerts</li> <li>• issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.</li> </ul>
31.	Keywords	-
32.	Details of existing review of same topic by same authors	NA

33.	Additional information	-
34.	Details of final publication	<a href="http://www.nice.org.uk">www.nice.org.uk</a>

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2 **Table 6: Health economic review protocol**

<b>Review question</b>	<b>All questions – health economic evidence</b>
<b>Objectives</b>	To identify health economic studies relevant to any of the review questions.
<b>Search criteria</b>	<ul style="list-style-type: none"> <li>• Populations, interventions and comparators must be as specified in the clinical review protocol above.</li> <li>• Studies must be of a relevant health economic study design (cost–utility analysis, cost-effectiveness analysis, cost–benefit analysis, cost–consequences analysis, comparative cost analysis).</li> <li>• Studies must not be a letter, editorial or commentary, or a review of health economic evaluations. (Recent reviews will be ordered although not reviewed. The bibliographies will be checked for relevant studies, which will then be ordered.)</li> <li>• Unpublished reports will not be considered unless submitted as part of a call for evidence.</li> <li>• Studies must be in English.</li> </ul>
<b>Search strategy</b>	A health economic study search will be undertaken using population-specific terms and a health economic study filter – see appendix B below.
<b>Review strategy</b>	<p>Studies not meeting any of the search criteria above will be excluded. Studies published before 2002. Abstract-only studies and studies from non-OECD countries or the USA will also be excluded.</p> <p>Each remaining study will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist which can be found in appendix H of Developing NICE guidelines: the manual (2014).<sup>258</sup></p> <p><b>Inclusion and exclusion criteria</b></p> <ul style="list-style-type: none"> <li>• If a study is rated as both ‘Directly applicable’ and with ‘Minor limitations’ then it will be included in the guideline. A health economic evidence table will be completed and it will be included in the health economic evidence profile.</li> <li>• If a study is rated as either ‘Not applicable’ or with ‘Very serious limitations’ then it will usually be excluded from the guideline. If it is excluded then a health economic evidence table will not be completed and it will not be included in the health economic evidence profile.</li> <li>• If a study is rated as ‘Partially applicable’, with ‘Potentially serious limitations’ or both then there is discretion over whether it should be included.</li> </ul> <p><b>Where there is discretion</b></p> <p>The health economist will make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the guideline committee if required. The ultimate aim is to include health economic studies that are helpful for decision-making in the context of the guideline and the current NHS setting. If several studies are considered of sufficiently high applicability and methodological quality that they could all be included, then the health economist, in discussion with the committee if required, may decide to include only the most applicable studies and to selectively exclude the remaining studies. All studies excluded on the basis of applicability or methodological limitations will be listed with explanation in the excluded health economic studies appendix below.</p> <p>The health economist will be guided by the following hierarchies.</p> <p><b>Setting:</b></p> <ul style="list-style-type: none"> <li>• UK NHS (most applicable).</li> </ul>

- OECD countries with predominantly public health insurance systems (for example, France, Germany, Sweden).
- OECD countries with predominantly private health insurance systems (for example, Switzerland).
- Studies set in non-OECD countries or in the USA will be excluded before being assessed for applicability and methodological limitations.

*Health economic study type:*

- Cost–utility analysis (most applicable).
- Other type of full economic evaluation (cost–benefit analysis, cost-effectiveness analysis, cost–consequences analysis).
- Comparative cost analysis.
- Non-comparative cost analyses including cost-of-illness studies will be excluded before being assessed for applicability and methodological limitations.

*Year of analysis:*

- The more recent the study, the more applicable it will be.
- Studies published in 2002 or later but that depend on unit costs and resource data entirely or predominantly from before 2002 will be rated as ‘Not applicable’.
- Studies published before 2002 will be excluded before being assessed for applicability and methodological limitations.

*Quality and relevance of effectiveness data used in the health economic analysis:*

- The more closely the clinical effectiveness data used in the health economic analysis match with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline.

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## 2 **Appendix B: Literature search strategies**

3 The literature searches for this review are detailed below and complied with the methodology  
4 outlined in Developing NICE guidelines: the manual.<sup>258</sup>

5 For more information, please see the Methods Report published as part of the accompanying  
6 documents for this guideline.

### 7 **B.1 Clinical search literature search strategy**

8 Searches were constructed using a PICO framework where population (P) terms were  
9 combined with Intervention (I) and in some cases Comparison (C) terms. Outcomes (O) are  
10 rarely used in search strategies for interventions as these concepts may not be well  
11 described in title, abstract or indexes and therefore difficult to retrieve. Search filters were  
12 applied to the search where appropriate.

13

Database	Dates searched	Search filter used
Medline (OVID)	1946 – 20 May 2020	Exclusions Randomised controlled trials Systematic review studies
Embase (OVID)	1974 – 20 May 2020	Exclusions Randomised controlled trials Systematic review studies
The Cochrane Library (Wiley)	Cochrane Reviews to 2020 Issue 5 of 12	None

Database	Dates searched	Search filter used
	CENTRAL to 2020 Issue 5 of 12	

1 **Medline (Ovid) search terms**

1.	chronic pain/ or pain, intractable/
2.	((persist* or intract* or chronic or longstanding or long standing or longterm or long term or refractory or prolong* or long last* or sustain* or linger* or syndrome*) adj3 pain*).ti,ab.
3.	or/1-2
4.	letter/
5.	editorial/
6.	news/
7.	exp historical article/
8.	Anecdotes as Topic/
9.	comment/
10.	case report/
11.	(letter or comment*).ti.
12.	or/4-11
13.	randomized controlled trial/ or random*.ti,ab.
14.	12 not 13
15.	animals/ not humans/
16.	exp Animals, Laboratory/
17.	exp Animal Experimentation/
18.	exp Models, Animal/
19.	exp Rodentia/
20.	(rat or rats or mouse or mice).ti.
21.	or/14-20
22.	3 not 21
23.	limit 22 to English language
24.	"Delivery of Health Care"/
25.	Self Care/
26.	telemedicine/ or telerehabilitation/
27.	Self-Help Groups/
28.	Pain Management/
29.	Professional Patient Relations/
30.	((tele adj2 (heal* or medicine or care)) or tele-health or tele-medicine or tele-care or telehealth or telemedicine or telecare).ti,ab.
31.	(caregiver* or self-car* or self-manag* or self-help or self-administrat* or self-monitor* or self-medicat* or selfcar* or selfmanagement or selfhelp or selfadministrat* or selfmonitor* or selfmedicat*).ti,ab.
32.	(Self adj2 (car* or manag* or progam or programs or programme or programmes or help or admistrat* or monitor* or medicat*)).ti,ab.
33.	disease management.ti,ab.
34.	expert patient*.ti,ab.
35.	((management or rehab*) adj3 (programme or programmes or program or programs or course* or session* or group* or class* or scheme* or strateg* or initiative* or training)).ti,ab.
36.	((professional or clinician or peer) adj3 (programme or program or programs or programmes)).ti,ab.

37.	(pain management adj2 (program or programs or programmes or programme or rehab*)).ti,ab.
38.	or/24-37
39.	randomized controlled trial.pt.
40.	controlled clinical trial.pt.
41.	randomi#ed.ti,ab.
42.	placebo.ab.
43.	randomly.ti,ab.
44.	Clinical Trials as topic.sh.
45.	trial.ti.
46.	or/39-45
47.	Meta-Analysis/
48.	exp Meta-Analysis as Topic/
49.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
50.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
51.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
52.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
53.	(search* adj4 literature).ab.
54.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
55.	cochrane.jw.
56.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
57.	or/47-56
58.	23 and 38
59.	58 and (46 or 57)

#### 1 Embase (Ovid) search terms

1.	chronic pain/ or intractable pain/
2.	((persist* or intract* or chronic or longstanding or long standing or longterm or long term or refractory or prolong* or long last* or sustain* or linger* or syndrome*) adj3 pain*).ti,ab.
3.	or/1-2
4.	letter.pt. or letter/
5.	note.pt.
6.	editorial.pt.
7.	case report/ or case study/
8.	(letter or comment*).ti.
9.	or/4-8
10.	randomized controlled trial/ or random*.ti,ab.
11.	9 not 10
12.	animal/ not human/
13.	nonhuman/
14.	exp Animal Experiment/
15.	exp Experimental Animal/
16.	animal model/
17.	exp Rodent/
18.	(rat or rats or mouse or mice).ti.

19.	or/11-18
20.	3 not 19
21.	limit 20 to English language
22.	"Delivery of Health Care"/
23.	self care/
24.	telemedicine/ or telehealth/ or telerehabilitation/
25.	self help/
26.	pain management/
27.	professional-patient relationship/
28.	((tele adj2 (heal* or medicine or care)) or tele-health or tele-medicine or tele-care or telehealth or telemedicine or telecare).ti,ab.
29.	(caregiver* or self-car* or self-manag* or self-help or self-administrat* or self-monitor* or self-medicat* or selfcar* or selfmanagement or selfhelp or selfadministrat* or selfmonitor* or selfmedicat*).ti,ab.
30.	(Self adj2 (car* or manag* or progam or programs or programme or programmes or help or admistrat* or monitor* or medicat*)).ti,ab.
31.	disease management.ti,ab.
32.	expert patient*.ti,ab.
33.	((management or rehab*) adj3 (programme or programmes or program or programs or course* or session* or group* or class* or scheme* or strateg* or initiative* or training)).ti,ab.
34.	((professional or clinician or peer) adj3 (programme or program or programs or programmes)).ti,ab.
35.	(pain management adj2 (program or programs or programmes or programme or rehab*)).ti,ab.
36.	or/22-35
37.	21 and 36
38.	random*.ti,ab.
39.	factorial*.ti,ab.
40.	(crossover* or cross over*).ti,ab.
41.	((doubl* or singl*) adj blind*).ti,ab.
42.	(assign* or allocat* or volunteer* or placebo*).ti,ab.
43.	crossover procedure/
44.	single blind procedure/
45.	randomized controlled trial/
46.	double blind procedure/
47.	or/38-46
48.	systematic review/
49.	meta-analysis/
50.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
51.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
52.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
53.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
54.	(search* adj4 literature).ab.
55.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
56.	cochrane.jw.
57.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.

58.	or/48-57
59.	37 and (47 or 58)

1 **Cochrane Library (Wiley) search terms**

#1.	MeSH descriptor: [Chronic Pain] explode all trees
#2.	MeSH descriptor: [Pain, Intractable] explode all trees
#3.	((persist* or intract* or chronic or longstanding or long standing or longterm or long term or refractory or prolong* or long last* or sustain* or linger* or syndrome*) near/3 pain*):ti,ab
#4.	(or #1-#3)
#5.	MeSH descriptor: [Delivery of Health Care] explode all trees
#6.	MeSH descriptor: [Self Care] explode all trees
#7.	MeSH descriptor: [Telemedicine] explode all trees
#8.	MeSH descriptor: [Telerehabilitation] explode all trees
#9.	MeSH descriptor: [Self-Help Groups] explode all trees
#10.	MeSH descriptor: [Pain Management] explode all trees
#11.	MeSH descriptor: [Professional-Patient Relations] explode all trees
#12.	((tele near/2 (heal* or medicine or care)) or tele-health or tele-medicine or tele-care or telehealth or telemedicine or telecare):ti,ab
#13.	(caregiver* or self-car* or self-manag* or self-help or self-administrat* or self-monitor* or self-medicat* or selfcar* or selfmanagement or selfhelp or selfadministrat* or selfmonitor* or selfmedicat*):ti,ab
#14.	(Self near/2 (car* or manag* or progam or programs or programme or programmes or help or admistrat* or monitor* or medicat*)):ti,ab
#15.	disease management:ti,ab
#16.	expert patient*:ti,ab
#17.	((management or rehab*) near/3 (programme or programmes or program or programs or course* or session* or group* or class* or scheme* or strateg* or initiative* or training)):ti,ab
#18.	((professional or clinician or peer) near/3 (programme or program or programs or programmes)):ti,ab
#19.	(painmanagement near/2 (program or programs or programmes or programme or rehab*)):ti,ab
#20.	(or #5-#19)
#21.	#4 and #20

## B.2 Health Economics literature search strategy

3 Health economic evidence was identified by conducting a broad search relating to a Chronic  
4 Pain population in NHS Economic Evaluation Database (NHS EED – this ceased to be  
5 updated after March 2015) and the Health Technology Assessment database (HTA) with no  
6 date restrictions. NHS EED and HTA databases are hosted by the Centre for Research and  
7 Dissemination (CRD). Additional searches were run on Medline and Embase for health  
8 economics and economic modelling.

9 **Table 7: Database date parameters and filters used**

Database	Dates searched	Search filter used
Medline	2014 – 20 May 2020	Exclusions Health economics studies

Database	Dates searched	Search filter used
		Health economics modelling studies
Embase	2014 – 20 May 2020	Exclusions Health economics studies Health economics modelling studies
Centre for Research and Dissemination (CRD)	HTA - Inception – 20 May 2020 NHSEED - Inception to March 2015	None

1

2 **Medline search terms**

1.	chronic pain/ or pain, intractable/
2.	((persist* or intract* or chronic or longstanding or long standing or longterm or long term or refractory or prolong* or long last* or sustain* or linger* or syndrome*) adj3 pain*).ti,ab.
3.	((chronic or persist* or idiopathic or atypical or a-typical) adj4 pain).ti,ab.
4.	exp Complex Regional Pain Syndromes/
5.	(complex regional pain syndrome* or CRPS or causalgia).ti,ab.
6.	fibromyalgia/
7.	((reflex or sympathetic) adj2 dystroph*).ti,ab.
8.	vulvodynia/
9.	(vulvodynia or vestibulodynia or dyspareunia or vulvar vestibulitis or vulvitis).ti,ab.
10.	interstitial cystitis/
11.	(interstitial adj2 cystitis).ti,ab.
12.	algodystrophy/
13.	(algodystroph* or sudek or sudeck*).ti,ab.
14.	exp myofascial pain syndromes/
15.	cystitis, interstitial/
16.	(loin pain adj (haematuria or hematuria) adj syndrome*).ti,ab.
17.	(LPHS or prostatodynia or CPPS or atypic* odontalgia or a-typic* odontalgia or burning mouth syndrome* or phantom tooth pain or neuropathic orofacial pain or "myofascial pain" or MPS).ti,ab.
18.	((pelvic or pelvis) adj pain syndrome*).ti,ab.
19.	((non-cardiac or noncardiac) adj3 chest adj3 pain).ti,ab.
20.	(temporomandibular adj3 joint adj3 pain).ti,ab.
21.	((prostate or vulv* or bladder or perineal) adj3 pain).ti,ab.
22.	(functional pain syndrome* or non-cancer pain or noncancer pain).ti,ab.
23.	((pelvic or pelvis or abdominal) adj3 pain adj3 (unknown or un-known or idiopathic or atypic* or a-typic*).ti,ab.
24.	(fibromyalgia* or fibrositis or myofascial pain syndrome).ti,ab.
25.	or/1-24
26.	letter/
27.	editorial/
28.	news/
29.	exp historical article/
30.	Anecdotes as Topic/

31.	comment/
32.	case report/
33.	(letter or comment*).ti.
34.	or/26-33
35.	randomized controlled trial/ or random*.ti,ab.
36.	34 not 35
37.	animals/ not humans/
38.	exp Animals, Laboratory/
39.	exp Animal Experimentation/
40.	exp Models, Animal/
41.	exp Rodentia/
42.	(rat or rats or mouse or mice).ti.
43.	or/36-42
44.	25 not 43
45.	Economics/
46.	Value of life/
47.	exp "Costs and Cost Analysis"/
48.	exp Economics, Hospital/
49.	exp Economics, Medical/
50.	Economics, Nursing/
51.	Economics, Pharmaceutical/
52.	exp "Fees and Charges"/
53.	exp Budgets/
54.	budget*.ti,ab.
55.	cost*.ti.
56.	(economic* or pharmaco?economic*).ti.
57.	(price* or pricing*).ti,ab.
58.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
59.	(financ* or fee or fees).ti,ab.
60.	(value adj2 (money or monetary)).ti,ab.
61.	or/45-60
62.	exp models, economic/
63.	*Models, Theoretical/
64.	*Models, Organizational/
65.	markov chains/
66.	monte carlo method/
67.	exp Decision Theory/
68.	(markov* or monte carlo).ti,ab.
69.	econom* model*.ti,ab.
70.	(decision* adj2 (tree* or analy* or model*)).ti,ab.
71.	or/62-70
72.	44 and (61 or 71)

1 **Embase (Ovid) search terms**

1.	chronic pain/ or pain, intractable/
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2.	((persist* or intract* or chronic or longstanding or long standing or longterm or long term or refractory or prolong* or long last* or sustain* or linger* or syndrome*) adj3 pain*).ti,ab.
3.	((chronic or persist* or idiopathic or atypical or a-typical) adj4 pain).ti,ab.
4.	exp Complex regional pain syndrome/
5.	(complex regional pain syndrome* or CRPS or causalgia).ti,ab.
6.	((reflex or sympathetic) adj2 dystroph*).ti,ab.
7.	fibromyalgia/
8.	(fibromyalgia* or fibrositis or myofascial pain syndrome).ti,ab.
9.	vulvodynia/
10.	(vulvodynia or vestibulodynia or dyspareunia or vulvar vestibulitis or vulvitis).ti,ab.
11.	interstitial cystitis/
12.	(interstitial adj2 cystitis).ti,ab.
13.	algodystrophy/
14.	(algodystroph* or sudek or sudeck*).ti,ab.
15.	myofascial pain/
16.	noncardiac chest pain/
17.	cystalgia/
18.	Pelvis pain syndrome/
19.	(loin pain adj (haematuria or hematuria) adj syndrome*).ti,ab.
20.	(LPHS or prostatodynia or CPPS or atypic* odontalgia or a-typic* odontalgia or burning mouth syndrome* or phantom tooth pain or neuropathic orofacial pain or "myofascial pain" or MPS).ti,ab.
21.	((pelvic or pelvis) adj pain syndrome*).ti,ab.
22.	((non-cardiac or noncardiac) adj3 chest adj3 pain).ti,ab.
23.	(temporomandibular adj3 joint adj3 pain).ti,ab.
24.	((prostate or vulv* or bladder or perineal) adj3 pain).ti,ab.
25.	(functional pain syndrome* or non-cancer pain or noncancer pain).ti,ab.
26.	((pelvic or pelvis or abdominal) adj3 pain adj3 (unknown or un-known or idiopathic or atypic* or a-typic*).ti,ab.
27.	or/1-26
28.	letter.pt. or letter/
29.	note.pt.
30.	editorial.pt.
31.	case report/ or case study/
32.	(letter or comment*).ti.
33.	or/28-32
34.	randomized controlled trial/ or random*.ti,ab.
35.	33 not 34
36.	animal/ not human/
37.	nonhuman/
38.	exp Animal Experiment/
39.	exp Experimental Animal/
40.	animal model/
41.	exp Rodent/
42.	(rat or rats or mouse or mice).ti.
43.	or/35-42
44.	27 not 43

45.	health economics/
46.	exp economic evaluation/
47.	exp health care cost/
48.	exp fee/
49.	budget/
50.	funding/
51.	budget*.ti,ab.
52.	cost*.ti.
53.	(economic* or pharmaco?economic*).ti.
54.	(price* or pricing*).ti,ab.
55.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
56.	(financ* or fee or fees).ti,ab.
57.	(value adj2 (money or monetary)).ti,ab.
58.	or/45-57
59.	statistical model/
60.	exp economic aspect/
61.	59 and 60
62.	*theoretical model/
63.	*nonbiological model/
64.	stochastic model/
65.	decision theory/
66.	decision tree/
67.	monte carlo method/
68.	(markov* or monte carlo).ti,ab.
69.	econom* model*.ti,ab.
70.	(decision* adj2 (tree* or analy* or model*)).ti,ab.
71.	or/61-70
72.	44 and (58 or 71)

1 **NHS EED and HTA (CRD) search terms**

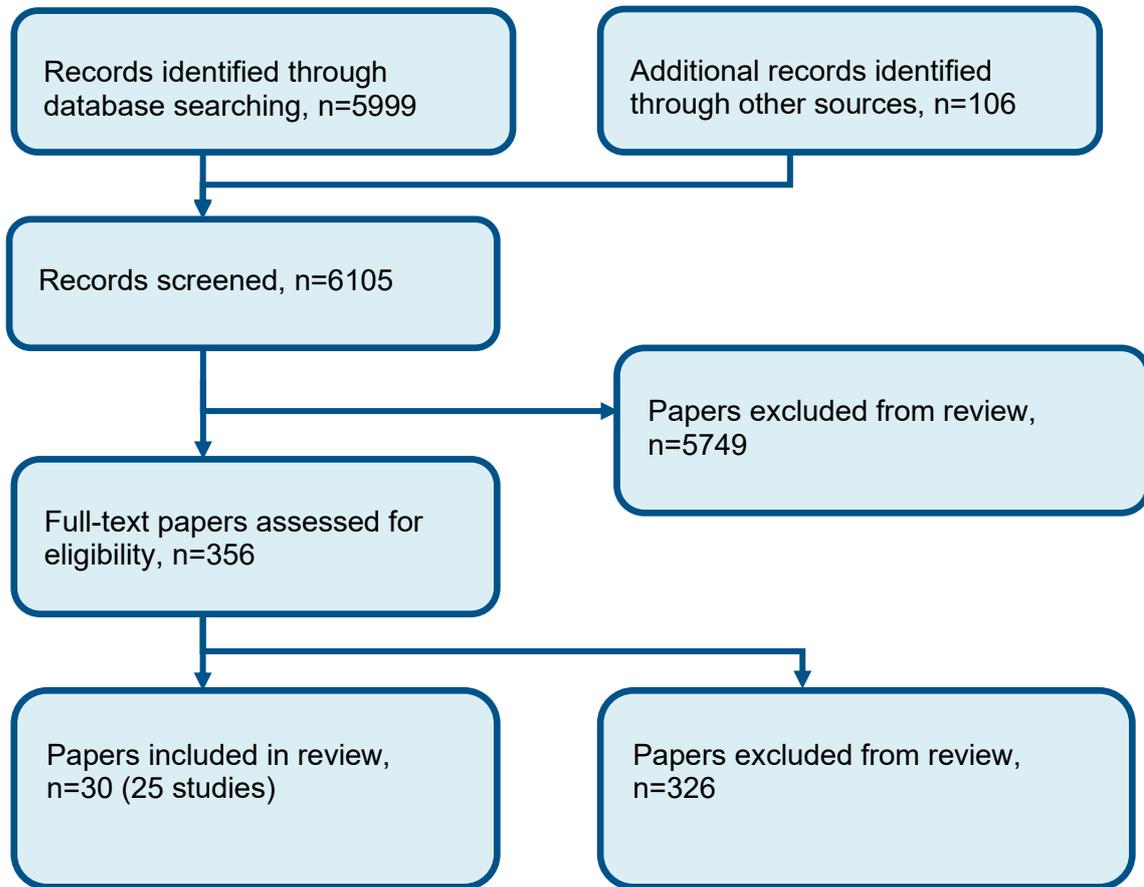
#1.	MeSH DESCRIPTOR Chronic Pain EXPLODE ALL TREES
#2.	(((persist* or intract* or chronic or longstanding or long standing or longterm or long term or refractory or prolong* or long last* or sustain* or linger* or syndrome*) adj3 pain*))
#3.	(((chronic or persist* or idiopathic or atypical or a-typical) adj4 pain))
#4.	MeSH DESCRIPTOR Complex Regional Pain Syndromes EXPLODE ALL TREES
#5.	((complex regional pain syndrome* or CRPS or causalgia))
#6.	MeSH DESCRIPTOR Fibromyalgia EXPLODE ALL TREES
#7.	(((reflex or sympathetic) adj2 dystroph*))
#8.	MeSH DESCRIPTOR Vulvodynia EXPLODE ALL TREES
#9.	((vulvodynia or vestibulodynia or dyspareunia or vulvar vestibulitis or vulvitis))
#10.	MeSH DESCRIPTOR Cystitis, Interstitial EXPLODE ALL TREES
#11.	((interstitial adj2 cystitis))
#12.	MeSH DESCRIPTOR Reflex Sympathetic Dystrophy EXPLODE ALL TREES
#13.	((algodystroph* or sudek or sudeck*))
#14.	MeSH DESCRIPTOR Myofascial Pain Syndromes EXPLODE ALL TREES
#15.	((loin pain adj (haematuria or hematuria) adj syndrome*))

#16.	((LPHS or prostatodynia or CPPS or atypic* odontalgia or a-typic* odontalgia or burning mouth syndrome* or phantom tooth pain or neuropathic orofacial pain or "myofascial pain" or MPS))
#17.	((((pelvic or pelvis) adj pain syndrome*))
#18.	((((non-cardiac or noncardiac) adj3 chest adj3 pain))
#19.	((temporomandibular adj3 joint adj3 pain))
#20.	((((prostate or vulv* or bladder or perineal) adj3 pain))
#21.	((functional pain syndrome* or non-cancer pain or noncancer pain))
#22.	((((pelvic or pelvis or abdominal) adj3 pain adj3 (unknown or un-known or idiopathic or atypic* or a-typic*)))
#23.	((fibromyalgia* or fibrositis or myofascial pain syndrome))
#24.	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23)

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# 1 Appendix C: Clinical evidence selection

Figure 1: Flow chart of clinical study selection for the review of pain management programmes



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# Appendix D: Clinical evidence tables

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Study	Bourgault 2015 <sup>42</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=58)
Countries and setting	Conducted in Canada; Setting: Two university-affiliated sites (outpatient)
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 11 weeks + 12 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: medical diagnosis of FMS based on the American College of Rheumatology (ACR) classification criteria for at least 6 months
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	18 years or older; able to read, understand and complete questionnaires in French; medical diagnosis of FMS based on the American College of Rheumatology (ACR) classification criteria for at least 6 months; reported FMS pain of at least moderate intensity ( $\geq 4/10$ ) in the 7 days prior to enrolment; FMS pain chief complaint if suffered from another chronic pain syndrome; motivated to attend all group sessions and to integrate the proposed self-management strategies; agreed to not introduce new pain medications or other new pain treatment modalities during the 11 weeks of the intervention.
Exclusion criteria	Pregnant or lactating women; presence of an active cancer; uncontrolled metabolic disease and other major physical or psychiatric disorder that could compromise patient participation in the study; outstanding litigation regarding patient's claim for disability payments.
Recruitment/selection of patients	Announcements in local newspapers, interested subjects invited to call the research coordinator
Age, gender and ethnicity	Age - Mean (SD): intervention group 49.98 (9.23), waiting list group 46.74 (11.42). Gender (M:F): 4/52. Ethnicity: intervention group 100% Caucasian, waiting list group 96.4% Caucasian
Further population details	1. Age 16-18 years: Not stated / Unclear 2. Cognitive impairment: Not stated / Unclear 3. First language not English: Not applicable 4. Homeless: Not homeless 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Indirectness of population	No indirectness: NA
Interventions	(n=29) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. PASSAGE program - structured multicomponent

<b>Study</b>	<b>Bourgault 2015<sup>42</sup></b>
	<p>interdisciplinary group program: 9 group sessions with 8 participants lasting 2.5 hours each. Each session involved 3 major components - psycho-educational tools, CBT-related techniques and patient-tailored exercise activities and the final session was devoted to the pharmacological and non-pharmacological treatments of FMS. First 8 sessions held over a period of 11 weeks and 9th final session 6 months later to review progress and gain maintenance. Sessions were interactive and led by two health care professionals who both acted as facilitators, one being mainly responsible for the psychological aspect of the intervention and the other for its physical aspect. Sessions started with customized exercise routines (15 min), including correction of posture and movements when needed. Participants were then asked to discuss their experiences with the prescribed tasks of the preceding week (including the practice of new self-management strategies) (15 min). Then, the two facilitators started the education part of the session during which various topics related to FMS symptoms and their management were covered. In the second portion of the sessions, the facilitators proposed new self-management strategies, specific exercises, and respiration techniques. Participants were invited to practice them during a 30-min period. Starting on Week 4, the exercise program ended with a relaxation session during which different techniques were taught and practiced (15 min). Finally, participants were prescribed tasks to be done during the following week(s). Duration 11 weeks. Concurrent medication/care: Participants had to accept to not introduce new pain medications or other new therapeutic modalities for pain management during the 11 weeks of the intervention. Indirectness: No indirectness; Indirectness comment: NA</p> <p>(n=29) Intervention 2: Standard care (a few GP appointments)/waiting list. Waiting list. Duration 11 weeks. Concurrent medication/care: continuation of treatment(s) as usual until they could take part in the PASSAGE Program—i.e., 3 months after the intervention group had completed the program. Changes in pharmacological or non-pharmacological treatments were allowed. Indirectness: No indirectness</p>
Funding	Other (Canadian Institutes of Health Research partnered with AstraZeneca Canada Inc. Additional funding also obtained from Pfizer Canada Inc.)

**RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST**

Protocol outcome 1: Quality of life

- Actual outcome: SF12 physical summary scale at 11 weeks (end of intervention); Group 1: mean 30.55 (SD 8.17); n=20, Group 2: mean 29.41 (SD 11.08); n=23; SF12 physical summary scale 0-100 Top=High is good outcome; Comments: Baseline values: intervention 31.21 (8.95), control 29.59 (10.46)

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - overall reasons only: 2 excluded from the program because of non-compliance; 3 no more able to attend the sessions due

Study	Bourgault 2015 <sup>42</sup>
	<p>to a scheduling conflict; 3 developed a medical disorder unrelated to FMS; 2 went through an episode of psychological instability; 1 had personal reasons.; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: stratified by study site and gender; proportion of patients who were using prescribed pain medication; this proportion was lower in the INT Group (78.57%, 22/28) than it was in the WL Group (100%, 28/28); Group 1 Number missing: 9, Reason: not reported ; Group 2 Number missing: 6, Reason: not reported</p> <p>- Actual outcome: SF12 physical summary scale at 6 months (3 months post intervention); Group 1: mean 30.49 (SD 7.9); n=20, Group 2: mean 28.65 (SD 9.09); n=23; SF12 physical summary scale 0-100 Top=High is good outcome; Comments: Baseline values: intervention 31.21 (8.95), control 29.59 (10.46)</p> <p>Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - overall reasons only: 2 excluded from the program because of non-compliance; 3 no more able to attend the sessions due to a scheduling conflict; 3 developed a medical disorder unrelated to FMS; 2 went through an episode of psychological instability; 1 had personal reasons.; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: stratified by study site and gender; proportion of patients who were using prescribed pain medication; this proportion was lower in the INT Group (78.57%, 22/28) than it was in the WL Group (100%, 28/28); Group 1 Number missing: 9, Reason: not reported ; Group 2 Number missing: 6, Reason: not reported</p> <p>- Actual outcome: SF12 mental summary scale at 11 weeks (end of intervention); Group 1: mean 40.74 (SD 8.42); n=20, Group 2: mean 39.07 (SD 11.28); n=23; SF12 mental summary scale 0-100 Top=High is good outcome; Comments: Baseline values: intervention 40.58 (11.39), control 40.94 (9)</p> <p>Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - overall reasons only: 2 excluded from the program because of non-compliance; 3 no more able to attend the sessions due to a scheduling conflict; 3 developed a medical disorder unrelated to FMS; 2 went through an episode of psychological instability; 1 had personal reasons.; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: stratified by study site and gender; proportion of patients who were using prescribed pain medication; this proportion was lower in the INT Group (78.57%, 22/28) than it was in the WL Group (100%, 28/28); Group 1 Number missing: 9, Reason: not reported ; Group 2 Number missing: 6, Reason: not reported</p> <p>- Actual outcome: SF12 mental summary scale at 6 months (3 months post intervention); Group 1: mean 40.75 (SD 10.49); n=20, Group 2: mean 37.59 (SD 9.76); n=23; SF12 mental summary scale 0-100 Top=High is good outcome; Comments: Baseline values: intervention 40.58 (11.39), control 40.94 (9)</p> <p>Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - overall reasons only: 2 excluded from the program because of non-compliance; 3 no more able to attend the sessions due to a scheduling conflict; 3 developed a medical disorder unrelated to FMS; 2 went through an episode of psychological instability; 1 had personal reasons.; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: stratified by study site and gender; proportion of patients who were using prescribed pain medication; this proportion was lower in the INT Group (78.57%, 22/28) than it was in the WL Group (100%, 28/28); Group 1 Number missing: 9, Reason: not reported ; Group 2 Number missing: 6, Reason: not reported</p> <p>Protocol outcome 2: Psychological distress (depression/anxiety)</p> <p>- Actual outcome: Beck depression inventory at 11 weeks (end of intervention); Group 1: mean 16.91 (SD 7.84); n=20, Group 2: mean 16.56 (SD 10.39); n=23; Beck depression inventory 0-63 Top=High is poor outcome; Comments: Baseline values: intervention 19.54 (9.39), control 18.61 (9.37)</p> <p>Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - overall reasons only: 2 excluded from the program because of non-compliance; 3 no more able to attend the sessions due to a scheduling conflict; 3 developed a medical disorder unrelated to FMS; 2 went through an episode of psychological instability; 1 had personal reasons.;</p>

**Study**

**Bourgault 2015<sup>42</sup>**

Indirectness of outcome: No indirectness, Comments: NA; Baseline details: stratified by study site and gender; proportion of patients who were using prescribed pain medication; this proportion was lower in the INT Group (78.57%, 22/28) than it was in the WL Group (100%, 28/28); Group 1 Number missing: 9, Reason: not reported ; Group 2 Number missing: 6, Reason: not reported  
 - Actual outcome: Beck depression inventory at 6 months (3 months post intervention); Group 1: mean 16.05 (SD 7.73); n=20, Group 2: mean 16.78 (SD 10); n=23; Beck depression inventory 0-63 Top=High is poor outcome; Comments: Baseline values: intervention 19.54 (9.39), control 18.61 (9.37)  
 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - overall reasons only: 2 excluded from the program because of non-compliance; 3 no more able to attend the sessions due to a scheduling conflict; 3 developed a medical disorder unrelated to FMS; 2 went through an episode of psychological instability; 1 had personal reasons.;  
 Indirectness of outcome: No indirectness, Comments: NA; Baseline details: stratified by study site and gender; proportion of patients who were using prescribed pain medication; this proportion was lower in the INT Group (78.57%, 22/28) than it was in the WL Group (100%, 28/28); Group 1 Number missing: 9, Reason: not reported ; Group 2 Number missing: 6, Reason: not reported

**Protocol outcome 3: Pain interference**

- Actual outcome: BPI interference at 11 weeks (end of intervention); Group 1: mean 4.63 (SD 2.15); n=20, Group 2: mean 4.99 (SD 2.32); n=23; Brief pain inventory interference subscale 0-10 Top=High is poor outcome; Comments: Baseline values: intervention 5.09 (2.38), control 5.36 (2.4)  
 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - overall reasons only: 2 excluded from the program because of non-compliance; 3 no more able to attend the sessions due to a scheduling conflict; 3 developed a medical disorder unrelated to FMS; 2 went through an episode of psychological instability; 1 had personal reasons.;  
 Indirectness of outcome: No indirectness, Comments: NA; Baseline details: stratified by study site and gender; proportion of patients who were using prescribed pain medication; this proportion was lower in the INT Group (78.57%, 22/28) than it was in the WL Group (100%, 28/28); Group 1 Number missing: 9, Reason: not reported ; Group 2 Number missing: 6, Reason: not reported  
 - Actual outcome: BPI interference at 6 months (3 months post intervention); Group 1: mean 4.08 (SD 2.14); n=20, Group 2: mean 4.72 (SD 2.24); n=23; Brief pain inventory interference subscale 0-10 Top=High is poor outcome; Comments: Baseline values: intervention 5.09 (2.38), control 5.36 (2.4)  
 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - overall reasons only: 2 excluded from the program because of non-compliance; 3 no more able to attend the sessions due to a scheduling conflict; 3 developed a medical disorder unrelated to FMS; 2 went through an episode of psychological instability; 1 had personal reasons.;  
 Indirectness of outcome: No indirectness, Comments: NA; Baseline details: stratified by study site and gender; proportion of patients who were using prescribed pain medication; this proportion was lower in the INT Group (78.57%, 22/28) than it was in the WL Group (100%, 28/28); Group 1 Number missing: 9, Reason: not reported ; Group 2 Number missing: 6, Reason: not reported

**Protocol outcome 4: Sleep**

- Actual outcome: CPSI overall sleep quality item at 11 weeks (end of intervention); Group 1: mean 4.09 (SD 2.04); n=20, Group 2: mean 3.72 (SD 2.3); n=23; Chronic Pain Sleep Inventory 0-10 Top=High is good outcome; Comments: Baseline values: intervention 2.75 (1.82), control 2.89 (2.59)  
 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - overall reasons only: 2 excluded from the program because of non-compliance; 3 no more able to attend the sessions due to a scheduling conflict; 3 developed a medical disorder unrelated to FMS; 2 went through an episode of psychological instability; 1 had personal reasons.;  
 Indirectness of outcome: No indirectness, Comments: NA; Baseline details: stratified by study site and gender; proportion of patients who were using

Study	Bourgault 2015 <sup>42</sup>
	<p>prescribed pain medication; this proportion was lower in the INT Group (78.57%, 22/28) than it was in the WL Group (100%, 28/28); Group 1 Number missing: 9, Reason: not reported ; Group 2 Number missing: 6, Reason: not reported</p> <p>- Actual outcome: CPSI overall sleep quality item at 6 months (3 months post intervention); Group 1: mean 4.33 (SD 2.18); n=20, Group 2: mean 3.57 (SD 2.37); n=23; Chronic Pain Sleep Inventory 0-10 Top=High is good outcome; Comments: Baseline values: intervention 2.75 (1.82), control 2.89 (2.59)</p> <p>Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - overall reasons only: 2 excluded from the program because of non-compliance; 3 no more able to attend the sessions due to a scheduling conflict; 3 developed a medical disorder unrelated to FMS; 2 went through an episode of psychological instability; 1 had personal reasons.;</p> <p>Indirectness of outcome: No indirectness, Comments: NA; Baseline details: stratified by study site and gender; proportion of patients who were using prescribed pain medication; this proportion was lower in the INT Group (78.57%, 22/28) than it was in the WL Group (100%, 28/28); Group 1 Number missing: 9, Reason: not reported ; Group 2 Number missing: 6, Reason: not reported</p> <p><b>Protocol outcome 5: Discontinuation</b></p> <p>- Actual outcome: Discontinuation at 11 weeks (end of intervention); Group 1: 9/29, Group 2: 6/29; Comments: 2 excluded due to non-compliance, 3 were no longer able to attend sessions due to scheduling conflict, 3 developed a medical disorder unrelated to FMS, 2 had an episode of psychological instability, 1 had personal reasons, 4 failed to return questionnaire</p> <p>Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - overall reasons only: 2 excluded from the program because of non-compliance; 3 no more able to attend the sessions due to a scheduling conflict; 3 developed a medical disorder unrelated to FMS; 2 went through an episode of psychological instability; 1 had personal reasons.;</p> <p>Indirectness of outcome: No indirectness, Comments: NA; Baseline details: stratified by study site and gender; proportion of patients who were using prescribed pain medication; this proportion was lower in the INT Group (78.57%, 22/28) than it was in the WL Group (100%, 28/28); Group 1 Number missing: ; Group 2 Number missing:</p> <p><b>Protocol outcome 6: Pain reduction</b></p> <p>- Actual outcome: Pain on average in the past 7 days (NRS 0-10) at 11 weeks (end of intervention); Group 1: mean 5.95 (SD 2.06); n=20, Group 2: mean 6.08 (SD 2.14); n=23; numeric rating scale 0-10 Top=High is poor outcome; Comments: Baseline values: intervention 6.57 (2.03), control 6.39 (1.83)</p> <p>Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - overall reasons only: 2 excluded from the program because of non-compliance; 3 no more able to attend the sessions due to a scheduling conflict; 3 developed a medical disorder unrelated to FMS; 2 went through an episode of psychological instability; 1 had personal reasons.;</p> <p>Indirectness of outcome: No indirectness, Comments: NA; Baseline details: stratified by study site and gender; proportion of patients who were using prescribed pain medication; this proportion was lower in the INT Group (78.57%, 22/28) than it was in the WL Group (100%, 28/28); Group 1 Number missing: 9, Reason: not reported ; Group 2 Number missing: 6, Reason: not reported</p> <p>- Actual outcome: Pain on average in the past 7 days (NRS 0-10) at 6 months (3 months post intervention); Group 1: mean 5.36 (SD 1.74); n=20, Group 2: mean 5.91 (SD 2.29); n=23; numeric rating scale 0-10 Top=High is poor outcome; Comments: Baseline values: intervention 6.57 (2.03), control 6.39 (1.83)</p> <p>Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - overall reasons only: 2 excluded from the program because of non-compliance; 3 no more able to attend the sessions due to a scheduling conflict; 3 developed a medical disorder unrelated to FMS; 2 went through an episode of psychological instability; 1 had personal reasons.;</p>

<b>Study</b>	<b>Bourgault 2015<sup>42</sup></b>
Indirectness of outcome: No indirectness, Comments: NA; Baseline details: stratified by study site and gender; proportion of patients who were using prescribed pain medication; this proportion was lower in the INT Group (78.57%, 22/28) than it was in the WL Group (100%, 28/28); Group 1 Number missing: 9, Reason: not reported ; Group 2 Number missing: 6, Reason: not reported	
Protocol outcomes not reported by the study	Physical function; Use of healthcare services; Pain self-efficacy

1

<b>Study</b>	<b>Castel 2013<sup>68</sup></b>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=174)
Countries and setting	Conducted in Spain; Setting: unclear, kinesiotherapy in a gymnasium
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 12 weeks + 12 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: diagnosis of FM based on the diagnostic criteria of the American College of Rheumatology
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	Female sex, a diagnosis of FM based on the diagnostic criteria of the American College of Rheumatology, age between 18 and 60 years, and between 3 and 8 years of schooling
Exclusion criteria	Another severe chronic pain pathology (e.g., sciatica or complex regional pain syndrome), having been diagnosed with inflammatory rheumatic disease, being physically unable to perform the exercises, an open wound, a skin disease, being under psychiatric and/or psychological treatment within the past 3 years, significant suicidal ideation, cognitive or sensorial deterioration that impedes an adequate follow up to the treatment, or a pending legal resolution for disability
Recruitment/selection of patients	Consecutive patients meeting the inclusion criteria, recruited from consultation with a rheumatologist
Age, gender and ethnicity	Age - Mean (SD) 48.9 (7) years. Gender (M:F): 0/174. Ethnicity: not reported
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: No cognitive impairment 3. First language not English: Not applicable 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : No sensory impairment
Indirectness of population	No indirectness: NA

Study	Castel 2013 <sup>68</sup>
Interventions	<p>(n=19) Intervention 1: Total 24 sessions; 1 x hour of CBT and 1 x hour of physical, 2 days per week in groups of 8 patients.</p> <ul style="list-style-type: none"> <li>• CBT included information about FM, theory of pain perception, cognitive restructuring skills training, CBT for primary insomnia, assertiveness training, goal setting, activity pacing and pleasant activity scheduling training, life values, and relapse prevention</li> <li>• physical therapy treatment emphasized aerobic capacity, muscular strengthening and flexibility and alternated with sessions of hydrokinesiotherapy in a heated pool and kinesiotherapy in a gymnasium</li> <li>• all sessions included overall aerobic work, coordination exercises, and flexibility exercises</li> <li>• difficulty of the exercises was individually tailored and progressively increased through the use of resistance media and a slow execution velocity</li> <li>• participants practiced Schultz autogenic training during sessions and given an audio CD to practice at home</li> <li>• physical therapy supplemented with an exercise routine between sessions and a scheduled daily march to facilitate the incorporation of the regular exercise into daily life.</li> </ul> <p>Duration 12 weeks. Concurrent medication/care: Conventional pharmacologic treatment: analgesics, antidepressants (tricyclics, selective serotonin reuptake inhibitors, and dual reuptake inhibitors), benzodiazepine, and nonbenzodiazepine hypnotics. Drug treatment adjusted as recommended by guidelines. Indirectness: No indirectness; Indirectness comment: NA</p> <p>(n=27) Intervention 2: Standard care (a few GP appointments)/waiting list. Conventional pharmacologic treatment: analgesics, antidepressants (tricyclics, selective serotonin reuptake inhibitors, and dual reuptake inhibitors), benzodiazepine, and nonbenzodiazepine hypnotics. Drug treatment adjusted as recommended by guidelines. Duration 12 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness; Indirectness comment: NA</p>
Funding	Other funding: the Foundation Marato TV3 (charitable foundation)

**RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST**

Protocol outcome 1: Quality of life

- Actual outcome: Fibromyalgia Impact Questionnaire score at 12 weeks (immediately post treatment) ; Group 1: mean 47.7 (SD 20.2); n=81, Group 2: mean 65.9 (SD 16.1); n=74; Fibromyalgia Impact Questionnaire 0-100 Top=High is poor outcome; Comments: Baseline values: PMP 64.6 (16), control 66.6 (17.4)

Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low,

Study	Castel 2013 <sup>68</sup>
	<p>Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: baseline differences between groups in Dartmouth COOP/WONCA Functional Health Assessment Charts used to assess quality of life; outcome removed from analysis; Group 1 Number missing: 8; Group 2 Number missing: 5</p> <p>- Actual outcome: Fibromyalgia Impact Questionnaire score at 15 months (12 month follow up); Group 1: mean 58.8 (SD 20.5); n=81, Group 2: mean 69.6 (SD 17.2); n=74; Fibromyalgia Impact Questionnaire 0-100 Top=High is poor outcome; Comments: Baseline values: PMP 64.6 (16), control 66.6 (17.4)</p> <p>Risk of bias: All domain – Very High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: Baseline details: baseline differences between groups in Dartmouth COOP/WONCA Functional Health Assessment Charts used to assess quality of life; outcome removed from analysis; Group 1 Number missing: 28; Group 2 Number missing: 39</p> <p>Protocol outcome 2: Psychological distress</p> <p>- Actual outcome: Hospital Anxiety and Depression Scale score at 12 weeks (immediately post treatment); Group 1: mean 14.3 (SD 9); n=81, Group 2: mean 21.7 (SD 8.4); n=74; Hospital Anxiety and Depression scale 0-42 Top=High is poor outcome; Comments: Baseline values: PMP 21.9 (8), control 23.2 (8.1)</p> <p>Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: baseline differences between groups in Dartmouth COOP/WONCA Functional Health Assessment Charts used to assess quality of life; outcome removed from analysis; Group 1 Number missing: 8; Group 2 Number missing: 5</p> <p>- Actual outcome: Hospital Anxiety and Depression Scale score at 15 months (12 month follow up); Group 1: mean 17.1 (SD 9.9); n=81, Group 2: mean 22.8 (SD 9.2); n=74; Hospital Anxiety and Depression scale 0-42 Top=High is poor outcome; Comments: Baseline values: PMP 21.9 (8), control 23.2 (8.1)</p> <p>Risk of bias: All domain – Very High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: Baseline details: baseline differences between groups in Dartmouth COOP/WONCA Functional Health Assessment Charts used to assess quality of life; outcome removed from analysis; Group 1 Number missing: 28; Group 2 Number missing: 39</p> <p>Protocol outcome 3: Pain reduction</p> <p>- Actual outcome: Pain intensity Numeric Rating Scale score at 12 weeks (immediately post treatment); Group 1: mean 5.7 (SD1.9); n=81, Group 2: mean 6.9 (SD 1.8); n=74; Pain intensity Numeric Rating Scale 0-10 Top=High is poor outcome; Comments: Baseline values: PMP 6.8 (1.4), control 7.1 (1.6)</p> <p>Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: baseline differences between groups in Dartmouth COOP/WONCA Functional Health Assessment Charts used to assess quality of life; outcome removed from analysis; Group 1 Number missing: 8; Group 2 Number missing: 5</p> <p>- Actual outcome: Pain intensity Numeric Rating Scale score at 15 months (12 month follow up); Group 1: mean 6.7 (SD1.6); n=81, Group 2: mean 7.1 (SD 1.8); n=74; Pain intensity Numeric Rating Scale 0-10 Top=High is poor outcome; Comments: Baseline values: PMP 6.8 (1.4), control 7.1 (1.6)</p>

Study	Castel 2013 <sup>68</sup>
	<p>Risk of bias: All domain – Very High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: Baseline details: baseline differences between groups in Dartmouth COOP/WONCA Functional Health Assessment Charts used to assess quality of life; outcome removed from analysis; Group 1 Number missing: 28; Group 2 Number missing: 39</p> <p>Protocol outcome 4: Sleep - Actual outcome: Medical Outcomes Study Sleep Scale score at 12 weeks (immediately post treatment); Group 1: mean 41.5 (SD 9.2); n=81, Group 2: mean 29.6 (SD 8.2); n=74; Medical Outcomes Study Sleep Scale 12-71 Top=good outcome; Comments: Baseline values: PMP 29 (8.9), control 27.9 (8.1) Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: baseline differences between groups in Dartmouth COOP/WONCA Functional Health Assessment Charts used to assess quality of life; outcome removed from analysis; Group 1 Number missing: 8; Group 2 Number missing: 5 - Actual outcome: Medical Outcomes Study Sleep Scale score at 12 weeks (immediately post treatment); Group 1: mean 36.3 (SD 9.2); n=81, Group 2: mean 28.8 (SD 8.6); n=74; Medical Outcomes Study Sleep Scale 12-71 Top=good outcome; Comments: Baseline values: PMP 29 (8.9), control 27.9 (8.1) Risk of bias: All domain – Very High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: Baseline details: baseline differences between groups in Dartmouth COOP/WONCA Functional Health Assessment Charts used to assess quality of life; outcome removed from analysis; Group 1 Number missing: 28; Group 2 Number missing: 39</p> <p>Protocol outcome 5: Discontinuation - Actual outcome: Discontinuation at 12 weeks (immediately post treatment); Group 1: 8/81, Group 2: 5/74; Comments: reasons for discontinuation not reported Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments NA ; Indirectness of outcome: Serious indirectness, Comments: study discontinuations - unclear whether programme was discontinued; Group 1 Number missing: 0; Group 2 Number missing: 0</p>
Protocol outcomes not reported by the study	Physical function; Pain interference; Pain self-efficacy; Use of healthcare services

1

Study	COMMENCE trial: Miller 2020 <sup>248</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=102)
Countries and setting	Conducted in Canada; Setting: community health center supporting marginalised populations e.g. low income, no health insurance, addiction, mental health concerns, isolated seniors

Study	COMMENCE trial: Miller 2020 <sup>248</sup>
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 6 weeks + 12 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: chronic non-cancer pain, present daily for over 3 months
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	adults with chronic non-cancer pain; ability read, write and speak English; pain could be constant or brought on by aggravating factors, consistent or fluctuating; present daily for over 3 months
Exclusion criteria	surgery or casted fracture within 6 months; signs or symptoms of upper motor neuron lesion and unexplained weight loss, urinary retention, saddle anaesthesia or fever.
Recruitment/selection of patients	referred by health care providers
Age, gender and ethnicity	Age - Mean (SD): intervention group 53.4 (13.5), wait list group 52.2 (11.7) years . Gender (M:F): 27/75. Ethnicity: not reported
Further population details	1. Age 16-18 years : Over 18 years 2. Cognitive impairment: Not stated / Unclear 3. First language not English: Not stated / Unclear (had to be able to read, write and speak English ). 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Extra comments	duration of pain (median (IQR)): intervention group 120 (59-201), wait list group 120 (37-228) months
Indirectness of population	No indirectness: NA
Interventions	(n=50) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. 2 visits per week over 6 weeks, led by a single trained physiotherapist. One 1.5 hour group visit incorporating education about self-management (informed by evidence, self-efficacy theory and social cognitive theory; strategies included progressive goal setting, activity scheduling, thought monitoring, relaxation, sleep education, reflection, self-monitoring, graded activity and exercise) and pain science (function of nervous system, other systems involved in pain, neuroplasticity, etc.) and cognitive behavioural principles to support behaviour change. One 30-45 minute 1:1 visit, individually tailored, aiming to support implementation of self-management plans and development of an exercise program tailored to participants' goals and

<b>Study</b>	<b>COMMENCE trial: Miller 2020<sup>248</sup></b>
	<p>abilities. 3 types of exercises encouraged: frequent pain-free movement, four to six times per day, six to ten repetitions at a time to reduce sensitivity to movement and build confidence with movement that does not increase pain; exercises that simulate functional tasks needed to perform goals, one to two times per day at an intensity that allows the individual to perform eight to 15 repetitions at a time to increase functional abilities needed to resume participation in life-role activities and participation goals; regular aerobic exercise. Also completed a program workbook and encouraged to continue self-management plans beyond the intervention. . Duration 6 weeks . Concurrent medication/care: treatments other than COMMENCE did not differ significantly between groups . Indirectness: No indirectness; Indirectness comment: NA Comments: 52% attended at least 9/12 sessions, 8% attended 6-8 sessions, 16% attended 3-5 sessions, 24% attended &lt;3 sessions</p> <p>(n=52) Intervention 2: Standard care (a few GP appointments)/waiting list . Waiting list - usual care most often included medication management, advice to stay active and referral to a specialist where appropriate. . Duration 6 weeks . Concurrent medication/care: treatments other than COMMENCE did not differ significantly between the groups . Indirectness: No indirectness; Indirectness comment: NA</p>
Funding	Academic or government funding (Ontario graduate scholarship and School of Rehabilitation Science at McMaster University; Canadian Institute for Health Research )

**RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST**

**Protocol outcome 1: Physical function**

- Actual outcome: Short-Musculoskeletal Function Assessment - Dysfunction Index at 7 weeks ; MD; -8.9 (95%CI -15.3 to -2.4) (p value : <0.1) SMFA-DI 34-170 Top=High is poor outcome, Comments: Mean difference adjusted for age, sex, PHQ-9 and no. of medications. Baseline values: intervention 44.3 (12.8), wait list 44.4 (16.2);

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: unable to locate (3), caregiver responsibilities (1), unreported reason (1); Group 2 Number missing: 5, Reason: unable to locate (5)

- Actual outcome: Short-Musculoskeletal Function Assessment - Dysfunction Index at 18 weeks ; MD; -8 (95%CI -14.7 to -1.3) (p value : <0.1) SMFA-DI 34-170 Top=High is poor outcome, Comments: Mean difference adjusted for age, sex, PHQ-9 and no. of medications. Baseline values: intervention 44.3

Study	COMMENCE trial: Miller 2020 <sup>248</sup>
<p>(12.8), wait list 44.4 (16.2); Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: unable to locate (5), time restraints (2), caregiver responsibilities (2), unreported reason (2), hospitalisation (1); Group 2 Number missing: 10, Reason: unable to locate (9), unexpected travel (1)</p> <p>Protocol outcome 2: Psychological distress (depression/anxiety) - Actual outcome: Patient Health Questionnaire (PHQ-9) - depressive symptoms at 7 weeks ; MD; -2.5 (95%CI -5.7 to 0.7) (p value : 0.06) PHQ-9 depressive symptoms 0-27 Top=High is poor outcome, Comments: Mean difference adjusted for age, sex, PHQ-9 and no. of medications. Baseline values: intervention 13.1 (6.4), wait list 13.1 (7.8); Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: unable to locate (3), caregiver responsibilities (1), unreported reason (1); Group 2 Number missing: 5, Reason: unable to locate (5) - Actual outcome: Patient Health Questionnaire (PHQ-9) - depressive symptoms at 18 weeks ; MD; -3 (95%CI -6.4 to 0.4) (p value : 0.03) PHQ-9 depressive symptoms 0-27 Top=High is poor outcome, Comments: Mean difference adjusted for age, sex, PHQ-9 and no. of medications. Baseline values: intervention 13.1 (6.4), wait list 13.1 (7.8); Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: unable to locate (5), time restraints (2), caregiver responsibilities (2), unreported reason (2), hospitalisation (1); Group 2 Number missing: 10, Reason: unable to locate (9), unexpected travel (1)</p> <p>Protocol outcome 3: Pain interference - Actual outcome: PROMIS Pain Interference Item Bank at 7 weeks ; MD; -1.4 (95%CI -4.4 to 1.6) (p value : 0-26) PROMIS pain interference 8-40 Top=High is poor outcome, Comments: Mean difference adjusted for age, sex, PHQ-9 and no. of medications. Baseline values: intervention 65.3 (7.2), wait list 65.2 (7.1). Baseline values higher than reported scale range ; Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: unable to locate (3), caregiver responsibilities (1), unreported reason (1); Group 2 Number missing: 5, Reason: unable to locate (5) - Actual outcome: PROMIS Pain Interference Item Bank at 18 weeks ; MD; -1.6 (95%CI -4.8 to 1.7) (p value : 0.25) PROMIS pain interference 8-40 Top=High is poor outcome, Comments: Mean difference adjusted for age, sex, PHQ-9 and no. of medications. Baseline values: intervention 65.3 (7.2), wait list 65.2 (7.1). Baseline values higher than reported scale range ; Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: unable to locate (5), time restraints (2), caregiver responsibilities (2), unreported reason (2), hospitalisation (1); Group 2 Number missing: 10, Reason: unable to locate (9), unexpected travel (1)</p> <p>Protocol outcome 4: Use of healthcare services - Actual outcome: Primary health care visits during prior week at 18 weeks ; MD; -0.27 (95%CI -1.26 to 0.73) (p value : 0.6) no. of visits, Comments: Mean difference adjusted for age, sex, PHQ-9 and no. of medications. Baseline values: intervention 3.8 (4.1), wait list 4 (3.7); Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - High,</p>	

Study	COMMENCE trial: Miller 2020 <sup>248</sup>
	<p>Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: unable to locate (5), time restraints (2), caregiver responsibilities (2), unreported reason (2), hospitalisation (1); Group 2 Number missing: 10, Reason: unable to locate (9), unexpected travel (1)                      - Actual outcome: Emergency department visits during prior week at 18 weeks ; MD; 0.02 (95%CI -0.23 to 0.27) (p value : 0.87) no. of visits , Comments: Mean difference adjusted for age, sex, PHQ-9 and no. of medications. Baseline values: intervention 0.1 (0.4), wait list 0.4 (0.8) ;                      Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - High,                      Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: unable to locate (5), time restraints (2), caregiver responsibilities (2), unreported reason (2), hospitalisation (1); Group 2 Number missing: 10, Reason: unable to locate (9), unexpected travel (1)                      - Actual outcome: Specialist appointment visits during prior week at 18 weeks ; MD; -0.26 (95%CI -0.56 to 0.05) (p value : 0.09) no. of visits , Comments: Mean difference adjusted for age, sex, PHQ-9 and no. of medications. Baseline values: intervention 0.7 (1.2), wait list 0.4 (0.8);                      Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - High,                      Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: unable to locate (5), time restraints (2), caregiver responsibilities (2), unreported reason (2), hospitalisation (1); Group 2 Number missing: 10, Reason: unable to locate (9), unexpected travel (1)                      - Actual outcome: Diagnostic imaging visits during prior week at 18 weeks ; MD; -0.18 (95%CI -0.51 to 0.14) (p value: 0.27) no. of visits , Comments: Mean difference adjusted for age, sex, PHQ-9 and no. of medications. Baseline values: intervention 0.6 (0.8), wait list 0.8 (1) ;                      Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - High,                      Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: unable to locate (5), time restraints (2), caregiver responsibilities (2), unreported reason (2), hospitalisation (1); Group 2 Number missing: 10, Reason: unable to locate (9), unexpected travel (1)</p>
	<p>Protocol outcome 5: Pain reduction                      - Actual outcome: Numeric pain rating scale at 7 weeks ; MD; -1.4 (95%CI -2.4 to -0.5) (p value : &lt;.01) NPRS 0-10 Top=High is poor outcome, Comments: Mean difference adjusted for age, sex, PHQ-9 and no. of medications. Baseline values: intervention 7.2 (1.8), wait list 7.6 (1.8);                      Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low,                      Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: unable to locate (3), caregiver responsibilities (1), unreported reason (1); Group 2 Number missing: 5, Reason: unable to locate (5)                      - Actual outcome: Numeric pain rating scale at 18 weeks ; MD; -1 (95%CI -2.1 to -0.1) (p value: .02) NPRS 0-10 Top=High is poor outcome, Comments: Mean difference adjusted for age, sex, PHQ-9 and no. of medications. Baseline values: intervention 7.2 (1.8), wait list 7.6 (1.8) ;                      Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low,                      Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: unable to locate (5), time restraints (2), caregiver responsibilities (2), unreported reason (2), hospitalisation (1); Group 2 Number missing: 10, Reason: unable to locate (9), unexpected travel (1)</p>
	<p>Protocol outcome 6: Pain self-efficacy                      - Actual outcome: Pain self-efficacy questionnaire at 7 weeks ; MD; 5.2 (95%CI -0.7 to 11.2) (p value : .04) PSEQ 0-60 Top=High is good outcome, Comments: Mean difference adjusted for age, sex, PHQ-9 and no. of medications. Baseline values: intervention 31.4 (14.2), wait list 28.1 (13.5);                      Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low,                      Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: unable to locate (3), caregiver responsibilities (1), unreported reason (1); Group 2 Number missing: 5, Reason: unable to locate (5)                      - Actual outcome: Pain self-efficacy questionnaire at 18 weeks ; MD; 7 (95%CI 0.8 to 13.2) (p value : &lt;.01) PSEQ 0-60 Top=High is good outcome,</p>

Study	COMMENCE trial: Miller 2020 <sup>248</sup>
Comments: Mean difference adjusted for age, sex, PHQ-9 and no. of medications. Baseline values: intervention 31.4 (14.2), wait list 28.1 (13.5); Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: unable to locate (5), time restraints (2), caregiver responsibilities (2), unreported reason (2), hospitalisation (1); Group 2 Number missing: 10, Reason: unable to locate (9), unexpected travel (1)	
Protocol outcomes not reported by the study	Quality of life; Sleep; Discontinuation due to adverse events

1

Study	Corey 1996 <sup>77</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=214)
Countries and setting	Conducted in Canada; Setting: Health recovery clinic and 2 multidisciplinary rehabilitation facilities
Line of therapy	Not applicable
Duration of study	Intervention + follow up: Average 32.9 days + 17.9 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: NA
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	18-60 years of age; work-related soft tissue injury with no neurological involvement and disability longer than would be expected based on the nature of the injury; referred from 3-6 months post injury
Exclusion criteria	Documented history of alcoholism
Recruitment/selection of patients	Injured workers totally disabled from work, receiving workers compensation board wage loss benefits, chosen from computer generated files
Age, gender and ethnicity	Age - Range: 18-60 years. Gender (M:F): 137/63 (calculated from percentages). Ethnicity: not reported
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: Not stated / Unclear 3. First language not English: First language English (majority were conversant in English (intervention 75%, usual care 89%)). 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Indirectness of population	No indirectness: NA
Interventions	(n=100) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Functional restoration programme: treatment sessions limited to 6.5 hours per day to a maximum of 35 days (average 32.9 days) <ul style="list-style-type: none"> <li>· Focus on active physical therapy including stretching, strengthening and endurance building; work hardening; and education in posture and body mechanics.</li> <li>· Group education and counselling addressed pain-related disability issues, attitudinal barriers to recovery, sleep disruption etc.</li> <li>· Taught pain management strategies, stress management, problem solving techniques, relaxation and guided imagery techniques.</li> </ul> Duration average 32.9 days. Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA

	(n=100) Intervention 2: Standard care (a few GP appointments)/waiting list. Discharged back to treating physician with a note of assessment findings and recommendations for proactive management. Duration average 18.9 months. Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA
Funding	Other (financial contribution from the Workers' compensation board of Ontario)
<p><b>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST</b></p> <p>Protocol outcome 1: Pain reduction          - Actual outcome: Non-visual analogue scale at 9-27 months ; Group 1: mean 5.3 (SD 2.9); n=74, Group 2: mean 6.5 (SD 2.24); n=64; non-visual analogue scale 0-10 Top=High is poor outcome; Comments: Baseline values: intervention 6.4 (2.17), control 6.2 (2.24)          Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 26, Reason: lost to follow up. Study also reports 14 additional people excluded due to treatment refusal, quitting the programme early or noncompliance, however unclear from which group ; Group 2 Number missing: 36, Reason: lost to follow up</p>	
Protocol outcomes not reported by the study	Quality of life; Physical function; Psychological distress (depression/anxiety); Pain interference; Use of healthcare services; Sleep; Discontinuation; Pain self-efficacy

Study	Ersek 2008 <sup>106</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=256)
Countries and setting	Conducted in USA; Setting: 43 retirement facilities
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 12 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Over 65 years old, pain lasting >3 months, pain interfering with activities, >2 on pain scale, ability to complete questionnaires and attend programme.
Exclusion criteria	Active cancer, surgery within the past six months, and surgery planned in the next six months.
Recruitment/selection of patients	Through retirement facilities
Age, gender and ethnicity	Age - Mean (SD): 81.9(6.3):81.8(6.7). Gender (M:F): 15/85. Ethnicity: 93% Caucasian
Further population details	1. Age 16-18 years : 2. Cognitive impairment: 3. First language not English: 4. Homeless: 5. Learning difficulties: 6. Sensory impairment :
Indirectness of population	No indirectness
Interventions	<p>(n=133) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. 7 weekly 90 minute group sessions, incorporating basic education about persistent pain as well as training in and practice of pain self-management techniques. Included progressive muscle relaxation; selected range of motion, strengthening and balance exercises and application of heat and cold. Presentations and discussion also focused on pacing activities, challenging negative thoughts, dealing with pain flare-ups and setbacks in pain management activities, and pain medicines and complementary therapies. Participants also received a syllabus, relaxation CD and 2 hot/cold gel packs. Groups facilitated by 1 of 3 leaders (2 nurses and 1 clinical psychologist). Duration 7 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness</p> <p>(n=123) Intervention 2: Standard care (a few GP appointments)/waiting list. Participants received a copy of 'The chronic pain workbook' or 'Managing your pain before it manages you'. Both include self-management approaches to chronic pain. Facilitators telephoned participants 1 and 4 weeks after they received the book using a standard script asked questions about current pain &amp; functioning. Duration 7 weeks. Concurrent</p>

	medication/care: Not reported. Indirectness: No indirectness
Funding	Academic or government funding (National Institute of Nursing Research)
<p><b>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST</b></p> <p><b>Protocol outcome 1: Physical function</b>          - Actual outcome: Roland Morris Disability Questionnaire at Post intervention (7 weeks); Group 1: mean 11.8 Roland Morris Disability Questionnaire (SD 4.9); n=123, Group 2: mean 12.4 Roland Morris Disability Questionnaire (SD 5.4); n=101; Roland Morris 0-24 Top=High is poor outcome; Comments: Baseline values mean (SD) Intervention 12.2(4.7) Control 13.0(4.5)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Cluster randomisation potentially means different assessment-centres could be a confounder to between-group comparisons; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: not reported ; Group 2 Number missing: 22, Reason: not reported          - Actual outcome: Roland Morris Disability Questionnaire at 1 year; Group 1: mean 11.6 (SD 5.7); n=114, Group 2: mean 11.9 (SD 5.6); n=103; Roland Morris 0-24 Top=High is poor outcome; Comments: 12.2(4.7):13.0(4.5)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Cluster randomisation potentially means different assessment-centres could be a confounder to between-group comparisons; Indirectness of outcome: No indirectness ; Group 1 Number missing: 18, Reason: Unable to contact: 3, death: 5, illness: 7, refusal: 4 ; Group 2 Number missing: 20, Reason: Unable to contact: 3, death: 4, illness: 5, refusal: 8</p> <p><b>Protocol outcome 2: Psychological distress (depression/anxiety)</b>          - Actual outcome: Geriatric depression scale at 1 year; Group 1: mean 11.2 (SD 3.1); n=114, Group 2: mean 10.8 (SD 2.7); n=103; Geriatric depression scale 0-30 Top=High is poor outcome; Comments: 11.1 (2.8) : 11.0 (3.0)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Cluster randomisation potentially means different assessment-centres could be a confounder to between-group comparisons; Indirectness of outcome: No indirectness ; Group 1 Number missing: 18, Reason: Unable to contact: 3, death: 5, illness: 7, refusal: 4 ; Group 2 Number missing: 20, Reason: Unable to contact: 3, death: 4, illness: 5, refusal: 8          - Actual outcome: Geriatric depression scale at Post intervention (7 weeks); Group 1: mean 11.1 (SD 2.9); n=123, Group 2: mean 10.9 (SD 3.3); n=101; Geriatric depression score 0-30 Top=High is poor outcome; Comments: 11.1 (2.8) : 11.0 (3.0)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: not reported ; Group 2 Number missing: 22, Reason: not reported</p> <p><b>Protocol outcome 3: Pain interference</b>          - Actual outcome: Pain interference range at 1 year; Group 1: mean 3.7 (SD 2.2); n=114, Group 2: mean 3.9 (SD 2.3); n=103; Interference scale 0-10 Top=High is poor outcome; Comments: 4.2 (2.0) : 4.5 (2.0)</p>	

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Cluster randomisation potentially means different assessment-centres could be a confounder to between-group comparisons; Indirectness of outcome: No indirectness ; Group 1 Number missing: 18, Reason: Unable to contact: 3, death: 5, illness: 7, refusal: 4 ; Group 2 Number missing: 20, Reason: Unable to contact: 3, death: 4, illness: 5, refusal: 8  
- Actual outcome: Pain interference range at Post intervention (7 weeks); Group 1: mean 4.1 (SD 2); n=123, Group 2: mean 4.2 (SD 2.2); n=101; VAS scale 0-10 Top=High is poor outcome; Comments: 4.2 (2.0) : 4.5 (2.0)

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Cluster randomisation potentially means different assessment-centres could be a confounder to between-group comparisons; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: not reported ; Group 2 Number missing: 22, Reason: not reported

Protocol outcome 4: Discontinuation

- Actual outcome: Discontinuation any reason at Post intervention (7 weeks); Group 1: 10/133, Group 2: 22/123; Comments: reasons for discontinuation not reported

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Cluster randomisation potentially means different assessment-centres could be a confounder to between-group comparisons; Indirectness of outcome: No indirectness ; Group 1 Number missing; Group 2 Number missing

Protocol outcome 5: Pain reduction

- Actual outcome: Pain VAS at Post intervention (7 weeks); Group 1: mean 4.9 VAS pain (SD 1.9); n=123, Group 2: mean 5 VAS pain (SD 2.1); n=101; VAS 0-10 Top=High is poor outcome; Comments: 5.4 (1.9) : 5.4 (1.8)

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Cluster randomisation potentially means different assessment-centres could be a confounder to between-group comparisons; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: not reported ; Group 2 Number missing: 22, Reason: not reported

- Actual outcome: Pain VAS at 1 year; Group 1: mean 5 (SD 2.1); n=114, Group 2: mean 4.5 (SD 2.1); n=103; VAS pain 0-10 Top=High is poor outcome; Comments: 5.4 (1.9) : 5.4 (1.8)

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Cluster randomisation potentially means different assessment-centres could be a confounder to between-group comparisons; Indirectness of outcome: No indirectness ; Group 1 Number missing: 18, Reason: unable to contact: 3, death: 5, illness: 7, refusal: 4 ; Group 2 Number missing: 20, Reason: unable to contact: 3, death: 4, illness: 5, refusal: 8

Protocol outcomes not reported by the study

Quality of life; Use of healthcare services; Sleep; Pain self-efficacy

Study	Gatchel 2009 <sup>128</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=66)
Countries and setting	Conducted in USA; Setting: 2 Army medical centres
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 12 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: diagnosed musculoskeletal disorder for longer than 3 months
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	diagnosed musculoskeletal disorder; pain duration >3 months; active duty military (all 4 services eligible to participate); at least 18 months retainability on active duty; decreased ability to perform duty requirements because of pain and disability
Exclusion criteria	medical evaluation board in progress; current plan for surgery, morphine pump or spinal cord stimulator
Recruitment/selection of patients	not reported
Age, gender and ethnicity	Age - Mean (SD): PMP 36.9 (7.5), control 34.4 (6.9). Gender (M:F): 44/22. Ethnicity: PMP: Asian 3%, African-American 17%, Caucasian 63%, Hispanic 13%, other 3%; Control: Asian 6%, African-American 19%, Caucasian 67%, Hispanic 8%, other 0%
Further population details	1. Age 16-18 years: Not stated / Unclear 2. Cognitive impairment: Not stated / Unclear 3. First language not English: Not stated / Unclear 4. Homeless: Not homeless 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : No sensory impairment
Indirectness of population	No indirectness: NA
Interventions	(n=30) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Functional restoration: Interdisciplinary team approach consisting of 3 major components; physical therapy, occupational therapy, and psychosocial intervention. An aggressive psychosocial and physical reconditioning program. Not traditional passive physical treatment modalities. Treatment initially guided by quantified measurements of function. Psychosocial and return-to-work issues are simultaneously addressed by the psychology and occupational therapy component of the program. Also receive standard treatment as necessary to manage their pain. Led by: a supervising nurse and physician team. Duration Not reported. Concurrent medication/care: Standard care: Treatment similar to specialty pain treatment available at many larger military medical treatment facilities. Common treatments include: Management of pain medications, proper use of antidepressant medications as appropriate, nerve blocks and steroid injections, a basic exercise programme when appropriate. Led by: anesthesiologists with

	<p>training in pain management or pain medicine. Indirectness: Serious indirectness; Indirectness comment: Not comparable with non-military programmes</p> <p>(n=36) Intervention 2: Standard care (a few GP appointments)/waiting list . Standard treatment (standard anaesthesia pain clinic medical care): Treatment similar to speciality pain treatment available at many larger military medical treatment facilities. Common treatments include: Management of pain medications, proper use of antidepressant medications as appropriate, nerve blocks and steroid injections, a basic exercise programme when appropriate. Led by: anesthesiologists with training in pain management or pain medicine. Duration Not reported. Concurrent medication/care: NA. Indirectness: Serious indirectness; Indirectness comment: Usual care = military usual care</p>
Funding	Academic or government funding (supported in part by grants from the Congressionally Directed Medical Research Program's Peer Review Medical Research Program and the National Institutes of Health )

**RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST**

**Protocol outcome 1: Quality of life**

- Actual outcome: SF-36 Physical composite at Post treatment; Group 1: mean 43.5 (SD 8.6); n=30, Group 2: mean 34.3 (SD 7.6); n=36; Comments: Baseline values: PMP 32.5 (9.5), control 35.6 (9)
- Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0
- Actual outcome: SF-36 Mental composite at Post treatment; Group 1: mean 53.5 (SD 5.9); n=30, Group 2: mean 50.6 (SD 8.4); n=36; SF-36 mental composite score 0-100 Top=High is good outcome; Comments: Baseline values: PMP 51.6 (9.1), 48.3 (8.8)
- Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0
- Actual outcome: SF-36 Physical composite at 6 months; Group 1: mean 43.3 (SD 8.6); n=22, Group 2: mean 35.1 (SD 7.6); n=23; SF36 physical composite score 0-100 Top=High is good outcome; Comments: Baseline values: PMP 32.5 (9.5), control 35.6 (9)
- Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 8, Reason: not reported ; Group 2 Number missing: 13, Reason: not reported
- Actual outcome: SF-36 Mental composite at 6 months; Group 1: mean 52 (SD 8.1); n=22, Group 2: mean 45.5 (SD 10.2); n=23; SF36 mental composite score 0-100 Top=High is good outcome; Comments: Baseline values: PMP 51.6 (9.1), control 48.3 (8.8)
- Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 8, Reason: not reported ; Group 2 Number missing: 13, Reason: not reported

**Protocol outcome 2: Physical function**

- Actual outcome: Oswestry disability scale at Post treatment; Group 1: mean 11 (SD 5.4); n=30, Group 2: mean 17.8 (SD 4.5); n=36; Oswestry disability score 0-100 Top=High is poor outcome; Comments: Baseline values: PMP 18.1 (8.6), control 18.9 (6.1)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0

- Actual outcome: Oswestry disability scale at 6 months; Group 1: mean 10.3 (SD 7.7); n=22, Group 2: mean 19.5 (SD 5.5); n=23; Oswestry disability scale 0-100 Top=High is poor outcome; Comments: Baseline values: PMP 18.1 (8.6), control 18.9 (6.1)

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 8, Reason: not reported ; Group 2 Number missing: 13, Reason: not reported

Protocol outcome 3: Psychological distress (depression/anxiety)

- Actual outcome: Beck depression inventory at Post treatment; Group 1: mean 5.5 (SD 4.1); n=30, Group 2: mean 10.5 (SD 8.2); n=36; Beck depression inventory 0-63 Top=High is poor outcome; Comments: Baseline values: PMP 11.3 (8.1), control 13.8 (9.4)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0

- Actual outcome: Beck depression inventory at 6 months; Group 1: mean 6.4 (SD 7.3); n=22, Group 2: mean 13.8 (SD 8.3); n=23; Beck depression inventory 0-63 Top=High is poor outcome; Comments: Baseline values: PMP 11.3 (8.1), control 13.8 (9.4)

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 8, Reason: not reported ; Group 2 Number missing: 13, Reason: not reported

Protocol outcome 4: Pain interference

- Actual outcome: Multidimensional pain inventory, interference sub scale at Post treatment; Group 1: mean 30.1 (SD 10.6); n=30, Group 2: mean 39.5 (SD 9.3); n=36; Multidimensional pain inventory interference subscale not reported Top=High is poor outcome; Comments: Baseline values: PMP 37.7 (11.1), control 36.7 (8.4)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0

- Actual outcome: Multidimensional pain inventory, interference sub scale at 6 months; Group 1: mean 28.1 (SD 10); n=22, Group 2: mean 38.4 (SD 13.9); n=23; Comments: Baseline values: PMP 37.7 (11.1), control 36.7 (8.4)

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 8, Reason: not reported ; Group 2 Number missing: 13, Reason: not reported

Protocol outcome 5: Use of healthcare services

- Actual outcome: Total no. of MD and/or ER visits for pain care at 12 months ; Group 1: mean 5.1 visits (SD 7.8); n=12, Group 2: mean 23.1 visits (SD 56.3); n=12; Comments: also reported: no. who met medical board within 1 year, no. who continued seeking medical care for pain, no. who continued taking pain medication, no. who had new surgical procedures for pain and total no. of different health care providers seen for pain

Risk of bias: All domain – Very high; Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - High,

Crossover - Low; Indirectness of outcome: No indirectness

Protocol outcome 6: Discontinuation

- Actual outcome: Discontinuation any reason at Post treatment; Group 1: 0/30, Group 2: 0/36

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 7: Pain reduction

- Actual outcome: Pain VAS at Post treatment; Group 1: mean 3.8 (SD 2.3); n=30, Group 2: mean 6 (SD 2.1); n=36; VAS 0-10 Top=High is poor outcome; Comments: Baseline values: PMP 6.1 (2.1), control 6.1 (1.8)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0

- Actual outcome: Pain VAS at 6 months; Group 1: mean 4 (SD 2.3); n=22, Group 2: mean 6.6 (SD 2); n=23; VAS 0-10 Top=High is poor outcome; Comments: Baseline values: PMP 6.1 (2.1), control 6.1 (1.8)

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 8, Reason: not reported ; Group 2 Number missing: 13, Reason: not reported

Protocol outcomes not reported by the study

Sleep; Pain self-efficacy

Study	Hamnes 2012 <sup>158</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=147)
Countries and setting	Conducted in Norway; Setting: Hospital for Rheumatic Diseases
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 1 week + 3 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: diagnosis of FM according to the American College of Rheumatology's criteria
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	Diagnosis of FM according to the American College of Rheumatology's criteria, a desire to participate in the SMP, an ability to speak the Norwegian language, age between 20 and 70 years, and willingness to give written informed consent
Exclusion criteria	Previous participation in an SMP, cognitive impairment, vision or hearing problems, and serious mental disorders
Recruitment/selection of patients	Referred to the hospital for the SMP
Age, gender and ethnicity	Age - Mean (SD): intervention 45.4 (9.4), control 49.7 (4). Gender (M:F): 6/141. Ethnicity: not reported
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: No cognitive impairment 3. First language not English: Not applicable 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : No sensory impairment
Indirectness of population	No indirectness: NA
Interventions	(n=75) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. 1 week multidisciplinary inpatient programme based on a cognitive behavioural approach and focused on enhancing self-efficacy and coping with the disease and daily life, including: <ul style="list-style-type: none"> <li>• an education unit with up to 16 patients and 5 spouses/relatives/partners per week</li> <li>• individual consultations with the multidisciplinary team if needed</li> <li>· Setting goals</li> <li>· Swimming pool exercises</li> </ul>

	<ul style="list-style-type: none"> <li>· Medication consultation</li> <li>· Relaxation</li> <li>· Education on mechanisms of disease</li> <li>· Self-management techniques such as awareness of coping strategies, communication etc.</li> <li>· Stress management</li> <li>· Walking</li> <li>· Education and discussion on healthy eating</li> <li>· Group discussions</li> </ul> <p>Duration 1 week. Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA Comments: intervention group waited one to six months for SMP</p> <p>(n=72) Intervention 2: Standard care (a few GP appointments)/waiting list. Did not receive any treatment at the hospital in the period from inclusion to participation in the SMP. Duration 8 months or more. Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA</p>
Funding	Academic or government funding (Hospital for Rheumatic Diseases, Lillehammer, Norway, Norwegian Fibromyalgia Association, Norwegian Rheumatism Association, The Norwegian Nurses Organisation and Per Ryghs Legacy, University of Oslo, Norway).
<p><b>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST</b></p> <p>Protocol outcome 1: Quality of life          - Actual outcome: Fibromyalgia Impact Questionnaire at 3 weeks (3 weeks after the end of the programme); Group 1: mean 55.9; n=58, Group 2: mean 61; n=60; Fibromyalgia Impact Questionnaire 0-100 Top=High is poor outcome; Comments: 95% CI: intervention 7-90.5, control 23.2-93.2, baseline values: intervention 59 (16.1-89.6), control 59.7 (23.9-92.5)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: 6 males in the intervention group (8%), 0 in the control group; Group 1 Number missing: 17, Reason: 12 withdrawals, 5 lost to follow up; Group 2 Number missing: 12, Reason: 6 withdrawals, 6 lost to follow up</p> <p>Protocol outcome 2: Psychological distress (depression/anxiety)          - Actual outcome: Psychological distress (General Health Questionnaire) at 3 weeks; Group 1: mean 25; n=58, Group 2: mean 24.6; n=60; General Health Questionnaire 0-60 Top=High is poor outcome; Comments: 95% CI: intervention 6-49.1, control 10-57.2, baseline values: intervention 27 (11-57.2), control 26.4 (10-50.2)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: 6 males in the intervention group (8%), 0 in the control group; Group 1 Number missing: 17, Reason: 12 withdrawals, 5 lost to follow up; Group 2 Number missing: 12, Reason: 6 withdrawals, 6 lost to follow up</p>	

Protocol outcome 3: Discontinuation

- Actual outcome: Withdrawals and loss to follow up at 3 weeks; Group 1: 17/75, Group 2: 12/72; Comments: intervention 12 withdrew, 5 lost to follow up (reasons not reported); control 6 withdrew, 6 lost to follow up (reasons not reported)

Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: 6 males in the intervention group (8%), 0 in the control group; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 4: Pain self-efficacy

- Actual outcome: Arthritis Self-Efficacy scale pain subscale at 3 weeks; Group 1: mean 54.8; n=58, Group 2: mean 52.3; n=60; Arthritis Self-Efficacy Scale pain subscale 10-100 Top=High is good outcome; Comments: 95% CI: intervention16-94, control10-82, baseline values: intervention 50.6 (18-82), control 51.4 (10-98)

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: 6 males in the intervention group (8%), 0 in the control group; Group 1 Number missing: 17, Reason: 12 withdrawals, 5 lost to follow up; Group 2 Number missing: 12, Reason: 6 withdrawals, 6 lost to follow up

Protocol outcomes not reported by the study

Physical function; Pain interference; Use of healthcare services; Sleep; Pain reduction

Study	Heuts 2005 <sup>164</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=273)
Countries and setting	Conducted in Netherlands; Setting: not reported
Line of therapy	Not applicable
Duration of study	Follow up (post intervention): 21 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: International Classification of Health Care Problems in Primary Care criteria
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	characteristic radiological appearance; Heberden's nodes; joint disorder of at least 3 months' duration with no constitutional symptoms and at least 3 of the following - irregular swelling, crepitation, stiffness or limitation of movement, normal erythrocyte sedimentation rate, rheumatoid factor tests and uric acid and age >40 years
Exclusion criteria	rheumatoid arthritis; ankylosing spondylitis; gout
Recruitment/selection of patients	academic registration networks of primary care practices and local advertisements
Age, gender and ethnicity	Age - Mean (SD): intervention 51 (5), control 52.2 (5.1). Gender (M:F): 110/163. Ethnicity: not reported
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: Not stated / Unclear 3. First language not English: Not stated / Unclear 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Indirectness of population	No indirectness: NA
Interventions	(n=149) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Self-management programme: 6 x 2 hour sessions, led by: 2 physiotherapists <ul style="list-style-type: none"> <li>· Goal setting, self-incentives and motivators to optimise activity level</li> <li>· Discussion of rational use of medication</li> <li>· Self-relaxation training, problem solving and self-diagnostic skills</li> <li>· Moving and exercising (no further details provided)</li> <li>· Standardised training materials e.g. information sheets, handbook on OA and self-management</li> </ul> Duration not reported. Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA  (n=148) Intervention 2: Standard care (a few GP appointments)/waiting list. Care prescribed by a family

	physician or consulted specialist. Duration not reported. Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA
Funding	Other (Dutch Arthritis Association and the Rehabilitation Foundation Limburg)
<p><b>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST</b></p> <p><b>Protocol outcome 1: Physical function</b>          - Actual outcome: Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at 3 months (from start of intervention); Group 1: mean - 2.46 (SD 9.49); n=94, Group 2: mean 0.53 (SD 9.74); n=103; WOMAC Likert version not reported Top=High is poor outcome; Comments: Baseline values: intervention 32.7 (14.7), control 35.7 (17.3)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 55, Reason: not reported ; Group 2 Number missing: 45, Reason: not reported          - Actual outcome: Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at 21 months (from start of intervention); Group 1: mean 30.1 (SD 16.8); n=94, Group 2: mean 35.1 (SD 17.6); n=113; WOMAC likert version not reported Top=High is poor outcome; Comments: Baseline values: intervention 32.7 (14.7), control 35.7 (17.3)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 55, Reason: not reported ; Group 2 Number missing: 35, Reason: not reported</p> <p><b>Protocol outcome 2: Discontinuation</b>          - Actual outcome: discontinuation at 3 months (from start of intervention); Group 1: 22/149, Group 2: 7/148; Comments: Intervention: 17 withdrew before the start of the intervention for practical reasons, 3 withdrew during the intervention because they were not satisfied, 1 because of knee pain and 1 because of home situation. Control: 7 withdrew before the start of the intervention for practical reasons          Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing; Group 2 Number missing</p> <p><b>Protocol outcome 3: Pain reduction</b>          - Actual outcome: VAS knee pain at 3 months (from start of intervention); Group 1: mean -0.67 (SD 2.1); n=95, Group 2: mean -0.01 (SD 2); n=107; VAS 0-10 Top=High is poor outcome; Comments: Baseline values: intervention 4.3 (2.4), control 3.8 (2.9)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 54, Reason: not reported ; Group 2 Number missing: 41, Reason: not reported          - Actual outcome: VAS knee pain at 21 months (from start of intervention); Group 1: mean 3.7 (SD 2.6); n=96, Group 2: mean 4.2 (SD 2.7); n=118; VAS 0-10 Top=High is poor outcome; Comments: Baseline values: intervention 4.3 (2.4), control 3.8 (2.9)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low,</p>	

Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 53, Reason: not reported ; Group 2 Number missing: 30, Reason: not reported  
 - Actual outcome: VAS hip pain at 3 months (from start of intervention); Group 1: mean -0.22 (SD 1.95); n=96, Group 2: mean -0.28 (SD 1.83); n=107; VAS 0-10 Top=High is poor outcome; Comments: Baseline values: intervention 3.2 (2.6), control 3.5 (2.9)  
 Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 53, Reason: not reported ; Group 2 Number missing: 41, Reason: not reported  
 - Actual outcome: VAS hip pain at 21 months (from start of intervention); Group 1: mean 3 (SD 2.9); n=96, Group 2: mean 3.5 (SD 2.7); n=117; VAS 0-10 Top=High is poor outcome; Comments: Baseline values: intervention 3.2 (2.6), control 3.5 (2.9)  
 Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 53, Reason: not reported ; Group 2 Number missing: 31, Reason: not reported

Protocol outcome 4: Pain self-efficacy  
 - Actual outcome: Arthritis self-efficacy scale at 3 months (from start of intervention); Group 1: mean 0.07 (SD 0.57); n=91, Group 2: mean 0.03 (SD 0.62); n=101; ASES not reported Top=High is good outcome; Comments: Baseline values: intervention 3.8 (0.7), control 3.7 (0.8)  
 Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 58, Reason: not reported ; Group 2 Number missing: 47, Reason: not reported  
 - Actual outcome: Arthritis self-efficacy scale at 21 months (from start of intervention); Group 1: mean 3.9 (SD 0.8); n=89, Group 2: mean 3.7 (SD 0.9); n=106; ASES not reported Top=High is good outcome; Comments: Baseline values: intervention 3.8 (0.7), control 3.7 (0.8)  
 Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 60, Reason: not reported ; Group 2 Number missing: 42, Reason: not reported

Protocol outcomes not reported by the study

Quality of life; Psychological distress (depression/anxiety); Pain interference; Use of healthcare services; Sleep

Study	IMPROVe trial: Amris 2014 <sup>9</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=191)
Countries and setting	Conducted in Denmark; Setting: Outpatient clinic of the Department of Rheumatology, single hospital centre
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Diagnosis according to the American College of Rheumatology 1990 definition of widespread pain
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	Aged >18 years; chronic widespread pain diagnosed according to the American College of Rheumatology 1990 definition.
Exclusion criteria	Concurrent psychiatric disorders not related to the pain disorder; other uncontrolled rheumatic or medical disease capable of causing chronic widespread pain
Recruitment/selection of patients	For every 16 patients included, participants were randomly assigned to either intervention or control with a 1:1 allocation, per a computer generated randomisation schedule. The sequence was concealed until interventions were assigned.
Age, gender and ethnicity	Age - Mean (SD): PMP group 44.4 (10.9), control group 44.2 (10.8). Gender (M:F): 0/191. Ethnicity: not reported
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: No cognitive impairment 3. First language not English: Not applicable 4. Homeless: Not stated / Unclear 5. Learning difficulties: No learning difficulties 6. Sensory impairment : Not stated / Unclear
Indirectness of population	No indirectness: NA
Interventions	(n=96) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Non-residential, group based, multi component treatment course conducted by a psychologist, a rheumatologist, a nurse, and occupational and physiotherapists including: 3-hour counselling session; educational sessions focused on information about chronic widespread pain and ways to manage pain; group discussions focused on shared experiences of living with chronic pain and strategies to cope with this; physical therapy included information about the principles of graded exercise and activity pacing, as well as supervised training sessions (aerobic, pool exercises, balance training, proprioception) and relaxation; occupational therapy focused on pain-related interference and how to adapt to this; sessions led by psychologists (no further details), and a rheumatologist consultation.

	<p>Duration 2 weeks. Concurrent medication/care: Participants continued to take their usual medications. Indirectness: No indirectness; Indirectness comment: NA</p> <p>(n=95) Intervention 2: Standard care (a few GP appointments)/waiting list. Informed that they would receive no treatment during the first phase of the study, but would be offered the same 2 week course at the end of the waiting list. Duration 2 weeks. Concurrent medication/care: participants continued to take their usual medications. Indirectness: No indirectness; Indirectness comment: NA</p>
Funding	Academic or government funding (grants from The Oak Foundation, Schioldanns Fond and The Danish Rheumatism Association )

**RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST**

**Protocol outcome 1: Quality of life**

- Actual outcome: SF36 mental composite score at 6 months; Group 1: mean 2.29 (SD 8.66); n=84, Group 2: mean 1.15 (SD 8.77); n=86; SF36 mental composite score 0-100 Top=High is good outcome; Comments: Baseline values: PMP 39.4 (12.2), control 37.8 (9.8)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: 4 withdrew due to logistical problems (change of address, long transportation, vacation), 2 withdrew due to illness in close family, 2 withdrew due to own illness not related to pain condition, 4 withdrew consent to participate in follow up assessment; Group 2 Number missing: 9, Reason: 3 withdrew due to logistical problems (work, vacation), 1 withdrew due to illness in close family, 2 withdrew due to worsening of the pain condition, 3 withdrew consent to participate

- Actual outcome: SF36 physical composite score at 6 months; Group 1: mean 1.35 (SD 4.98); n=84, Group 2: mean 0.78 (SD 5.04); n=86; SF36 physical composite score 0-100 Top=High is good outcome; Comments: Baseline values: PMP 27.1 (6.9), control 27.2 (7)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: 4 withdrew due to logistical problems (change of address, long transportation, vacation), 2 withdrew due to illness in close family, 2 withdrew due to own illness not related to pain condition, 4 withdrew consent to participate in follow up assessment; Group 2 Number missing: 9, Reason: 3 withdrew due to logistical problems (work, vacation), 1 withdrew due to illness in close family, 2 withdrew due to worsening of the pain condition, 3 withdrew consent to participate

**Protocol outcome 2: Psychological distress (depression/anxiety)**

- Actual outcome: GAD-10 anxiety score at 6 months; Group 1: mean -0.78 (SD 5.8); n=88, Group 2: mean -0.54 (SD 6.19); n=95; GAD-10 0-10 Top=High is poor outcome

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: 4 withdrew due to logistical problems (change of address, long transportation, vacation), 2 withdrew due to illness in close family, 2 withdrew due to own illness not related to pain condition, 4 withdrew consent to participate in follow up assessment; Group 2 Number missing: 9, Reason: 3 withdrew due to logistical problems (work, vacation), 1 withdrew due to illness in close family, 2 withdrew due to worsening of the pain condition, 3 withdrew consent to participate

**Protocol outcome 3: Pain reduction**

- Actual outcome: VAS pain (from FIQ) at 6 months; Group 1: mean 0.07 (SD 1.75); n=84, Group 2: mean -0.14 (SD -1.8); n=86; VAS 0-10 Top=High is poor outcome; Comments: SDs calculated from CIs reported in the study  
 Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Intervention 7.12 (1.96) Control 7.44 (1.71); Group 1 Number missing: 12, Reason: 4 withdrew due to logistical problems (change of address, long transportation, vacation), 2 withdrew due to illness in close family, 2 withdrew due to own illness not related to pain condition, 4 withdrew consent to participate in follow up assessment; Group 2 Number missing: 9, Reason: 3 withdrew due to logistical problems (work, vacation), 1 withdrew due to illness in close family, 2 withdrew due to worsening of the pain condition, 3 withdrew consent to participate

**Protocol outcome 4: Pain self-efficacy**

- Actual outcome: pain self-efficacy questionnaire at 6 months; Group 1: mean 3.1 (SD 8.17); n=84, Group 2: mean 1.48 (SD 8.49); n=86; pain self-efficacy questionnaire 0-60 Top=High is good outcome; Comments: Baseline values median (quartiles): PMP 25 (16-33), control 22 (17-30) (convert to SDs for analysis)  
 Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Median (IQR) Intervention 25 (16-33) Control 22 (17-30); Group 1 Number missing: 12, Reason: 4 withdrew due to logistical problems (change of address, long transportation, vacation), 2 withdrew due to illness in close family, 2 withdrew due to own illness not related to pain condition, 4 withdrew consent to participate in follow up assessment; Group 2 Number missing: 9, Reason: 3 withdrew due to logistical problems (work, vacation), 1 withdrew due to illness in close family, 2 withdrew due to worsening of the pain condition, 3 withdrew consent to participate

Protocol outcomes not reported by the study

Physical function; Pain interference; Use of healthcare services; Sleep; Discontinuation

Study (subsidiary papers)	Jensen 2001 <sup>186</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=214 in all 4 arms. Arms analysed: BM (n=63) and CG (n=48))
Countries and setting	Conducted in Sweden; Setting: Multi-centre rehabilitation clinics
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 18 months

Method of assessment of guideline condition	Adequate method of assessment/diagnosis: NA
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	Non-specific spinal pain, continuous sickness absence for 1 and 6 months, aged 18-60, fluent Swedish.
Exclusion criteria	Serious spinal pathology, physical trauma within 6 months of examination, need for surgery, serious co-morbidities, ongoing rehabilitation and pregnancy.
Recruitment/selection of patients	Recruited consecutively from AGS insurance scheme records. Block randomized, opaque envelopes concealed from screening assessor.
Age, gender and ethnicity	Age - Mean (SD): 43 (11). Gender (M:F): 53/58. Ethnicity: Swedish origin - BM: 82%, control group: 81%
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: Not stated / Unclear 3. First language not English: Not applicable 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Indirectness of population	No indirectness: NA
Interventions	<p>(n=63) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Combined physical therapy and CBT programmes for 40 hours per week. Physical therapy behaviourally oriented 20 hours a week, individually tailored training, education with practical examples, goal setting, increasing exercise to improve muscular endurance, aerobic training, pool training, relaxation, and body awareness therapy. CBT component aimed to improve the subjects' ability to manage pain and resume normal level of activity. Scheduled activities for approx 13-14 hours per week. Basic elements included activity planning, goal setting, problem solving, applied relaxation, cognitive coping techniques, activity pacing, training in how to break vicious circles, assertion training and the role of significant others. Tailored homework assignments given at the end of each session. Led by physiotherapists, psychologists, physicians (all experienced in management of non-specific spinal pain). 6 x 90 minute booster sessions held over 1 year post-treatment. Duration 4 weeks. Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA</p> <p>(n=48) Intervention 2: Standard care (a few GP appointments)/waiting list. No treatment offered as part of research project. Normal routine of healthcare followed. Duration 4 weeks. Concurrent medication/care: not reported . Indirectness: No indirectness; Indirectness comment: NA</p>
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST

Protocol outcome 1: Quality of life

- Actual outcome: SF-36 Bodily pain at 19 months (4 weeks + 18 month follow up); Group 1: mean 42.6 (SD 26.3); n=63, Group 2: mean 30.93 (SD 14.11); n=48; SF-36 0-100 Top=High is poor outcome; Comments: 25.33 (15.03) : 42.8 (26.14)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Details not reported per group for attrition but overall percentage given. Outcome reporting not per protocol (stratified); Indirectness of outcome: Serious indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; Group 2 Number missing

- Actual outcome: SF-36 Physical function at 19 months (4 weeks + 18 month follow up); Group 1: mean 59.8 (SD 24.4); n=63, Group 2: mean 56.8 (SD 20.84); n=48; SF-36 0-100 Top=High is good outcome; Comments: 52.51(20.39) : 60.3(23.8)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Details not reported per group for attrition but overall percentage given. Outcome reporting not per protocol (stratified); Indirectness of outcome: Serious indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; Group 2 Number missing

- Actual outcome: SF-36 Physical function at post intervention (immediately after 4 week programme); Group 1: mean 57.64 (SD 20.71); n=63, Group 2: mean 58.18 (SD 19.6); n=48; SF-36 0-100 Top=High is good outcome; Comments: 52.51(20.39) : 60.3(23.8)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Details not reported per group for attrition but overall percentage given. Outcome reporting not per protocol (stratified); Indirectness of outcome: Serious indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; Group 2 Number missing

- Actual outcome: SF-36 Bodily pain at post intervention (immediately after 4 week programme); Group 1: mean 32.06 (SD 17.73); n=63, Group 2: mean 28.7 (SD 15.84); n=48; SF-36 0-100 Top=High is poor outcome; Comments: 25.33 (15.03) : 42.8 (26.14)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Details not reported per group for attrition but overall percentage given. Outcome reporting not per protocol (stratified); Indirectness of outcome: No indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; Group 2 Number missing

- Actual outcome: SF-36 Role physical at post intervention (immediately after 4 week programme); Group 1: mean 19.54 (SD 32.19); n=63, Group 2: mean 10.5 (SD 23.32); n=48; SF36 role physical subscale 0-100 Top=High is good outcome

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Details not reported per group for attrition but overall percentage given. Results not reported as per protocol (stratified); Indirectness of outcome: No indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; Group 2 Number missing

- Actual outcome: SF-36 Role physical at 19 months (4 weeks + 18 month follow up); Group 1: mean 36 (SD 42.5); n=63, Group 2: mean 17.8 (SD 30.6); n=48; SF36 0-100 Top=High is good outcome

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Details not reported per group for attrition but overall percentage given. Results not reported as per protocol (stratified); Indirectness of outcome: No indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; Group 2 Number missing

- Actual outcome: SF-36 General health at post intervention (immediately after 4 week programme); Group 1: mean 49.9 (SD 22.9); n=63, Group 2: mean 53.7 (SD 20.2); n=48; SF36 0-100 Top=High is good outcome  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Details not reported per group for attrition but overall percentage given. Results not reported as per protocol (stratified); Indirectness of outcome: No indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; Group 2 Number missing

- Actual outcome: SF-36 General health at 19 months (4 weeks + 18 month follow up); Group 1: mean 53.6 (SD 24.4); n=63, Group 2: mean 46.6 (SD 22.6); n=48; SF36 0-100 Top=High is good outcome  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Details not reported per group for attrition but overall percentage given. Results not reported as per protocol (stratified); Indirectness of outcome: No indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; Group 2 Number missing

- Actual outcome: SF-36 Vitality at post intervention (immediately after 4 week programme); Group 1: mean 41.81 (SD 21.96); n=63, Group 2: mean 39.4 (SD 20.7); n=48; SF36 0-100 Top=High is good outcome  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Details not reported per group for attrition but overall percentage given. Results not reported as per protocol (stratified); Indirectness of outcome: No indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; Group 2 Number missing

- Actual outcome: SF-36 Vitality at 19 months (4 weeks + 18 month follow up); Group 1: mean 44 (SD 24); n=63, Group 2: mean 33.4 (SD 23.9); n=48; SF36 0-100 Top=High is good outcome  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; ; Group 2 Number missing;

- Actual outcome: SF-36 Social functioning at post intervention (immediately after 4 week programme); Group 1: mean 64.45 (SD 24.58); n=63, Group 2: mean 60.4 (SD 25.6); n=48; SF36 0-100 Top=High is good outcome  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Details not reported per group for attrition but overall percentage given. Results not reported as per protocol (stratified); Indirectness of outcome: No indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; Group 2 Number missing

- Actual outcome: SF-36 Social functioning at 19 months (4 weeks + 18 month follow up); Group 1: mean 70.6 (SD 27.2); n=63, Group 2: mean 62.8 (SD 29.9); n=48; SF36 0-100 Top=High is good outcome  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Details not reported per group for attrition but overall percentage given. Results not reported as per protocol (stratified); Indirectness of outcome: No indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; Group 2 Number missing

- Actual outcome: SF-36 Role emotional at post intervention (immediately after 4 week programme); Group 1: mean 54.5 (SD 45.5); n=63, Group 2: mean 51.5 (SD 43.5); n=48; SF36 0-100 Top=High is good outcome  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low,

Crossover - Low, Comments - Details not reported per group for attrition but overall percentage given. Results not reported as per protocol (stratified); Indirectness of outcome: No indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; Group 2 Number missing  
 - Actual outcome: SF-36 Role emotional at 19 months (4 weeks + 18 month follow up); Group 1: mean 66.4 (SD 44.2); n=63, Group 2: mean 48.29 (SD 46.3); n=48; SF36 0-100 Top=High is good outcome  
 Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Details not reported per group for attrition but overall percentage given. Results not reported as per protocol (stratified); Indirectness of outcome: No indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; Group 2 Number missing  
 - Actual outcome: SF-36 Mental health at post intervention (immediately after 4 week programme); Group 1: mean 64.8 (SD 20.4); n=63, Group 2: mean 64.6 (SD 18.9); n=48; SF36 0-100 Top=High is good outcome  
 Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Details not reported per group for attrition but overall percentage given. Results not reported as per protocol (stratified); Indirectness of outcome: No indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; Group 2 Number missing  
 - Actual outcome: SF-36 Mental health at 19 months (4 weeks + 18 month follow up); Group 1: mean 65.5 (SD 21.3); n=63, Group 2: mean 58.9 (SD 25); n=48; SF36 0-100 Top=High is good outcome  
 Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Details not reported per group for attrition but overall percentage given. Results not reported as per protocol (stratified); Indirectness of outcome: No indirectness, Comments: Reviewer reports average results for men and women which were reported separately; Group 1 Number missing; Group 2 Number missing

Protocol outcomes not reported by the study

Physical function; Psychological distress (depression/anxiety); Pain interference; Use of healthcare services; Sleep; Discontinuation; Pain reduction; Pain self-efficacy

Study	Johansson 1998 <sup>187</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=42)
Countries and setting	Conducted in Sweden; Setting: Department of Rehabilitation Medicine, single centre
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 4 weeks + 4 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: screening procedure to see if they met the criteria
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	Chronic musculoskeletal pain significantly disrupting life, no further medical or surgical treatment was appropriate
Exclusion criteria	Psychotic illness
Recruitment/selection of patients	Referral by GPs or medical specialists at other hospitals
Age, gender and ethnicity	Age - Mean (SD): 43.5 (7.6) years. Gender (M:F): 8/28 (completers). Ethnicity: not reported
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: Not stated / Unclear 3. First language not English: Not applicable 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Indirectness of population	No indirectness: NA
Interventions	(n=21) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Inpatient pain management programme: 5 full days per week for 4 weeks and 2 day booster sessions after 2 months <ul style="list-style-type: none"> <li>· Education on gate control theory of pain, activity in daily life, exercise and relaxation, overweight and sleep, time management and goals</li> <li>· Goal setting regarding work, leisure, social pursuits and domestic duties, using graded activity training</li> <li>· Exercise and individually tailored muscle training programmes including cycling, swimming and outdoor sports</li> <li>· Pacing of activities relevant for workplace and leisure e.g. typing, cleaning, cooking etc.</li> <li>· Applied relaxation and cognitive techniques such as distraction, imagery and positive coping self-statements</li> <li>· Social skills training on assertiveness and handling conflicts</li> <li>· Drug reduction methods and planning of return to work</li> </ul>

	<p>Led by: clinical psychologist, physiotherapist, occupational therapist, physical education teacher, vocational counsellor, physician and a nurse Duration 4 weeks . Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA</p> <p>(n=21) Intervention 2: Standard care (a few GP appointments)/waiting list. Waiting list. Duration 4 weeks. Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA</p>
Funding	Academic or government funding (Swedish National Institute for Working Life)
<p><b>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST</b></p> <p><b>Protocol outcome 1: Pain interference</b> - Actual outcome: Pain interference VAS at 8 weeks (4 week follow up); Group 1: mean 47.6 mm (SD 23.6); n=17, Group 2: mean 48.2 mm (SD 17.2); n=19; VAS 0-100 Top=High is poor outcome; Comments: Baseline values: intervention 50.8 (18.5), control 46.9 (15) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 4, Reason: 3 did not start programme, 1 did not complete follow up assessment; Group 2 Number missing: 2, Reason: 2 did not complete the pre and follow up assessment</p> <p><b>Protocol outcome 2: Discontinuation</b> - Actual outcome: Discontinuation at 8 weeks (4 week follow up); Group 1: 4/21, Group 2: 2/21; Comments: intervention: 3 did not begin the programme, 1 did not complete follow up. Control: 2 did not complete pre and post treatment assessment Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0; Group 2 Number missing: 0</p> <p><b>Protocol outcome 3: Pain reduction</b> - Actual outcome: Pain intensity VAS at 8 weeks (4 week follow up); Group 1: mean 54.2 mm (SD 24.2); n=17, Group 2: mean 53.2 mm (SD 17.7); n=19; VAS 0-100 Top=High is poor outcome; Comments: Baseline values: intervention 52.8 (17.2), control 53.3 (18.4) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 4, Reason: 3 did not start programme, 1 did not complete follow up assessment; Group 2 Number missing: 2, Reason: 2 did not complete the pre and follow up assessment</p>	
Protocol outcomes not reported by the study	Quality of life; Physical function; Psychological distress (depression/anxiety); Use of healthcare services ; Sleep; Pain self-efficacy

Study	Kwok 2016 <sup>204</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=46)
Countries and setting	Conducted in China; Setting: Single mobile health centre, Hong Kong
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 6 weeks + 1 month
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: persistent knee pain for at least 3 months
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	Aged ≥60 years of age; persistent knee pain for at least 3 months (musculoskeletal pain based on self-report, no diagnostic investigations conducted); VAS score ≥40; able to communicate in Cantonese.
Exclusion criteria	Osteoporosis; rheumatoid arthritis; gout; mental disorder; complicated spinal problem; problems following instructions (e.g. hearing impairment); undergone surgery or been hospitalised in the previous 6 months; active cancer; participation in other intensive health promotion programs or receipt of other treatment modalities within the previous 6 months
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Other: Aged 60 or over (mean not reported). Gender (M:F): not reported. Ethnicity: not reported
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: No cognitive impairment 3. First language not English: Not applicable 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment: No sensory impairment
Indirectness of population	No indirectness: NA
Interventions	(n=19) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Self-management programme (arthritis self-management programme: 2-hourly interactive group sessions of 6-7, once a week for 6 weeks): patient-generated short term action plan; interactive session including lectures, group discussions, problem solving role plays and trying out skills introduced; an overview of self-management principles; cognitive symptom management skills (distraction & relaxation, managing depressive moods); skills for communicating with family members and health professionals; training in ADLs; training in problem-solving skills and social skills; counselling and therapy; social support; exercise; healthy eating. Led by: professionally led, but further details not provided. Duration 6 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness; Indirectness comment: NA

	(n=27) Intervention 2: Standard care (a few GP appointments)/waiting list. Wait list control (programme delivered one week after the post-control period assessment). Duration 6 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness; Indirectness comment: NA
Funding	Academic or government funding (supported in part by the PolyU-Henry G. Leong Mobile Integrative Health Centre, which is funded by the Tai Hung Fai Charitable Foundation )

**RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST**

**Protocol outcome 1: Quality of life**

- Actual outcome: SF36 physical composite score at within 1 week post treatment ; Group 1: mean 44.06 (SD 5.68); n=19, Group 2: mean 38.04 (SD 7.92); n=27; SF36 physical composite score 0-100 Top=High is good outcome; Comments: Baseline values: PMP 39 (5.67), control 40.27 (8.17)

Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: difference in general health domain of SF36, demographic data not reported but says 'no differences'; Group 1 Number missing: 0; Group 2 Number missing: 0

- Actual outcome: SF36 mental composite score at within 1 week post treatment ; Group 1: mean 55.05 (SD 10.46); n=19, Group 2: mean 51.24 (SD 13.13); n=27; SF36 mental composite score 0-100 Top=High is good outcome; Comments: Baseline values: PMP 53.19 (9.39), control 53.19 (9.39) (suspect control group baseline value is a typo)

Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: difference in general health domain of SF36, demographic data not reported but says 'no differences'; Group 1 Number missing: 0; Group 2 Number missing: 0

**Protocol outcome 2: Physical function**

- Actual outcome: 6 min walk test at within 1 week post treatment ; Group 1: mean 387.08 Metres (SD 85.57); n=19, Group 2: mean 306.06 Metres (SD 102.5); n=27; Metres Infinite Top=High is good outcome; Comments: 299.25 (78.05) : 342.93 (123.64)

Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: difference in general health domain of SF36, demographic data not reported but says 'no differences'; Group 1 Number missing: 0; Group 2 Number missing: 0

**Protocol outcome 3: Discontinuation**

- Actual outcome: Discontinuation at within 1 week post treatment ; Group 1: 0/19, Group 2: 0/27

Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: difference in general health domain of SF36, demographic data not reported but says 'no differences'; Group 1 Number missing: 0; Group 2 Number missing: 0

**Protocol outcome 4: Pain reduction**

- Actual outcome: VAS at within 1 week post treatment ; ANOVA F statistic and p value: F 3.034, p 0.089 VAS 0-10 Top=;

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 5: Pain self-efficacy

- Actual outcome: Pain self-efficacy questionnaire at within 1 week post treatment; Group 1: mean 46.26 (SD 11.96); n=19, Group 2: mean 39.59 (SD 13.43); n=27; Pain self-efficacy questionnaire 0-60 Top=High is good outcome; Comments: Baseline values: PMP 36.58 (16.56), control 41.07 (13.43)

Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness, Comments: Only reported as incomplete ANOVA results, final values and change from baseline left out of subsequent tables - no explanation why; Baseline details: difference in general health domain of SF36, demographic data not reported but says 'no differences'; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcomes not reported by the study

Psychological distress (depression/anxiety); Pain interference; Use of healthcare services; Sleep

Study	Laforest 2008 <sup>205</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=113)
Countries and setting	Conducted in Canada; Setting: participants homes
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 8 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: examination of medical records and a screening tool
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	housebound; 50 years of age or more; reporting moderate to severe pain; suffering from osteoarthritis or rheumatoid arthritis; reporting difficulties in performing domestic or daily living activities; able to speak English or French
Exclusion criteria	diagnosis of polymyalgia; recent health problems requiring rehabilitation services; cognitive problems; previous participation in a similar intervention
Recruitment/selection of patients	home care case managers recruited participants by telephone
Age, gender and ethnicity	Age - Mean (SD): 77.7 (10.3) years. Gender (M:F): Define. Ethnicity: not reported
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: No cognitive impairment 3. First language not English: Not applicable 4. Homeless: Not homeless 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Indirectness of population	No indirectness: NA
Interventions	(n=65) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. I'm taking charge of my arthritis! Programme: Weekly 1 hour individual home visits by a healthcare professional over 6 weeks <ul style="list-style-type: none"> <li>· Life with arthritis – basic principles of management and intro to personal contract</li> <li>· Physical exercises and relaxation techniques</li> <li>· Managing pain and stiffness, including how to manage medication</li> <li>· Positive thinking, managing emotions, easing loneliness and distraction techniques</li> <li>· Managing energy – sleeping and eating well</li> <li>· Building partnerships with health professionals</li> </ul> Led by: occupational therapists, physical therapists, social workers and kinesiologists. Duration 6 weeks. Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA

	(n=48) Intervention 2: Standard care (a few GP appointments)/waiting list. Details not reported. Duration 6 weeks. Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA
Funding	Academic or government funding (Canadian Health Institutes of Research )
<p><b>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST</b></p> <p><b>Protocol outcome 1: Physical function</b>          - Actual outcome: Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) functional limitations scale at 8 weeks (immediately post intervention); Group 1: mean 3.27 (SD 0.8); n=58, Group 2: mean 3.33 (SD 0.8); n=39; WOMAC 1-5 Top=High is poor outcome; Comments: Baseline values: intervention 3.34 (0.7), control 3.28 (0.8)          Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 7, Reason: not reported ; Group 2 Number missing: 9, Reason: not reported</p> <p><b>Protocol outcome 2: Discontinuation</b>          - Actual outcome: Discontinuation at 8 weeks (immediately post intervention); Group 1: 7/65, Group 2: 9/48; Comments: Reasons for discontinuation not reported          Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0; Group 2 Number missing: 0</p> <p><b>Protocol outcome 3: Pain reduction</b>          - Actual outcome: Pain intensity VAS at 8 weeks (immediately post intervention); Group 1: mean 64.84 mm (SD 25); n=58, Group 2: mean 66.03 mm (SD 25); n=39; VAS 0-100 Top=High is poor outcome; Comments: Baseline values: intervention 66.54 (25.8), control 59.58 (23)          Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 7, Reason: not reported ; Group 2 Number missing: 9, Reason: not reported</p>	
Protocol outcomes not reported by the study	Quality of life; Psychological distress (depression/anxiety); Pain interference; Use of healthcare services; Sleep; Pain self-efficacy

Study	Martin 2012 <sup>236</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=180)
Countries and setting	Conducted in Spain; Setting: Galdakao-Usansolo hospital pain management unit
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Fibromyalgia (ACR criteria); aged over 18; continuous chronic pain for >6 months
Exclusion criteria	Psychiatric disorder, suffering from a severe psychiatric or organic disorder, or were involved in legal proceedings related to FM
Recruitment/selection of patients	Recruited from pain management unit of the Hospital Galdakao-Usansolo - contacted by telephone and invited.
Age, gender and ethnicity	Age - Mean (SD): Intervention 50.15 (9.26) Control: 51.57 (9.65). Gender (M:F): 15/151. Ethnicity: Not reported
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: No cognitive impairment 3. First language not English: Not applicable 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Indirectness of population	No indirectness
Interventions	(n=90) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. 6 week programme delivered by a treatment team consisted of a physician, clinical psychologist and a physiotherapist. Twice weekly group sessions of 105 minutes (12 sessions total). Psychological component: CBT by qualified psychologist including cognitive, physiological and behavioural components aimed to identify and change negative thoughts, improve coping and training on breathing and muscle relaxation. Training on assertiveness and communication skills was also given, as well as pacing of activities Group sessions (12 people or less): practical exercises and other activities on the topic of the day covered, practical breathing and relaxation exercises, explanation of tasks to do at home. Physiotherapy: Warming and stretching exercises with a regular exercise programme focusing on activity modification principles. Educational component: related to characteristics of fibromyalgia

	<p>and its nature, course, appropriate organisation of day-to-day life, physician-patient relationship. Duration 6 weeks. Concurrent medication/care: Standard pharmaceutical care (for FM in Spain) including treatment with amitriptyline (max dose 75mg/24hr), paracetamol (max dose 4g/24hr) and tramadol (max dose 400mg/24hr) (Same as control group). Indirectness: No indirectness</p> <p>(n=90) Intervention 2: Standard care (a few GP appointments)/waiting list. Standard pharmaceutical care (for FM in Spain) including treatment with amitriptyline (max dose 75mg/24hr), paracetamol (max dose 4g/24hr) and tramadol (max dose 400mg/24hr). Duration 6 weeks. Concurrent medication/care: NR. Indirectness: No indirectness</p>
Funding	Academic or government funding (Department of Health of the Basque Country)
<p><b>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST</b></p> <p>Protocol outcome 1: Quality of life          - Actual outcome: FIQ total score at 6 months; Group 1: mean 70.33 0-100 (SD 16.48); n=54, Group 2: mean 76.81 0-100 (SD 14.18); n=56; FIQ 0-100 Top=High is poor outcome; Comments: Baseline values 76.28(13.57):76.23(14.88)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Other 1 - High, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 36, Reason: 11 lost to follow-up, 4 had FM pain, 11 did not attend programme; Group 2 Number missing: 34, Reason: 15 lost to follow-up, 19 missed appointments</p> <p>Protocol outcome 2: Psychological distress (depression/anxiety)          - Actual outcome: HADS depression score at 6 months; Group 1: mean 9.77 0-21 (SD 4.09); n=56, Group 2: mean 10.2 0-21 (SD 4.22); n=54; HADS depression scale 0-21 Top=High is poor outcome; Comments: Baseline values: 10.63 (4.51): 10.57 (4.06)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Other 1 - High, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 36, Reason: 11 lost to follow-up, 4 had FM pain, 11 did not attend programme; Group 2 Number missing: 34, Reason: 15 lost to follow-up, 19 missed appointments          - Actual outcome: HADS anxiety score at 6 months; Group 1: mean 9.77 HADS Anxiety (SD 4.09); n=54, Group 2: mean 10.2 HADS Anxiety (SD 4.22); n=54; HADS 0-21 Top=High is poor outcome; Comments: Baseline values: 10.63 (4.51):10.57(4.06)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Other 1 - High, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 36, Reason: 11 lost to follow-up, 4 had FM pain, 11 did not attend programme; Group 2 Number missing: 34, Reason: 15 lost to follow-up, 19 missed appointments</p>	
Protocol outcomes not reported by the study	Physical function; Pain interference; Use of healthcare services; Sleep; Pain reduction; Pain self-efficacy; Discontinuation

Study	Mcbeth 2012 <sup>240</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=442)
Countries and setting	Conducted in United Kingdom; Setting: Research nurse-led clinic
Line of therapy	Not applicable
Duration of study	Follow up (post intervention): 9 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	>25 years old with chronic widespread pain (ACR definition) for which physician was contacted in last year
Exclusion criteria	Severe psychiatric disorder, health condition which would prevent exercise or which was not suitable for intervention.
Recruitment/selection of patients	Screening questionnaire sent to people registered with 8 practices in Aberdeen and Macclesfield
Age, gender and ethnicity	Age - Mean (SD): 56 (13). Gender (M:F): 70.5% female. Ethnicity: Not reported
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: Not stated / Unclear 3. First language not English: Not stated / Unclear 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated/ Unclear
Extra comments	.
Indirectness of population	No indirectness
Interventions	(n=112) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. CBT + Exercise combined programme. TBCBT included an initial assessment (45-60 mins) 7 weekly sessions, 30-45 mins) and 1 session at 3 months and 1 session 6 months after randomisation. Therapists conducted a patient centred assessment, developed a shared understanding and formulation of the problem, and identified 2 to 3 patient defined goals. Patients received a self-management CBT manual. TBCBT was delivered by 4 therapists. As part of the exercise sessions patients received leisure-facility- and gym based exercise program consistent with American College of Sport Medicine (ACSM) guidelines for improving cardiorespiratory fitness. 21 Following an induction session, patients were offered 6 fitness instructor-led monthly appointments for program reassessment. Exercise intensity increased until exercise levels were sufficient to achieve 40% to 85% of heart rate reserve. Exercises negotiated between fitness instructor and patient. Telephone CBT: 7 weekly sessions of 30-45 minutes during which goals were defined. Patients could choose the style of CBT and were given a manual called "Managing Chronic Widespread Pain." Duration 6 months. Concurrent medication/care: Treatment as

	<p>usual. Indirectness: No indirectness</p> <p>(n=109) Intervention 2: Standard care (a few GP appointments)/waiting list. Treatment as usual. Duration 6 months. Concurrent medication/care: None. Indirectness: No indirectness</p>
Funding	Academic or government funding (Arthritis Research UK,
<p><b>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST</b></p> <p>Protocol outcome 1: Quality of life                      - Actual outcome: EQ-5D at 9 months; Group 1: mean 0.701 (SD 0.22); n=90, Group 2: mean 0.645 (SD 0.262); n=83; EQ-5D 0-1 Top=High is good outcome                      Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness ; Baseline details: Stratified according to disability level; Group 1 Number missing: 22, Reason: Withdrew from treatment, not contactable, telephone questionnaires only; Group 2 Number missing: 26, Reason: Withdrew from treatment, not contactable, telephone questionnaires only.</p> <p>Protocol outcome 2: Sleep                      - Actual outcome: Sleep scale at 9 months; Group 1: mean 13.1 (SD 5.4); n=102, Group 2: mean 11.2 (SD 5.4); n=88; Sleep scale 0-20 Top=High is poor outcome                      Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness ; Baseline details: Stratified according to disability level; Group 1 Number missing: 10, Reason: Withdrew from treatment, not contactable, telephone questionnaires only; Group 2 Number missing: 11, Reason: Withdrew from treatment, not contactable, telephone questionnaires only.</p>	
Protocol outcomes not reported by the study	Physical function; Psychological distress (depression/anxiety); Pain interference; Use of healthcare services ; Discontinuation; Pain reduction; Pain self-efficacy

Study	Mehlsen 2017 <sup>244</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=424)
Countries and setting	Conducted in Denmark; Setting: Health centres
Line of therapy	Not applicable
Duration of study	Follow up (intervention + follow up): 5 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	Pain duration 3 months, self-rated pain intensity 5 on a 10-point Likert scale at the time of enrolment, aged over 18, understands, speaks, and reads Danish
Exclusion criteria	Pain should not be caused by conditions presently undergoing significant change where the condition and not pain itself is of primary concern to the participant, e.g., curative cancer treatment, pregnancy, no substance abuse, psychiatric, or physical disease preventing participation in weekly sessions
Recruitment/selection of patients	Via 75 Danish health centres
Age, gender and ethnicity	Age - Mean (SD): intervention group 54.2(13.3), control group 54.8(12.8) years. Gender (M:F): 120/304. Ethnicity: Not reported
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: Not stated / Unclear 3. First language not English: Not applicable 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Indirectness of population	No indirectness: NA
Interventions	(n=216) Intervention 1: Peer led pain management programmes - Peer led pain management programmes. 6, 2 ½ hour weekly workshops focusing on how to manage pain in daily life, groups of 8-16. A manual is followed to deliver the process. Themes encompass: Managing feelings such as frustration, anger and depression; Managing fatigue, social isolation and poor sleep quality; Improving and maintaining strength, flexibility, Effective communication; Nutrition; Pacing and evaluation of new treatment possibilities. Includes lectures and exercises in light physical activity, visualisation, relaxation and communication. Instruction focus on how to implement these exercises at home and implementing action plans which they perform on a weekly basis. Lay led, facilitated by 2 workshop leaders of whom at least 1 also suffers from a long-term pain condition, the other may suffer from a pain condition, other long-term condition or be a close relative to a person with a long-term condition. Duration 6 weeks. Concurrent medication/care: Not reported.

	Indirectness: No indirectness  (n=208) Intervention 2: Standard care (a few GP appointments)/waiting list. Usual treatment - not restricted in terms of access to their usual treatment or new interventions. Could not join pain management programme in their community until 5 months after 1st session of the course. Duration 6 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness
Funding	Study funded by industry (Tryg Foundation)

**RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PEER LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST**

**Protocol outcome 1: Physical function**

- Actual outcome: Modified Roland Morris Disability questionnaire at 6 weeks; Group 1: mean 13.6 (SD 4.7); n=205, Group 2: mean 14.8 (SD4.2); n=194  
Modified RMDQ 0-24 Top=High is poor outcome; Comments: Baseline values: 14.7 (4.4) 14.8 (3.9)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness, Comments: NA; Blinding details: No blinding details; Group 1 Number missing: 11, Reason: 5 declined to continue, 6 unknown; Group 2 Number missing: 14, Reason: 7 declined to continue, 6 unknown, 1 could not be located

- Actual outcome: Modified Roland Morris Disability questionnaire at 5 months; Group 1: mean 13.7 (SD 4.6); n=205, Group 2: mean 14.2 (SD 4.6); n=186; Modified RMDQ 0-24 Top=High is poor outcome; Comments: Baseline values: 14.7 (4.4) 14.8 (3.9)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness, Comments: NA; Blinding details: No blinding details; Group 1 Number missing: 11, Reason: 5 declined to continue, 1 unknown; Group 2 Number missing: 22, Reason: 15 declined to continue, 6 unknown, 1 could not be located

**Protocol outcome 2: Psychological distress**

- Actual outcome: Pain catastrophising PCS at 6 weeks; Group 1 mean 22.1 (SD 10.4); n=205, Group 2 mean 23.7 (SD10.9); n=194; PCS 0-52 Top=High is poor outcome; Comments: Baseline values: 25.0 (10.1) 25.2 (10.6)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness ; Blinding details: No blinding details; Group 1 Number missing: 11, Reason: 5 declined to continue, 6 unknown, 1 lost to follow up; Group 2 Number missing: 14, Reason: 7 declined to continue, 6 unknown, 1 could not be located

- Actual outcome: Pain catastrophising PCS at 5 months; Group 1: mean 21.3 (SD 10.4); n=205, Group 2: mean 22.4 (SD 11.1); n=186; PCS 0-52 Top=High is poor outcome; Comments: Baseline values: 25.0 (10.1) 25.2 (10.6)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness ; Blinding details: No blinding details; Group 1 Number missing: 11, Reason: 5 declined to continue, 6 unknown, 1 lost to follow up; Group 2 Number missing: 22, Reason: 15 declined to continue, 6 unknown, 1 could not be located

**Protocol outcome 3: Pain self-efficacy**

- Actual outcome: Arthritis self-efficacy scale (SES) at 6 weeks; Group 1: mean 21.1 (SD 9.3); n=205, Group 2: mean 23.8 (SD 9); n=194; SES 5-50 Top=High is good outcome; Comments: Baseline values: 22.2 (8.8) : 24.0 (9.3)  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness ; Blinding details: No blinding details; Group 1 Number missing: 11, Reason: 5 declined to continue, 6 unknown, 1 could not be located; Group 2 Number missing: 14, Reason: 7 declined to continue, 6 unknown, 1 could not be located

- Actual outcome: Arthritis self-efficacy scale (SES) at 5 months; Group 1: mean 20.1 (SD 9.6); n=205, Group 2: mean 23.5 (SD 10.4); n=186; SES 5-50 Top=High is good outcome; Comments: Baseline values: 22.2 (8.8) : 24.0 (9.3)  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness ; Blinding details: No blinding details; Group 1 Number missing: 11, Reason: 5 declined to continue, 6 unknown, 1 could not be located; Group 2 Number missing: 22, Reason: 15 declined to continue, 6 unknown, 1 could not be located

Protocol outcome 4: Use of healthcare services  
- Actual outcome: Total healthcare costs in Euros during treatment and follow up at 5 months; Group 1: mean 2231 (95% CI 1719-2943); n=210, Group 2: mean 2153 (95% CI 1709-2861); n=200  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness ; Blinding details: No blinding details; Group 1 Number missing: 6, Reason: unclear; Group 2 Number missing: 8, Reason: unclear

Protocol outcome 5: Pain reduction  
- Actual outcome: VAS pain scale at 6 weeks; Group 1: 54.3 (SD 15.1); n=205, Group 2: mean 53.9 (SD 16); n=194; VAS 0-100 Top=High is poor outcome; Comments: Baseline values; Intervention 56.1 (16.7) Control 57 (18)  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness ; Blinding details: No blinding details; Group 1 Number missing: 11, Reason: 5 declined to continue, 6 unknown, 1 could not be located; Group 2 Number missing: 14, Reason: 7 declined to continue, 6 unknown, 1 could not be located

- Actual outcome: VAS pain scale at 5 months; Group 1: mean 51.7 VAS (SD 19.9); n=205, Group 2: mean 53.7 VAS (SD 18.4); n=186; VAS 0-100 Top=High is poor outcome; Comments: Baseline values; Intervention 56.1 (16.7) Control 57 (18)  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness ; Blinding details: No blinding details; Group 1 Number missing: 11, Reason: 5 declined to continue, 6 unknown, 1 could not be located; Group 2 Number missing: 22, Reason: 15 declined to continue, 6 unknown, 1 could not be located

Protocol outcomes not reported by the study

Quality of life; Pain interference; Sleep; Discontinuation

Study	Nicholas 2013 <sup>263</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=88)
Countries and setting	Conducted in Australia; Setting: Single pain management and research centre, Australia
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Chronic pain conditions referred by doctor for treatment
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	Aged ≥65 years; history of persisting, non-cancer pain for >6 months; still seeking help for pain and its effects on lifestyle or mood; able to attend the 2 hour sessions at the pain centre twice weekly for 4 weeks; ability to read and speak adequate English; score of ≥22 in the Rowland Universal Dementia Assessment scale (normal range short-term memory functioning); clearance by doctors for participation in a light exercise and stretch program; agree to accept randomisation to one of the intervention groups
Exclusion criteria	Active major mental disorder (psychoses, dementia, major depression with active suicidal ideation); further medical/surgical treatments or investigations for pain condition planned; evidence of a primary drug addiction problem.
Recruitment/selection of patients	Consecutive - those meeting the inclusion criteria during the recruitment period.
Age, gender and ethnicity	Age - Mean (SD): 73.9 (6.5). Gender (M:F): 52/89. Ethnicity: not reported
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: No cognitive impairment 3. First language not English: First language English 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Indirectness of population	No indirectness: NA
Interventions	(n=49) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Pain management programme (8 2h sessions, over 4 weeks): self-management reading texts; psychological sessions (coping strategies, goals of management, sleep management); exercise sessions (relaxation, stretching, functional exercises); education: discussions of mechanisms of chronic pain. Led by: Psychologist and physiotherapist. Duration 4 weeks. Concurrent medication/care: No new pain treatments initiated by the pain service for at least 3 months from admission to the programme but participants were free to continue doing whatever their treating doctor and other health care providers recommended. Indirectness: No indirectness; Indirectness comment: NA

	(n=39) Intervention 2: Standard care (a few GP appointments)/waiting list. Waiting list control group - informed that their group would commence in 12 weeks. Duration 12 weeks. Concurrent medication/care: No new pain treatments initiated by the pain service for at least 3 months from admission to the programme but participants were free to continue doing whatever their treating doctor and other health care providers recommended. Indirectness: No indirectness; Indirectness comment: NA
Funding	Academic or government funding (grant from the Australian Health Ministers Advisory Council )
<p><b>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST</b></p> <p><b>Protocol outcome 1: Physical function</b>          - Actual outcome: 6 minute walk test at 1 month follow up ; Group 1: mean 4.3 metres (SD 142); n=43, Group 2: mean 26 metres (SD 78); n=29;          Comments: 341 (142.1) : 287 (131)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Differential dropout rate; Indirectness of outcome: No indirectness; Baseline details: As reported by authors; Group 1 Number missing: 6; Group 2 Number missing: 10</p> <p><b>Protocol outcome 2: Psychological distress (depression/anxiety)</b>          - Actual outcome: Depression Anxiety Stress Scale at 1 month follow up; Group 1: mean 0.28 (SD 5.8); n=49, Group 2: mean -0.6 (SD 11); n=39;          Depression Anxiety Stress Scale 0-42 Top=High is poor outcome; Comments: Baseline values: intervention 10.8 (11.06), control 12 (10.4)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Differential dropout rate; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 6, Reason: NR; Group 2 Number missing: 10, Reason: NR</p> <p><b>Protocol outcome 3: Discontinuation</b>          - Actual outcome: Discontinuation any cause at 1 month follow up ; Group 1: 43/49, Group 2: 29/39          Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness; Group 1 Number missing: 6, Reason: NA ; Group 2 Number missing: 10, Reason: NA</p> <p><b>Protocol outcome 4: Pain reduction</b>          - Actual outcome: Usual pain in past week (NRS) at 1 month follow up ; Group 1: mean -0.53 (SD 1.2); n=43, Group 2: mean -0.56 (SD 1.7); n=29; NRS 0-10 Top=High is poor outcome; Comments: 5.48 (2.11) : 5.67 (2.26)          Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: Serious indirectness; Group 1 Number missing: 6, Reason: NR; Group 2 Number missing: 10, Reason: NR</p>	

Protocol outcome 5: Pain self-efficacy

- Actual outcome: PSEQ Pain self-efficacy at 1 month follow up; Group 1: mean 2.6 (SD 8.6); n=49, Group 2: mean -0.46 (SD 8.6); n=29; PSEQ 0-60 Top=High is good outcome; Comments: Baseline values 35.18 (12.6) : 33.85 (11.7)

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: Serious indirectness; Group 1 Number missing: 6, Reason: NR; Group 2 Number missing: 10, Reason: NR

Protocol outcomes not reported by the study

Quality of life; Pain interference; Use of healthcare services; Sleep

Study	Peters 1990 <sup>280</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=85)
Countries and setting	Conducted in New Zealand; Setting: One hospital
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 11 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Outpatients in a pain clinic, chronic non-malignant pain >6 months, no psychotic or serious illness
Exclusion criteria	NR
Recruitment/selection of patients	Pain clinic, Auckland Hospital
Age, gender and ethnicity	Age - Mean (SD): 43.9 (13.7). Gender (M:F): 13/21. Ethnicity: European n=63, Maori n=3, Polynesian n=2
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: Not stated / Unclear 3. First language not English: Not stated / Unclear 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Extra comments	Demographic data only includes the people who completed the study.
Indirectness of population	No indirectness
Interventions	<p>(n=29) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Outpatient programme. 9 weekly sessions, 2 hour sessions maximum of 10 patients to each session. Programme: education based (no further details). Practical advice on increasing exercise and achieving activity goals, medication and stress management, biomechanics and relaxation training. The final session included input from members of the local community Pain Care Group. Led by: Occupational therapists with contributions from a psychiatrist, rheumatologist, physiotherapist and nursing staff. Duration 9 weeks. Concurrent medication/care: NR</p> <p>(n=23) Intervention 2: Standard care (a few GP appointments)/waiting list. Standard treatment on outpatients' clinic. Informed they would be assessed 4 times in 1 year. Medical treatment accessed through the out-patient clinic but not to participate in the in or out patient pain management programme until completion of the 12 month follow up period. Duration 10 weeks. Concurrent medication/care: NR</p> <p>(n=33) Intervention 3: Professional led/professional and peer led pain management programmes -</p>

	<p>Professional led pain management programmes. In-patient pain management programme. Treatment in a general medical ward by a MDT (psychiatrist, medical and nursing staff, psychologist, occupational therapist, physiotherapist and a vocational rehabilitation officer). Social worker was available for the first half of the study. A pain nurse was only full time member of staff. Patients were admitted Monday to Friday and went home at the weekend for 4 weeks. Programme CBT based with 7 main areas; 1. education on physiology and psychology of pain, 2. teaching of behavioural pain management strategies, 3. the promotion of adaptive cognitions via cognitive restructuring, visualisation and imagery techniques, 4. structured exercise (for example speed walking), 5. individual, group and family and vocational counselling, 6. medication management, 7. staff verbal reinforcement of patient's activity and well 'behaviours'. Duration 4 weeks. Concurrent medication/care: NR</p>
<p>Funding</p>	<p>Academic or government funding (Auckland medical research foundation)</p>
<p><b>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED OUT-PATIENT PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST</b></p> <p><b>Protocol outcome 1: Psychological distress (depression/anxiety)</b>          - Actual outcome: Beck depression inventory at post intervention; Group 1: mean 10.73 (SD 6.16); n=22, Group 2: mean 11.07 (SD 5.82); n=15; Beck Depression Inventory 0- Top=High is poor outcome; Comments: out patient baseline: 13.55(6.03) usual care 12.33 (7.29)          Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Throw of the dice; Group 1 Number missing: 6, Reason: n=4 did not start treatment, n=2 dropped out ; Group 2 Number missing: 7, Reason: n=3 withdrew on assigned to control group, n=3 withdrew before assessments, n=1 died of narcotic overdose after being hospitalised for an acute medical condition.</p> <p><b>Protocol outcome 2: Discontinuation</b>          - Actual outcome: discontinuation any cause at post intervention; Group 1: 6/29, Group 2: 7/23; Comments: intervention: 4 did not begin treatment, 2 dropped out during programme. Control: 3 withdrew on being assigned to control, 3 withdrew before pre and post-treatment assessments were completed, 1 died of an overdose          Risk of bias: All domain - High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Throw of the dice; Group 1 Number missing; Group 2 Number missing:</p> <p><b>Protocol outcome 3: Pain reduction</b>          - Actual outcome: VAS at post intervention; Group 1: mean 4.25 (SD 2.18); n=16, Group 2: mean 5.29 (SD 2.7); n=14; VAS 0-10 Top=High is poor outcome; Comments: baseline: outpatient group 5.25(2.46) : standard care 4.21 (2.55)          Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Throw of the dice; Group 1 Number missing: 6, Reason: n=4, did not begin treatment, n=2 dropped out during the programme; Group 2 Number missing: 7, Reason: n=3 after being assigned to the control group, n=3 withdrew before assessments were made, n=1 died of a narcotic overdose after being hospitalised for an acute medical condition.</p>	

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED IN-PATIENT PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST

Protocol outcome 1: Psychological distress (depression/anxiety)

- Actual outcome: Beck depression inventory at post intervention; Group 1: mean 12.25 (SD 15.64); n=28,

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness ; Baseline details: Throw of the dice; Group 1 Number missing: 4, Reason: n=1 asked to leave because of disruptive behaviour, n=2 acute medical conditions (appendicitis and herniated bowel) , 1 dropped out in the second week; Group 2 Number missing: 7, Reason: n=3 withdrew after being assigned to the control group, n=3 withdrew before assessments, n=1 died of narcotic overdose after being hospitalised for an acute medical condition.

Protocol outcome 2: Discontinuation

- Actual outcome: discontinuation any cause at post intervention; Group 1: 4/33, Group 2: 7/23; Comments: intervention: 1 asked to leave due to disruptive behaviour, 2 left due to acute medical conditions, 1 dropped out

control: 3 withdrew on being assigned to control, 3 withdrew before pre and post-treatment assessments were completed, 1 died of an overdose

Risk of bias: All domain - High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness ; Baseline details: Throw of the dice; Group 1 Number missing; Group 2 Number missing

Protocol outcome 3: Pain reduction

- Actual outcome: VAS at post intervention; Group 1: mean 3.92 (SD 2.33); n=25, Group 2: mean 5.29 (SD 2.7); n=14; VAS 0-10 Top=High is poor outcome; Comments: Baseline in-patient 5.12(2.56) control 4.21 (2.55)

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness ; Baseline details: Throw of the dice; Group 1 Number missing: 4, Reason: n=1 asked to leave because of disruptive behaviour, n=2 acute medical conditions (appendicitis and herniated bowel) , 1 dropped out in the second week; Group 2 Number missing: 7, Reason: n=3 withdrew after being assigned to the control group, n=3 withdrew before assessments, n=1 died of narcotic overdose after being hospitalised for an acute medical condition.

Protocol outcomes not reported by the study

Quality of life; Physical function; Pain interference; Use of healthcare services; Sleep; Pain self-efficacy

Study (subsidiary papers)	Smeets 2006 <sup>307</sup> (Smeets 2008 <sup>305</sup> , Smeets 2006 <sup>306</sup> )
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=223)
Countries and setting	Conducted in Netherlands; Setting: 3 outdoor rehabilitation centres
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 10 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: clinical assessment
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	age between 18 and 65 years, non-specific low back pain with or without radiation to leg for more than 3 months resulting in functional limitations (Roland Disability Questionnaire score > 3), ability to walk at least 100 meters without interruption
Exclusion criteria	vertebral fracture, spinal inflammatory disease, spinal infections or malignancy, current nerve root pathology, spondylolysis or spondylolisthesis, lumbar spondylodesis, medical co-morbidity making intensive exercising impossible (e.g. cardiovascular or metabolic disease), ongoing diagnostic procedures or treatment for CLBP at the time of referral or a clear treatment preference, not proficient in Dutch, pregnancy and substance abuse that could interfere with the rehabilitation treatment
Recruitment/selection of patients	referral by GPs and medical specialists and invitation by consulting rehabilitation physician to participate
Age, gender and ethnicity	Age - Mean (SD): intervention 40.67 (10.14), waiting list 40.55 (11.17). Gender (M:F): 63/49. Ethnicity: not reported
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: Not stated / Unclear 3. First language not English: Not applicable 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Indirectness of population	No indirectness: NA
Interventions	(n=61) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Combined active physical treatment and cognitive behavioural treatment: 19 sessions with a total duration of 11 hours over 10 weeks <ul style="list-style-type: none"> <li>· Active physical treatment including 30 minutes of aerobic bicycle training and 75 minutes of strength and endurance training 3 times per week for 10 weeks, supervised by physiotherapists</li> <li>· CBT consisting of operant behavioural graded activity techniques and problem solving training</li> </ul>

	<ul style="list-style-type: none"> <li>· Graded activity started with 3 group sessions followed by a maximum of 17 30 minute individual sessions; daily performance graphically registered in a personal diary and discussed regularly</li> <li>· Problem solving training – 10 1.5 hour sessions, max 4 patients. Course book with additional information, session summaries and homework</li> <li>· Integration of APT, GA and PST; e.g. patients told that parallel increase in fitness expected to facilitate graded activity and therapists delivering APT periodically asked patients to present performance graphs</li> </ul> <p>Led by: physiotherapists, psychologist and social worker. Duration 10 weeks. Concurrent medication/care: No other interventions than those chosen for the programme were given. In case of acute and severe psychosocial stress or pathology, a consultation of a clinical psychologist or social worker was possible. Indirectness: No indirectness; Indirectness comment: NA</p> <p>(n=51) Intervention 2: Standard care (a few GP appointments)/waiting list . Patients requested to wait 10 weeks after which they were offered individual rehabilitation. Not allowed to participate in diagnostic or therapeutic procedures during this time. Duration 10 weeks. Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA</p>
Funding	Academic or government funding (Zorgonderzoek Nederland/Medische Wetenschappen and the Rehabilitation Centre Blixembosch)
<p><b>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST</b></p> <p>Protocol outcome 1: Physical function          - Actual outcome: Roland Morris Disability Questionnaire at 10 weeks (immediately post treatment); MD; -2.56 (95%CI -4.27 to -0.85) Roland Morris Disability Questionnaire 0-24 Top=High is poor outcome, Comments: Baseline values: intervention 13.51 (3.92), control 13.96 (3.88);          Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 6, Reason: 1 unreachable, 1 admission to psychiatric ward, 1 rejected treatment, 2 lack of time, 1 questionnaire lost ; Group 2 Number missing: 1, Reason: 1 other medical reason</p> <p>Protocol outcome 2: Psychological distress (depression/anxiety)          - Actual outcome: Beck Depression Inventory at 10 weeks (immediately post treatment); MD; 0.04 (95%CI -1.71 to 1.79) Beck depression inventory 0-63 Top=High is poor outcome, Comments: Baseline values: intervention 9.75 (6.68), control 9.78 (7.67);          Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 6, Reason: 1 unreachable, 1 admission to psychiatric ward, 1 rejected treatment, 2 lack of time, 1 questionnaire lost ; Group 2 Number missing: 1, Reason: 1 other medical reason</p> <p>Protocol outcome 3: Discontinuation          - Actual outcome: Discontinuation at 10 weeks (immediately post treatment); Group 1: 6/61, Group 2: 1/51; Comments: intervention: 1 unreachable, 1</p>	

admission to psychiatric ward, 1 rejected treatment, 2 lack of time, 1 questionnaire lost Control: 1 other medical reason  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 4: Pain reduction

- Actual outcome: Current pain at 10 weeks (immediately post treatment); MD; -8.23 (95%CI -16.37 to -0.1) 100 mm VAS 0-100 Top=High is poor outcome, Comments: Baseline values: intervention 45.98 (23.95), control 51.02 (25.4);

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 6, Reason: 1 unreachable, 1 admission to psychiatric ward, 1 rejected treatment, 2 lack of time, 1 questionnaire lost ; Group 2 Number missing: 1, Reason: 1 other medical reason

Protocol outcomes not reported by the study

Quality of life; Pain interference; Use of healthcare services; Sleep; Pain self-efficacy

Study	Smith 2019 <sup>308</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=91)
Countries and setting	Conducted in Australia; Setting: web-based programme, developed at a single hospital
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 28 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: pain >3 months
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	Define
Exclusion criteria	Define
Recruitment/selection of patients	through the virtual clinic; the study was advertised throughout the hospital campus via online pain groups, social media and the 'this way up' service provider network
Age, gender and ethnicity	Age - Mean (SD): 45 (13.86) years . Gender (M:F): Define. Ethnicity: not reported
Further population details	1. Age 16-18 years : Over 18 years 2. Cognitive impairment: Not stated / Unclear 3. First language not English: Not stated / Unclear (participants had to be fluent in English ). 4. Homeless: Not stated / Unclear (participants had to have access to a computer). 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Extra comments	59% had pain for >5 years; 90% were taking prescribed pain medications
Indirectness of population	No indirectness: NA
Interventions	(n=45) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Reboot Online - 8 online sessions over 16 weeks. A 2 week gap between each lesson provided participants timeto revisit the content, view the resources and practice the skills. Participants would access the online program at any time. In order for a lesson to be fully completed, the participant had to print the lesson summary/homework. Over the course of each lesson, participants follow an illustrated story of a fictional character, who learns to self-manage her chronic pain using a multidisciplinary approach. The comprehensive content delivers psychoeducation on the socio-psycho-bio-medical nature of chronic painwithin a multidisciplinary framework. Educational video content accompaniedeach lesson and incorporated specialist information from a variety of medicaldisciplines including pain medicine, rehabilitation medicine, psychiatry, anaesthetics, rheumatology, and radiology; in addition to allied healthdisciplines including occupational therapy and dietetics. Core physiotherapyand psychotherapy modules were embedded in each lesson and were combined with agraded exercise program

	<p>focusing on activity and exercise reactivation within pacing and goal-setting. This was couple with evidence-based CBT skills including thought challenging, activity planning, problem solving, effective communication and flare-up management. Patients had access to: 1) downloadable lesson homework summaries, containing activities and skills practice; 2) 'Extra information and resources' (PDFS); 3) 'Expert videos' from a wide range of pain management specialists; and 4) audio-recordings labelled the 'RelaxationStation' which included relaxation files 15-30 minutes in length. Participants were also mailed a DVD demonstrating a graded Tai Chi program with instructions from a physiotherapist for completion over the program duration. The program incorporated a sizeable graded exercise component called the 'Movement station' whereby a physiotherapist narrated a series of videos of an actor performing an exercise and the patient was instructed to repeat the exercise then move on to the next step within gradual pacing guidelines. The movement station was divided into 3 sections: flexibility, strength and stability. The patient was asked to select their own cardiovascular exercise (e.g. swimming, walking), again increasing with gradual pacing. Participants received regular automatic and manual email communication to notify them that a lesson was available and encourage completion. Participants were contacted via email or phone by the research technician after the first 2 lessons then as requested by the participant related to any queries, or by a clinician in response to an increase in distress or suicidal ideation.. Duration 16 weeks . Concurrent medication/care: not reported . Indirectness: No indirectness; Indirectness comment: NA</p> <p>(n=46) Intervention 2: Standard care (a few GP appointments)/waiting list . Usual care - continued with treatments already commenced at their intake assessment and were permitted to engage in any new interventions for chronic pain management during the study period. Participants in this group were offered the Reboot Online programme after follow up assessment was complete. . Duration study duration . Concurrent medication/care: NA. Indirectness: No indirectness; Indirectness comment: NA</p>
Funding	Academic or government funding (St Vincent's Clinic foundation; the Motor Accidents Authority, NSW Government; Australian National Health and Medical research Council and Medical Research Future Foundation)

**RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST**

**Protocol outcome 1: Psychological distress (depression/anxiety)**

- Actual outcome: Kessler-10 Psychological Distress Scale at 28 weeks ; Group 1: mean 21.78 (SD 6.71); n=41, Group 2: mean 19.95 (SD 7.03); n=39; Kessler-10 Psychological Distress Scale 10-50 Top=High is poor outcome; Comments: Baseline values: PMP 26.05 (10.05), usual care 23.36 (11.68)  
 Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: more participants in the intervention group took simple analgesia at baseline ; Blinding details: usual care group free to engage in other treatment methods ; Group 1 Number missing: 14, Reason: withdrew before start (n=2), did not log in (n=1), did not consent (n=1), did not complete follow up questionnaires (n=10); Group 2 Number missing: 13, Reason: did not consent (n=1), withdrew before start (n=4), did not complete pre-questionnaires (n=2), did not complete follow up questionnaires (n=6)

Protocol outcome 2: Pain interference

- Actual outcome: Brief Pain Inventory - pain interference at 28 weeks ; Group 1: mean 5.19 (SD 1.98); n=41, Group 2: mean 4.64 (SD 2.05); n=39; BPI pain interference 0-10 Top=High is poor outcome; Comments: Baseline values: PMP 6.7 (2.1), usual care 5.88 (2.1)

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: more participants in the intervention group took simple analgesia at baseline ; Blinding details: usual care group free to engage in other treatment methods ; Group 1 Number missing: 14, Reason: withdrew before start (n=2), did not log in (n=1), did not consent (n=1), did not complete follow up questionnaires (n=10); Group 2 Number missing: 13, Reason: did not consent (n=1), withdrew before start (n=4), did not complete pre-questionnaires (n=2), did not complete follow up questionnaires (n=6)

Protocol outcome 3: Pain reduction

- Actual outcome: Brief Pain Inventory - pain severity at 28 weeks ; Group 1: mean 4.38 (SD 1.58); n=41, Group 2: mean 4.77 (SD 1.64); n=39; BPI pain severity 0-10 Top=High is poor outcome; Comments: Baseline values: PMP 5.4 (1.66), usual care 5.05 (1.66)

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: more participants in the intervention group took simple analgesia at baseline ; Blinding details: usual care group free to engage in other treatment methods ; Group 1 Number missing: 14, Reason: withdrew before start (n=2), did not log in (n=1), did not consent (n=1), did not complete follow up questionnaires (n=10); Group 2 Number missing: 13, Reason: did not consent (n=1), withdrew before start (n=4), did not complete pre-questionnaires (n=2), did not complete follow up questionnaires (n=6)

Protocol outcome 4: Pain self-efficacy

- Actual outcome: Pain Self-efficacy Questionnaire at 28 weeks ; Group 1: mean 35 (SD 8.57); n=41, Group 2: mean 28.55 (SD 8.78); n=39; Pain self-efficacy questionnaire 0-60 Top=High is good outcome; Comments: Baseline values: PMP 25.23 (8.81), usual care 26.26 (8.88)

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: more participants in the intervention group took simple analgesia at baseline ; Blinding details: usual care group free to engage in other treatment methods ; Group 1 Number missing: 14, Reason: withdrew before start (n=2), did not log in (n=1), did not consent (n=1), did not complete follow up questionnaires (n=10); Group 2 Number missing: 13, Reason: did not consent (n=1), withdrew before start (n=4), did not complete pre-questionnaires (n=2), did not complete follow up questionnaires (n=6)

Protocol outcomes not reported by the study

Quality of life; Physical function; Use of healthcare services; Sleep; Discontinuation due to adverse events

Study	Tavafian 2007 <sup>318</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=102)
Countries and setting	Conducted in Iran; Setting: Rheumatology Research Center of a University of Medical Sciences
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 4 days + 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Physicians confirmed the inclusion and exclusion criteria through a complete and exact clinical assessment before the participants were enrolled in the study
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	age 18 years and over, suffering from chronic back pain (persisting for 90 days or more), and having a telephone number for regular contact with a responsible caregiver
Exclusion criteria	back surgery within the two years prior to the initial observation, or if the complaint was restricted to the sacroiliac joint or the cervical or thoracic regions, or if there was congenital spine disease, low back complaint that had persisted less than 90 days
Recruitment/selection of patients	recruited from outpatient rheumatology clinics
Age, gender and ethnicity	Age - Mean (SD): intervention 42.9 (10.7), control 44.7 (10.8). Gender (M:F): 0/102. Ethnicity: not reported
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: Not stated / Unclear 3. First language not English: Not applicable 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Indirectness of population	No indirectness: NA
Interventions	(n=50) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Professional led back school programme: 4-day, 5-session programme: <ul style="list-style-type: none"> <li>· Assessment of knowledge, perceptions and beliefs concerning health, non-healthy behaviours and approaches and motivation to changing non-healthy behaviour.</li> <li>· Psychological evaluations and focus on individual coping skills, anger management and relaxation</li> <li>· Back school classes, including anatomy and physiology of the spine</li> <li>· Instruction in the natural history of spinal conditions, lifestyle factors that accelerate chronic low back pain and techniques for preventing further injury.</li> <li>· Instruction in lumbar stabilization, body mechanics and prevention techniques</li> <li>· Weight-bearing exercise and optimal aerobic fitness programme</li> </ul> Led by: PhD level educator, clinical psychologist, rheumatologist, physical therapist. Duration 4 days.

	<p>Concurrent medication/care: Medication for both groups was the same (Acetaminophen, NSAID, and Chlordiazepoxide). Indirectness: No indirectness; Indirectness comment: NA</p> <p>(n=52) Intervention 2: Standard care (a few GP appointments)/waiting list. Received only medication under the supervision of a leading physician. Duration 3 months. Concurrent medication/care: Medication for both groups was the same (Acetaminophen, NSAID, and Chlordiazepoxide). Indirectness: No indirectness; Indirectness comment: NA</p>
Funding	Funding not stated

**RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST**

Protocol outcome 1: Quality of life

- Actual outcome: SF36 physical functioning at 3 months; Group 1: mean 79.3 (SD 18.6); n=44, Group 2: mean 54.4 (SD 27); n=47; SF36 physical functioning 0-100 Top=High is good outcome; Comments: Baseline values: intervention 55.5 (24), control 53.4 (20.8)  
 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 6, Reason: 2 withdrew consent, 4 did not comply with programme ; Group 2 Number missing: 5, Reason: 1 withdrew consent, 4 lost to follow up

- Actual outcome: SF36 role physical at 3 months; Group 1: mean 78.9 (SD 28.5); n=44, Group 2: mean 40.9 (SD 36.6); n=47; SF36 role physical 0-100 Top=High is good outcome; Comments: Baseline values: intervention 31.2 (26.4), control 32.9 (35.7)  
 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 6, Reason: 2 withdrew consent, 4 did not comply with programme ; Group 2 Number missing: 5, Reason: 1 withdrew consent, 4 lost to follow up

- Actual outcome: SF36 bodily pain at 3 months; Group 1: mean 71.5 (SD 16.2); n=44, Group 2: mean 56.6 (SD 30); n=47; SF36 bodily pain 0-100 Top=High is good outcome; Comments: Baseline values: intervention 43.4 (19.6), control 43.5 (25.8)  
 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 6, Reason: 2 withdrew consent, 4 did not comply with programme ; Group 2 Number missing: 5, Reason: 1 withdrew consent, 4 lost to follow up

- Actual outcome: SF36 general health at 3 months; Group 1: mean 61.6 (SD 22.7); n=44, Group 2: mean 47.3 (SD 26.1); n=47; SF36 general health 0-100 Top=High is good outcome; Comments: Baseline values: intervention 43.9 (23.1), control 42.2 (22.4)  
 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 6, Reason: 2 withdrew consent, 4 did not comply with programme ; Group 2 Number missing: 5, Reason: 1 withdrew consent, 4 lost to follow up

- Actual outcome: SF36 mental health at 3 months; Group 1: mean 74 (SD 22.8); n=44, Group 2: mean 54.3 (SD 26.6); n=47; SF36 mental health 0-100 Top=High is good outcome; Comments: Baseline values: intervention 52.7 (28), control 48.8 (22.9)  
 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 6, Reason: 2 withdrew consent, 4 did not comply with programme ; Group 2 Number missing: 5, Reason: 1 withdrew consent, 4 lost to follow up

- Actual outcome: SF36 role emotional at 3 months; Group 1: mean 72.8 (SD 40.6); n=44, Group 2: mean 34 (SD 42.4); n=47; SF36 role emotional 0-100 Top=High is good outcome; Comments: Baseline values: intervention 35.6 (42), control 32.6 (40.4)

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 6, Reason: 2 withdrew consent, 4 did not comply with programme ; Group 2 Number missing: 5, Reason: 1 withdrew consent, 4 lost to follow up

- Actual outcome: SF36 vitality at 3 months; Group 1: mean 73.2 (SD 22); n=44, Group 2: mean 56.8 (SD 25.6); n=47; SF36 vitality 0-100 Top=High is good outcome; Comments: Baseline values: intervention 48.7 (23.4), control 48.6 (21.4)

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 6, Reason: 2 withdrew consent, 4 did not comply with programme ; Group 2 Number missing: 5, Reason: 1 withdrew consent, 4 lost to follow up

- Actual outcome: SF36 social functioning at 3 months; Group 1: mean 87.7 (SD 21.6); n=44, Group 2: mean 69.1 (SD 32.7); n=47; SF36 social functioning 0-100 Top=High is good outcome; Comments: Baseline values: intervention 62.5 (28.2), control 64 (29.3)

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 6, Reason: 2 withdrew consent, 4 did not comply with programme ; Group 2 Number missing: 5, Reason: 1 withdrew consent, 4 lost to follow up

#### Protocol outcome 2: Discontinuation

- Actual outcome: Discontinuation at 3 months; Group 1: 6/50, Group 2: 5/52; Comments: intervention: 2 withdrew consent, 4 did not comply with the programme. Control: 1 withdrew consent, 4 lost to follow up

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcomes not reported by the study

Physical function; Psychological distress (depression/anxiety); Pain interference; Use of healthcare services ; Sleep; Pain reduction; Pain self-efficacy

Study	Tavafian 2011 <sup>319</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=197)
Countries and setting	Conducted in Iran; Setting: Clinic in Tehran
Line of therapy	Not applicable
Duration of study	Follow up (post intervention): 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Chronic low back pain, >18 years old, pain >90 days, referred to rheumatology clinics,
Exclusion criteria	Back surgery within the past two years, fracture or malignancy, spinal stenosis or spondylolisthesis, inability to comply with intervention and follow-ups, non-fluent in Farsi, non-resident in Tehran, pregnant.
Recruitment/selection of patients	Hospital clinics
Age, gender and ethnicity	Age - Mean (SD): 45.26 (10.79). Gender (M:F): 43:154. Ethnicity: Iranian
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: Not stated / Unclear 3. First language not English: Not applicable 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment: Not stated / Unclear
Indirectness of population	No indirectness
Interventions	(n=97) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Group based rehabilitation programme with biological and psychosocial aspects. 5x 2hour initial classes, over one week, administered by members of different specialties delivered over one week. Followed by monthly motivational conversations by telephone and booster sessions. Classes were in anatomy, physiology, lifestyle, pain prevention techniques, posture, stretching, strengthening, risk factors, coping with stress and threatening events, emotional regulation strategies and CBT. A core leader took questions to any experts who were not in attendance. Duration One week of classes. Concurrent medication/care: Oral drug treatment. Indirectness: No indirectness  (n=100) Intervention 2: Standard care (a few GP appointments)/waiting list. Oral drug treatment alone. Duration 1 week. Concurrent medication/care: NR. Indirectness: No indirectness
Funding	Academic or government funding (Tehran University of medical sciences)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus	

STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST

Protocol outcome 1: Quality of life

- Actual outcome: SF-36 Physical function 3 months at 3 months; Group 1: mean 68.64 (SD 23.39); n=92, Group 2: mean 60.93 (SD 22.04); n=97; SF-36 0-100 Top=High is good outcome

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 3, Reason: Failed to be contacted (1), refused to continue the study (2)

- Actual outcome: SF-36 Physical function 6 months at 6 months; Group 1: mean 77.77 (SD 18.71); n=92, Group 2: mean 63.698 (SD 21.88); n=96; SF36 0-100 Top=High is good outcome

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 4, Reason: Failed to be contacted (2), refused to continue the study (2)

- Actual outcome: SF-36 Role physical 3 months at 3 months; Group 1: mean 57.88 (SD 68.33); n=92, Group 2: mean 39.58 (SD 36.93); n=97; SF36 0-100 Top=High is good outcome

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 3, Reason: Failed to be contacted (1), refused to continue the study (2)

- Actual outcome: SF-36 Role physical 6 months at 6 months; Group 1: mean 66.03 (SD 36.79); n=92, Group 2: mean 47.13 (SD 39.04); n=96; SF36 0-100 Top=High is good outcome

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 4, Reason: Failed to be contacted (2), refused to continue the study (2)

- Actual outcome: SF-36 General health 3 months at 3 months; Group 1: mean 59.67 (SD 21.59); n=92, Group 2: mean 52.65 (SD 23.34); n=97; SF36 0-100 Top=High is good outcome

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 3, Reason: Failed to be contacted (1), refused to continue the study (2)

- Actual outcome: SF-36 General health 6 months at 6 months; Group 1: mean 61.01 (SD 21.96); n=92, Group 2: mean 53.29 (SD 22.83); n=96; SF36 0-100 Top=High is good outcome

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 4, Reason: Failed to be contacted (2), refused to continue the study (2)

- Actual outcome: SF-36 Vitality 3 months at 3 months; Group 1: mean 60.1 (SD 23.25); n=92, Group 2: mean 55.05 (SD 20.74); n=97; SF36 0-100 Top=High is good outcome

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 3, Reason: Failed to be contacted (1), refused to continue the study (2)

- Actual outcome: SF-36 Vitality 6 months at 6 months; Group 1: mean 65.7 (SD 22.25); n=92, Group 2: mean 59.84 (SD 22.35); n=96; SF36 0-100 Top=High is good outcome  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 4, Reason: Failed to be contacted (2), refused to continue the study (2)

- Actual outcome: SF-36 Social function 3 months at 3 months; Group 1: mean 59.78 (SD 21.12); n=92, Group 2: mean 51.77 (SD 21.2); n=97; SF36 0-100 Top=High is good outcome  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 3, Reason: Failed to be contacted (1), refused to continue the study (2)

- Actual outcome: SF-36 Social function 6 months at 6 months; Group 1: mean 76.9 (SD 23.5); n=92, Group 2: mean 69.37 (SD 26.65); n=96; SF36 0-100 Top=High is good outcome  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 4, Reason: Failed to be contacted (2), refused to continue the study (2)

- Actual outcome: SF-36 Emotional role 3 months at 3 months; Group 1: mean 50.72 (SD 45.15); n=92, Group 2: mean 41.31 (SD 44.25); n=97; SF36 0-100 Top=High is good outcome  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 3, Reason: Failed to be contacted (1), refused to continue the study (2)

- Actual outcome: SF-36 Emotional role 6 months at 6 months; Group 1: mean 58.33 (SD 45.99); n=92, Group 2: mean 52.43 (SD 47.07); n=96; SF36 0-100 Top=High is good outcome  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 4, Reason: Failed to be contacted (2), refused to continue the study (2)

- Actual outcome: SF-36 Mental health 3 months at 3 months; Group 1: mean 65.13 (SD 21.59); n=92, Group 2: mean 57.7 (SD 23.22); n=97; SF36 0-100 Top=High is good outcome  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 3, Reason: Failed to be contacted (1), refused to continue the study (2)

- Actual outcome: SF-36 Mental health 6 months at 6 months; Group 1: mean 66.04 (SD 23.67); n=92, Group 2: mean 61.41 (SD 23.25); n=97; SF36 0-100 Top=High is good outcome  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 4, Reason: Failed to be contacted (2), refused to continue the study (2)

Protocol outcome 2: Physical function  
- Actual outcome: Roland Morris Disability Questionnaire 3 months at 3 months; Group 1: mean 9.01 (SD 5.71); n=92, Group 2: mean 10.56 (SD 5.78);

<p>n=97; RMDQ 0-24 Top=High is poor outcome; Comments: 9.80(5.07):10.04(5.28) Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 3, Reason: Failed to be contacted (1), refused to continue the study (2) - Actual outcome: Roland Morris Disability Questionnaire 6 months at 6 months; Group 1: mean 7.03 (SD 5.49); n=92, Group 2: mean 8.8 (SD 5.68); n=96; RMDQ 0-24 Top=High is poor outcome; Comments: 9.80(5.07):10.04(5.28) Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 4, Reason: Failed to be contacted (2), refused to continue the study (2)</p> <p>Protocol outcome 3: Discontinuation - Actual outcome: Discontinuation any cause at 3 months; Group 1: 5/97, Group 2: 3/100 Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5; Group 2 Number missing: 3 - Actual outcome: Discontinuation any cause at 6 months; Group 1: 5/97, Group 2: 4/100 Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5; Group 2 Number missing: 4</p> <p>Protocol outcome 4: Pain reduction - Actual outcome: SF-36 Bodily pain 3 months at 3 months; Group 1: mean 65.82 (SD 22.56); n=92, Group 2: mean 56.35 (SD 23.62); n=97; SF-36 pain 0-100 Top=High is good outcome; Comments: 43.27(22.29):47.45(23.59) Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 3, Reason: Failed to be contacted (1), refused to continue the study (2) - Actual outcome: SF-36 Bodily pain 6 months at 6 months; Group 1: mean 72.34 (SD 22.77); n=92, Group 2: mean 60.27 (SD 25.82); n=96; SF-36 pain 0-100 Top=High is good outcome; Comments: 43.27(22.29):47.45(23.59) Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Failed to be contacted (3), did not receive intervention (2), refused to participate (1), not eligible (1); Group 2 Number missing: 4, Reason: Failed to be contacted (2), refused to continue the study (2)</p>	
<p>Protocol outcomes not reported by the study</p>	<p>Psychological distress (depression/anxiety); Pain interference; Use of healthcare services; Sleep; Pain self-efficacy</p>

Study	Van eijk-hustings 2013 <sup>337</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=203)
Countries and setting	Conducted in Netherlands; Setting: outpatient rheumatology clinics of three medical centres
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 21-24 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: diagnosed FM patients according to the American College of Rheumatology criteria
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	recently (<3 months) diagnosed FM patients according to the American College of Rheumatology criteria, literate and between 18 and 65 years old
Exclusion criteria	pregnancy, involvement in litigation concerning work disability procedures, use of other non-pharmacological treatments such as psychological or physical treatment, interfering with the intervention, alcohol or drugs abuse and use of walking devices
Recruitment/selection of patients	consecutive patients meeting the inclusion criteria during the recruitment period
Age, gender and ethnicity	Age - Range of means: intervention 41 years, control 43 years. Gender (M:F): intervention 148/8 Ethnicity: not reported
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: Not stated / Unclear 3. First language not English: Not applicable 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Indirectness of population	No indirectness: NA
Interventions	(n=108) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. 1 year programme. Phase1 – 12 weeks course 3 half days per week with 2 therapy sessions of 1.5 hr duration per day: <ul style="list-style-type: none"> <li>· sociotherapy (twice a week, based on transactional analysis and aiming to increase social behaviour strategies and social support)</li> <li>· physiotherapy (twice a week, based on graded activity and comprising aerobic exercise, strength training, relaxation etc.)</li> <li>· psychotherapy (once a week, consisting of information about FM and pain mechanisms and using methods of core qualities, rational emotive therapy and transactional analysis)</li> <li>· creative arts therapy(once a week, allowing expression of feeling through visual arts)</li> </ul> Phase 2 – aftercare programme consisting of 5 meetings over 9 months:

	<ul style="list-style-type: none"> <li>repeat the key messages about coping in order to preserve the behavioural change achieved in phase 1</li> <li>maximum of 7 individual therapy sessions with one of the therapists could be scheduled if considered necessary. Duration 1 year. Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA</li> </ul> <p>(n=48) Intervention 2: Standard care (a few GP appointments)/waiting list . At least individualised education about FM and lifestyle advice by a rheumatologist or a specialised rheumatology nurse within one or two consultations, but could also include a diversity of other treatments such as physiotherapy or social support from the rheumatology nurse. Duration 1 year. Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA</p>
Funding	Other (supported by Maastricht University Medical Centre and by Care Renewal Grants of medical insurance companies in the region)

**RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST**

Protocol outcome 1: Quality of life

- Actual outcome: EQ-5D at 12 weeks; Group 1: mean 0.49; n=108, Group 2: mean 0.5; n=48; EQ-5D -0.59-1 Top=High is good outcome; Comments: intervention SE=0.03, control SE=0.04, baseline values: intervention 0.36 (SE 0.03), control 0.51 (SE 0.04), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: EQ-5D at 18 months (after 12 week programme); Group 1: mean 0.55; n=108, Group 2: mean 0.51; n=48; EQ-5D -0.59-1 Top=High is good outcome; Comments: intervention SE=0.03, control SE=0.05, baseline values: intervention 0.36 (SE 0.03), control 0.51 (SE 0.04), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: EQVAS at 12 weeks; Group 1: mean 54; n=108, Group 2: mean 48.3; n=48; EQ-5D Visual Analogue Scale 0-100 Top=High is good outcome; Comments: intervention SE=1.9, control SE=2.9, baseline values: intervention 48.1 (SE 1.7), control 54 (SE 2.6), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: EQVAS at 18 months (after 12 week programme); Group 1: mean 57.3; n=108, Group 2: mean 51.9; n=48; EQ-5D Visual Analogue Scale 0-100 Top=High is good outcome; Comments: intervention SE=2.3, control SE=3.3, baseline values: intervention 48.1 (SE 1.7), control 54 (SE 2.6), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

Protocol outcome 2: Physical function

- Actual outcome: FIQ physical function subscale at 12 weeks; Group 1: mean 3.9; n=108, Group 2: mean 4; n=48; FIQ physical function subscale 0-10 Top=High is poor outcome; Comments: intervention SE=0.2, control SE=0.3, baseline values: intervention 4.2 (SE 0.2), control 3.4 (SE 0.3), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: FIQ physical function subscale at 18 months (after 12 week programme); Group 1: mean 3.6; n=108, Group 2: mean 3.9; n=48; FIQ physical function subscale 0-10 Top=High is poor outcome; Comments: intervention SE=0.2, control SE=0.3, baseline values: intervention 4.2 (SE 0.2), control 3.4 (SE 0.3), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

Protocol outcome 3: Psychological distress (depression/anxiety)

- Actual outcome: FIQ anxiety subscale at 12 weeks; Group 1: mean 5; n=108, Group 2: mean 5.2; n=48; FIQ anxiety subscale 0-10 Top=High is poor outcome; Comments: intervention SE=0.2, control SE=0.4, baseline values: intervention 5.9 (SE 0.3), control 4.8 (SE 0.4), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: FIQ anxiety subscale at 18 months (after 12 week programme); Group 1: mean 4.7; n=108, Group 2: mean 4.8; n=48; FIQ anxiety subscale 0-10 Top=High is poor outcome; Comments: intervention SE=0.3, control SE=0.4, baseline values: intervention 5.9 (SE 0.3), control 4.8 (SE 0.4), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: FIQ depression subscale at 12 weeks; Group 1: mean 4.1; n=108, Group 2: mean 4.5; n=48; FIQ depression subscale 0-10 Top=High is poor outcome; Comments: intervention SE=0.3, control SE=0.4, baseline values: intervention 5.2 (SE 0.3), control 4.2 (SE 0.4), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: FIQ depression subscale at 18 months (after 12 week programme); Group 1: mean 3.9; n=108, Group 2: mean 4.2; n=48; FIQ

depression subscale 0-10 Top=High is poor outcome; Comments: intervention SE=0.3, control SE=0.4, baseline values: intervention 5.2 (SE 0.3), control 4.2 (SE 0.4), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

Protocol outcome 4: Use of healthcare services

- Actual outcome: GP contacts (2 monthly cost questionnaire) at 12 weeks; Group 1: mean 1; n=108, Group 2: mean 0.5; n=48; number of contacts; Comments: intervention SE=0.2, control SE=0.3 baseline values: intervention 2.3 (SE 0.3), control 1.4 (SE 0.3), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: GP contacts (2 monthly cost questionnaire) at 18 months (after 12 week programme); Group 1: mean 0.9; n=108, Group 2: mean 0.7; n=48; number of contacts; Comments: intervention SE=0.2, control SE=0.3, baseline values: intervention 2.3 (SE 0.3), control 1.4 (SE 0.3), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: medical specialist contacts (2 monthly cost questionnaire) at 12 weeks; Group 1: mean 0.1; n=108, Group 2: mean 0.2; n=48; number of contacts; Comments: intervention SE=0.1, control SE=0.1, baseline values: intervention 1.9 (SE 0.1), control 1.6 (SE 0.1), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: medical specialist contacts (2 monthly cost questionnaire) at 18 months (after 12 week programme); Group 1: mean 0.3; n=108, Group 2: mean 0.2; n=48; number of contacts; Comments: intervention SE=0.1, control SE=0.1, baseline values: intervention 1.9 (SE 0.1), control 1.6 (SE 0.1), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: physiotherapist contacts (2 monthly cost questionnaire) at 12 weeks; Group 1: mean 2.2; n=108, Group 2: mean 3.4; n=48; number of contacts; Comments: intervention SE=0.5, control SE=0.7, baseline values: intervention 2.7 (SE 0.5), control 1 (SE 0.5), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: physiotherapist contacts (2 monthly cost questionnaire) at 18 months (after 12 week programme); Group 1: mean 2.6; n=108, Group 2:

mean 2.8; n=48; number of contacts; Comments: intervention SE=0.5, control SE=0.7, baseline values: intervention 2.7 (SE 0.5), control 1 (SE 0.5), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: other paramedical professional contacts (2 monthly cost questionnaire) at 12 weeks ; Group 1: mean 0.8; n=108, Group 2: mean 0.8; n=48; number of contacts; Comments: intervention SE=0.3, control SE=0.4, baseline values: intervention 1.1 (SE 0.3), control 0.6 (SE 0.2), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: other paramedical professional contacts (2 monthly cost questionnaire) at 18 months (after 12 week programme) ; Group 1: mean 1; n=108, Group 2: mean 0.2; n=48; number of contacts; Comments: intervention SE=0.3, control SE=0.4, baseline values: intervention 1.1 (SE 0.3), control 0.6 (SE 0.2), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

#### Protocol outcome 5: Sleep

- Actual outcome: FIQ unrefreshed sleep subscale at 12 weeks; Group 1: mean 7.5; n=108, Group 2: mean 7.2; n=48; FIQ unrefreshed sleep subscale 0-10 Top=High is poor outcome; Comments: intervention SE=0.2, control SE=0.3, baseline values: intervention 8.2 (SE 0.2), control 7.6 (SE 0.3), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: FIQ unrefreshed sleep subscale at 18 months (after 12 week programme); Group 1: mean 7.1; n=108, Group 2: mean 7.6; n=48; FIQ unrefreshed sleep subscale 0-10 Top=High is poor outcome; Comments: intervention SE=0.3, control SE=0.4, baseline values: intervention 8.2 (SE 0.2), control 7.6 (SE 0.3), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

#### Protocol outcome 6: Discontinuation

- Actual outcome: discontinuation at 12 weeks; Group 1: 41/108, Group 2: 0/48; Comments: 41 participants in the intervention group did not start the programme. Some reasons for attrition were difficulties with transportation and a lack of motivation.

Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

Protocol outcome 7: Pain reduction

- Actual outcome: FIQ pain subscale at 12 weeks; Group 1: mean 5.5; n=108, Group 2: mean 5.7; n=48; FIQ pain subscale 0-10 Top=High is poor outcome; Comments: intervention SE=0.2, control SE=0.3, baseline values: intervention 6.3 (SE 0.2), control 5.5 (SE 0.3), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

- Actual outcome: FIQ pain subscale at 18 months (after 12 week programme); Group 1: mean 5.3; n=108, Group 2: mean 5.3; n=48; FIQ pain subscale 0-10 Top=High is poor outcome; Comments: intervention SE=0.2, control SE=0.3, baseline values: intervention 6.3 (SE 0.2), control 5.5 (SE 0.3), only 67 participants completed the intervention as per protocol

Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Group 1 Number missing: 0, Reason: NA; Group 2 Number missing: 0, Reason: NA

Protocol outcomes not reported by the study

Pain interference; Pain self-efficacy

Study	Van koulil 2010 <sup>339</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=158)
Countries and setting	Conducted in Netherlands; Setting: outpatient
Line of therapy	Not applicable
Duration of study	Follow up (post intervention): 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	Fibromyalgia (American College Rheumatology criteria ) <5 years,
Exclusion criteria	<18 years old, secondary FM, pregnancy, non-fluent in Dutch, severe physical/mental comorbidity, participation in other trials
Recruitment/selection of patients	Referred by rheumatologists and hospitals in Holland
Age, gender and ethnicity	Age - Mean (SD): 41.7 (10.9). Gender (M:F): 4/79. Ethnicity: NR
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: No cognitive impairment 3. First language not English: Not applicable 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Indirectness of population	No indirectness: NA
Interventions	<p>(n=68) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Highly structured out patients treatment programme in a group setting of 8 participants. Programme tailored to pain-avoidance or pain-persistence (groups assigned according to this). 16 twice weekly sessions and one booster session 3 months after treatment completion. Every session 2 hours of CBT delivered by CBT therapists trained in the programme then 2 hours of exercise training. The patient's partners attended the 3rd, 9th and 15th session. Consolidating homework - 1.5 hours a day. Booster session focused on relapse prevention. Duration 10 weeks. Concurrent medication/care: NR. Indirectness: No indirectness</p> <p>(n=90) Intervention 2: Standard care (a few GP appointments)/waiting list. Waiting list. Duration 10 weeks. Concurrent medication/care: NR. Indirectness: No indirectness</p>
Funding	Other (Dutch Arthritis Association and The Netherlands Organization for Health Research and Development)

**RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST**

**Protocol outcome 1: Quality of life**

- Actual outcome: Fibromyalgia impact questionnaire Total at post intervention; Group 1: mean 47.1 (SD 15); n=61, Group 2: mean 58.5 (SD 14.6); n=82; FIQ 0-100 Top=High is good outcome

Risk of bias: All domain - Very high, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - No p values for baseline between-group variance analysis. Reviewer calculated mean overall results when reported separately for each diagnostic group. After agreeing to patients placed into groups by psychiatric diagnostic group and then randomised into treatment group or waiting list control.; Indirectness of outcome: No indirectness ; Blinding details: self-report ; Group 1 Number missing: 6, Reason: withdrew (n=4), psychiatric comorbidity (n=1), physical comorbidity (n=1); Group 2 Number missing: 7, Reason: withdrew (n=6), pregnant (n=1)

- Actual outcome: Fibromyalgia impact questionnaire Total at 6 months; Group 1: mean 45.9 (SD 17.7); n=57, Group 2: mean 57.9 (SD 16.5); n=79; FIQ 0-100 Top=High is poor outcome

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - No p values for baseline between-group variance analysis. Reviewer calculated mean overall results when reported separately for each diagnostic group. After agreeing to patients placed into groups by psychiatric diagnostic group and then randomised into treatment group or waiting list control.; Indirectness of outcome: No indirectness ; Group 1 Number missing: 11, Reason: withdrew (n=7), psychiatric comorbidity (n=1), physical comorbidity (n=3); Group 2 Number missing: 10, Reason: withdrew (n=9), pregnant (n=1)

**Protocol outcome 2: Psychological distress (depression/anxiety)**

- Actual outcome: Impact of rheumatic diseases on general health and lifestyle (IRGL) Anxiety scale at post intervention; Group 1: mean 21.08 (SD 5); n=60, Group 2: mean 24.6 (SD 6); n=82; IRGL anxiety 10-40 Top=High is poor outcome

Risk of bias: All domain - Very high, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - No p values for baseline between-group variance analysis. Reviewer calculated mean overall results when reported separately for each diagnostic group. After agreeing to patients placed into groups by psychiatric diagnostic group and then randomised into treatment group or waiting list control.; Indirectness of outcome: No indirectness ; Blinding details: self-report ; Group 1 Number missing: 6, Reason: withdrew (n=4), psychiatric comorbidity (n=1), physical comorbidity (n=1); Group 2 Number missing: 7, Reason: withdrew (n=6), pregnant (n=1)

- Actual outcome: Impact of rheumatic diseases on general health and lifestyle (IRGL) Anxiety scale at 6 months; Group 1: mean 19.53 (SD 4.97); n=56, Group 2: mean 24.3 (SD 5.6); n=78; IRGL 10-40 Top=High is poor outcome

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - No p values for baseline between-group variance analysis. Reviewer calculated mean overall results when reported separately for each diagnostic group. After agreeing to patients placed into groups by psychiatric diagnostic group and then randomised into treatment group or waiting list control.; Indirectness of outcome: No indirectness ; Group 1 Number missing: 11, Reason: withdrew (n=7), psychiatric comorbidity (n=1), physical comorbidity (n=3); Group 2 Number missing: 10, Reason: withdrew (n=9), pregnant (n=1)

**Protocol outcome 3: Discontinuation**

- Actual outcome: Discontinuation any cause at Post intervention; Group 1: 6/68, Group 2: 7/90; Comments: Intervention: withdrew (n=4), psychiatric

comorbidity (n=1), physical comorbidity (n=1) Control : withdrew (n=6), pregnant (n=1)  
 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - No p values for baseline between-group variance analysis. Reviewer calculated mean overall results when reported separately for each diagnostic group. After agreeing to patients placed into groups by psychiatric diagnostic group and then randomised into treatment group or waiting list control.; Indirectness of outcome: No indirectness ; Group 1 Number missing: 6, Reason: withdrew (n=4), psychiatric comorbidity (n=1), physical comorbidity (n=1); Group 2 Number missing: 7, Reason: withdrew (n=6), pregnant (n=1)  
 - Actual outcome: Discontinuation any cause at 6 months; Group 1: 11/60, Group 2: 10/90; Comments: Intervention: withdrew (n=7), psychological comorbidity (n=1), physical comorbidity (n=3) Control: withdrew (n=9), pregnant (n=1)  
 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - No p values for baseline between-group variance analysis. Reviewer calculated mean overall results when reported separately for each diagnostic group. After agreeing to patients placed into groups by psychiatric diagnostic group and then randomised into treatment group or waiting list control.; Indirectness of outcome: No indirectness ; Group 1 Number missing: 11, Reason: withdrew (n=7), psychiatric comorbidity (n=1), physical comorbidity (n=3); Group 2 Number missing: 10, Reason: withdrew (n=9), pregnant (n=1)

Protocol outcomes not reported by the study

Physical function; Pain interference; Use of healthcare services; Sleep; Pain reduction; Pain self-efficacy

Study	Williams 1996 <sup>347</sup>
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=121)
Countries and setting	Conducted in United Kingdom; Setting: pain management unit, single centre
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 4 weeks/8 weeks + 1 month
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: interview by a clinical psychologist and an anaesthetist for medical review; information combined and compared with criteria for acceptance
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	chronic pain which significantly disrupted life and no further medical treatment appropriate; able and willing to attend whichever treatment was assigned; those in the inpatient group had to be relieved of work duties or the care of dependent relatives
Exclusion criteria	NA
Recruitment/selection of patients	referred by GPs or medical consultants, predominantly from other pain clinics
Age, gender and ethnicity	Age - Mean (SD): inpatient 48.7 (11.6), outpatient 50.4 (11.7), waiting list 51.1 (10.7) years. Gender (M:F): 57/64. Ethnicity: 84-88% in each group 'white'; remainder of Afro-Caribbean or Asian origin, although the majority were born in the UK
Further population details	1. Age 16-18 years: Over 18 years 2. Cognitive impairment: Not stated / Unclear 3. First language not English: Not stated / Unclear 4. Homeless: Not stated / Unclear 5. Learning difficulties: Not stated / Unclear 6. Sensory impairment : Not stated / Unclear
Indirectness of population	No indirectness: NA
Interventions	(n=43) Intervention 1: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Professional led inpatient cognitive behavioural pain management programme 4.5 days per week for 4 weeks, returning home at weekends: <ul style="list-style-type: none"> <li>· Exercise and stretch increasing gradually on a quota system</li> <li>· Goal setting covering work, leisure, social pursuits and domestic duties</li> <li>· Pacing of activities – regular schedule of activities and breaks increasing on the quota system</li> <li>· Education covering concepts of chronic and acute pain, medical/surgical treatments, disuse, sleep etc.</li> <li>· Cognitive and behavioural sessions on problem solving and cognitive techniques</li> <li>· Drug reduction aiming for nil by discharge</li> <li>· Relaxation technique</li> <li>· Sleep hygiene techniques</li> </ul>

	<ul style="list-style-type: none"> <li>· Relapse prevention using 'setback plans'</li> <li>· Family involvement by inviting spouses to attend part of the programme</li> <li>· Teaching supported by a manual given to patients at the end</li> </ul> <p>Duration 4 weeks. Concurrent medication/care: No other active treatments (such as nerve blocks or acupuncture) were used. Indirectness: No indirectness; Indirectness comment: NA</p> <p>(n=45) Intervention 2: Professional led/professional and peer led pain management programmes - Professional led pain management programmes. Professional led outpatient cognitive behavioural pain management programme 3.5 hours per week for 8 weeks. Programme components were the same as the inpatient programme. Unit staffed by a consultant anaesthetist, 2 clinical psychologists, a physiotherapist, an occupational therapist and a senior nurse. Duration 8 weeks. Concurrent medication/care: No other active treatments (such as nerve blocks or acupuncture) were used. Indirectness: No indirectness; Indirectness comment: NA</p> <p>(n=33) Intervention 3: Standard care (a few GP appointments)/waiting list. Waiting list: no new treatments initiated during the study programme period. Duration 12 weeks. Concurrent medication/care: NA. Indirectness: No indirectness; Indirectness comment: NA</p>
Funding	Academic or government funding (the King's Fund, supplemented by the Special Trustees of St Thomas' Hospital and the South East Thames Regional Health Authority)

**RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PROFESSIONAL LED PAIN MANAGEMENT PROGRAMMES versus STANDARD CARE (A FEW GP APPOINTMENTS)/WAITING LIST**

**Protocol outcome 1: Physical function**

- Actual outcome: Metres walked in 10 minutes (inpatient programme) at 8 weeks (1 month follow up) ; Group 1: mean 670 metres (SD 212); n=38, Group 2: mean 482 metres (SD 183); n=31; metres walked in 10 minutes NA Top=High is good outcome; Comments: Baseline values: inpatients 437 (220), waiting list 466 (194)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: inpatients scored lower on self-efficacy than the waiting list group ; Group 1 Number missing: 5, Reason: 2 defaulted after randomisation, 1 dropped out during treatment, 2 defaulted from follow up ; Group 2 Number missing: 2, Reason: 2 defaulted after randomisation

- Actual outcome: Metres walked in 10 minutes (outpatient programme) at 12 weeks (1 month follow up) ; Group 1: mean 531 metres (SD 278); n=30, Group 2: mean 482 metres (SD 183); n=31; metres walked in 10 minutes NA Top=High is good outcome; Comments: Baseline values: intervention 440 (238), waiting list 466 (194)

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: inpatients scored lower on self-efficacy than the waiting list group ; Group 1 Number missing: 15, Reason: 3 defaulted after randomisation, 5 dropped out during treatment, 7 defaulted from follow up ; Group 2

Number missing: 2, Reason: 2 defaulted after randomisation

Protocol outcome 2: Psychological distress (depression/anxiety)

- Actual outcome: Beck Depression Inventory (inpatient programme) at 8 weeks (1 month follow up) ; Group 1: mean 9.5 (SD 7.8); n=38, Group 2: mean 17.3 (SD 7); n=31; Beck Depression Inventory 0-63 Top=High is poor outcome; Comments: Baseline values: inpatients 17.8 (8), waiting list 16.6 (6.5)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: inpatients scored lower on self-efficacy than the waiting list group ; Group 1 Number missing: 5, Reason: 2 defaulted after randomisation, 1 dropped out during treatment, 2 defaulted from follow up ; Group 2

Number missing: 2, Reason: 2 defaulted after randomisation

- Actual outcome: State-Trait Anxiety Inventory (inpatient programme) at 8 weeks (1 month follow up) ; Group 1: mean 36.8 (SD 13.6); n=38, Group 2: mean 45 (SD 11.7); n=31; State-Trait Anxiety Inventory 20-80 Top=High is poor outcome; Comments: Baseline values: inpatients 45.1 (10.7), waiting list 44.8 (11.6)

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: inpatients scored lower on self-efficacy than the waiting list group ; Group 1 Number missing: 5, Reason: 2 defaulted after randomisation, 1 dropped out during treatment, 2 defaulted from follow up ; Group 2

Number missing: 2, Reason: 2 defaulted after randomisation

- Actual outcome: Beck Depression Inventory (outpatient programme) at 12 weeks (1 month follow up) ; Group 1: mean 12.2 (SD 6.3); n=30, Group 2: mean 17.3 (SD 7); n=31; Beck Depression Inventory 0-63 Top=High is poor outcome; Comments: Baseline values: intervention 16.8 (5.6), waiting list 16.6 (6.5)

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: inpatients scored lower on self-efficacy than the waiting list group ; Group 1 Number missing: 15, Reason: 3 defaulted after randomisation, 5 dropped out during treatment, 7 defaulted from follow up ; Group 2

Number missing: 2, Reason: 2 defaulted after randomisation

- Actual outcome: State-Trait Anxiety Inventory (outpatient programme) at 12 weeks (1 month follow up) ; Group 1: mean 42.3 (SD 10.6); n=30, Group 2: mean 45 (SD 11.7); n=31; State-Trait Anxiety Inventory 20-80 Top=High is poor outcome; Comments: Baseline values: intervention 45.7 (8.2), waiting list 44.8 (11.6)

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: inpatients scored lower on self-efficacy than the waiting list group ; Group 1 Number missing: 15, Reason: 3 defaulted after randomisation, 5 dropped out during treatment, 7 defaulted from follow up ; Group 2

Number missing: 2, Reason: 2 defaulted after randomisation

Protocol outcome 3: Discontinuation

- Actual outcome: Discontinuation (inpatient programme) at 8 weeks (1 month follow up) ; Group 1: 5/43, Group 2: 2/33; Comments: inpatients: 2 defaulted after randomisation, 1 dropped out during treatment, 2 defaulted from follow up  
waiting list: 2 defaulted after randomisation

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: inpatients scored lower on self-efficacy than the waiting list group ; Group 1 Number missing: 0; Group 2 Number missing: 0

- Actual outcome: Discontinuation (outpatient programme) at 12 weeks (1 month follow up) ; Group 1: 15/45, Group 2: 2/33; Comments: intervention: 3 defaulted after randomisation, 5 dropped out during treatment, 7 defaulted from follow up  
waiting list: 2 defaulted after randomisation  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: inpatients scored lower on self-efficacy than the waiting list group ; Group 1 Number missing: 0; Group 2 Number missing: 0

#### Protocol outcome 4: Pain reduction

- Actual outcome: Pain intensity scale (inpatient programme) at 8 weeks (1 month follow up) ; Group 1: mean 60 (SD 21.7); n=38, Group 2: mean 68.1 (SD 20.7); n=31; VAS/NRS 0-100 Top=High is poor outcome; Comments: Baseline values: inpatients 71.1 (19), waiting list 67.9 (22.3)  
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: inpatients scored lower on self-efficacy than the waiting list group ; Group 1 Number missing: 5, Reason: 2 defaulted after randomisation, 1 dropped out during treatment, 2 defaulted from follow up ; Group 2 Number missing: 2, Reason: 2 defaulted after randomisation  
- Actual outcome: Pain intensity scale (outpatient programme) at 12 weeks (1 month follow up) ; Group 1: mean 63.4 (SD 19.6); n=30, Group 2: mean 68.1 (SD 20.7); n=31; VAS/NRS 0-100 Top=High is poor outcome; Comments: Baseline values: intervention 68.6 (14.9), waiting list 67.9 (22.3)  
Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: inpatients scored lower on self-efficacy than the waiting list group ; Group 1 Number missing: 15, Reason: 3 defaulted after randomisation, 5 dropped out during treatment, 7 defaulted from follow up ; Group 2 Number missing: 2, Reason: 2 defaulted after randomisation

#### Protocol outcome 5: Pain self-efficacy

- Actual outcome: Pain self-efficacy questionnaire (inpatient programme) at 8 weeks (1 month follow up) ; Group 1: mean 39.1 (SD 13.3); n=38, Group 2: mean 26.7 (SD 9.2); n=31; Pain self-efficacy questionnaire 0-60 Top=High is good outcome; Comments: Baseline values: inpatients 24.7 (11.7), waiting list 26.3 (10.8)  
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: inpatients scored lower on self-efficacy than the waiting list group ; Group 1 Number missing: 5, Reason: 2 defaulted after randomisation, 1 dropped out during treatment, 2 defaulted from follow up ; Group 2 Number missing: 2, Reason: 2 defaulted after randomisation  
- Actual outcome: Pain self-efficacy questionnaire (outpatient programme) at 12 weeks (1 month follow up) ; Group 1: mean 33.7 (SD 9.4); n=30, Group 2: mean 26.7 (SD 9.2); n=31; Pain self-efficacy questionnaire 0-60 Top=High is good outcome; Comments: Baseline values: intervention 25.4 (9.1), control 26.3 (10.8)  
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness, Comments: NA; Baseline details: inpatients scored lower on self-efficacy than the waiting list group ; Group 1 Number missing: 5, Reason: 2 defaulted after randomisation, 1 dropped out during treatment, 2 defaulted from follow up ; Group 2 Number missing: 2, Reason: 2 defaulted after randomisation

Protocol outcomes not reported by the study

Quality of life; Pain interference; Use of healthcare services; Sleep

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- 3
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# 1 Appendix E: Forest plots

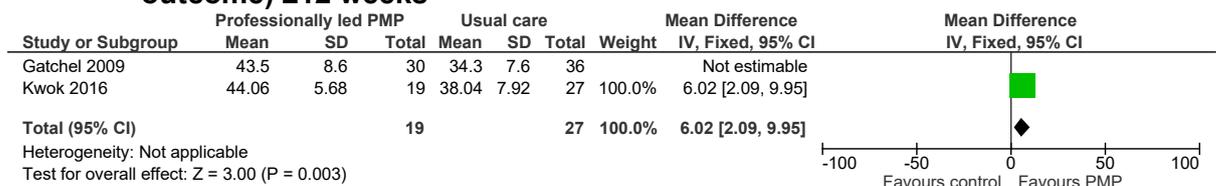
## E.1 Professional led pain management programmes versus control

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### 4 Quality of life

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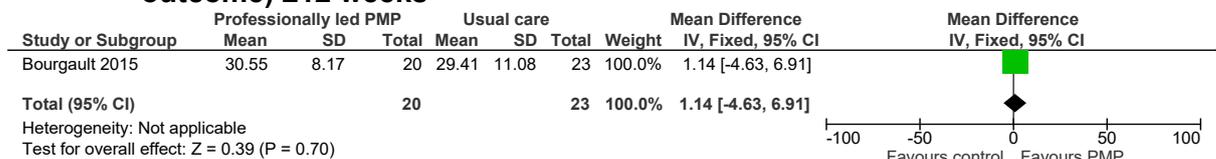
**Figure 2: Quality of life: SF36 Physical component final values (0-100, high is good outcome) ≤12 weeks**



6 *Source/Note: Sensitivity analysis has been performed (Gatchel 2009 removed as the population, intervention*  
7 *and control were considered to be significantly different from other studies and results were*  
8 *inconsistent).*

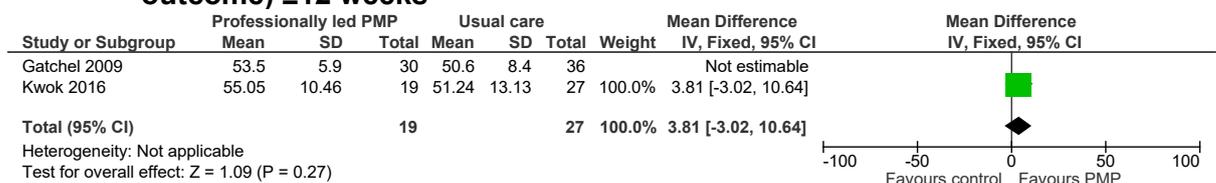
9

**Figure 3: Quality of life: SF12 Physical component final values (0-100, high is good outcome) ≤12 weeks**



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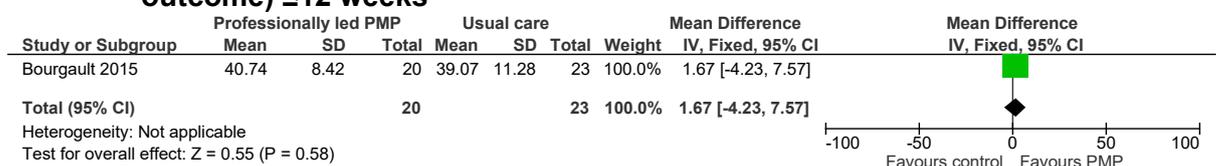
**Figure 4: Quality of life: SF36 Mental component final values (0-100, high is good outcome) ≤12 weeks**



11 *Source/Note: Sensitivity analysis has been performed (Gatchel 2009 removed as the population, intervention*  
12 *and control were considered to be significantly different from other studies and results were*  
13 *inconsistent).*

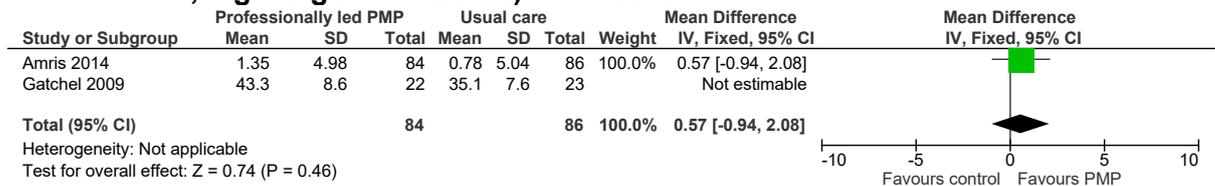
14

**Figure 5: Quality of life: SF12 Mental component final values (0-100, high is good outcome) ≤12 weeks**



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**Figure 6: Quality of life: SF36 Physical component final values and change scores (0-100, high is good outcome) >12 weeks**



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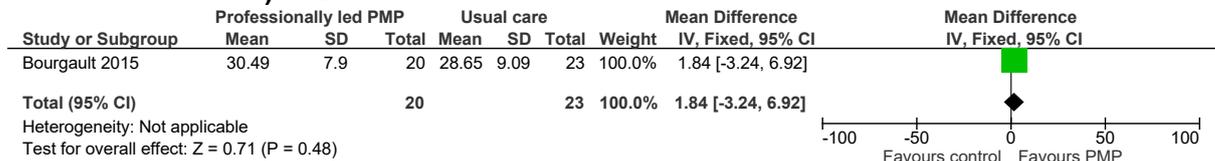
Source/Note: Sensitivity analysis has been performed (Gatchel 2009 removed as the population, intervention and control were considered to be significantly different from other studies and results were inconsistent).

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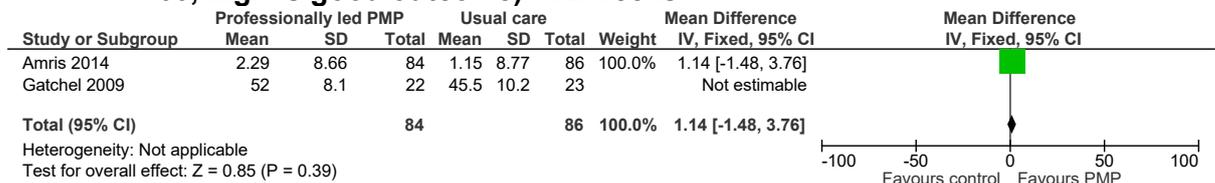
5

**Figure 7: Quality of life: SF12 Physical component final values (0-100, high is good outcome) >12 weeks**



6

**Figure 8: Quality of life: SF36 Mental component final values and change scores (0-100, high is good outcome) >12 weeks**



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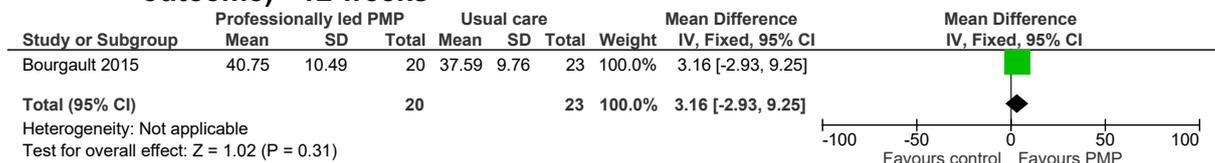
Source/Note: Sensitivity analysis has been performed (Gatchel 2009 removed as the population, intervention and control were considered to be significantly different from other studies and results were inconsistent).

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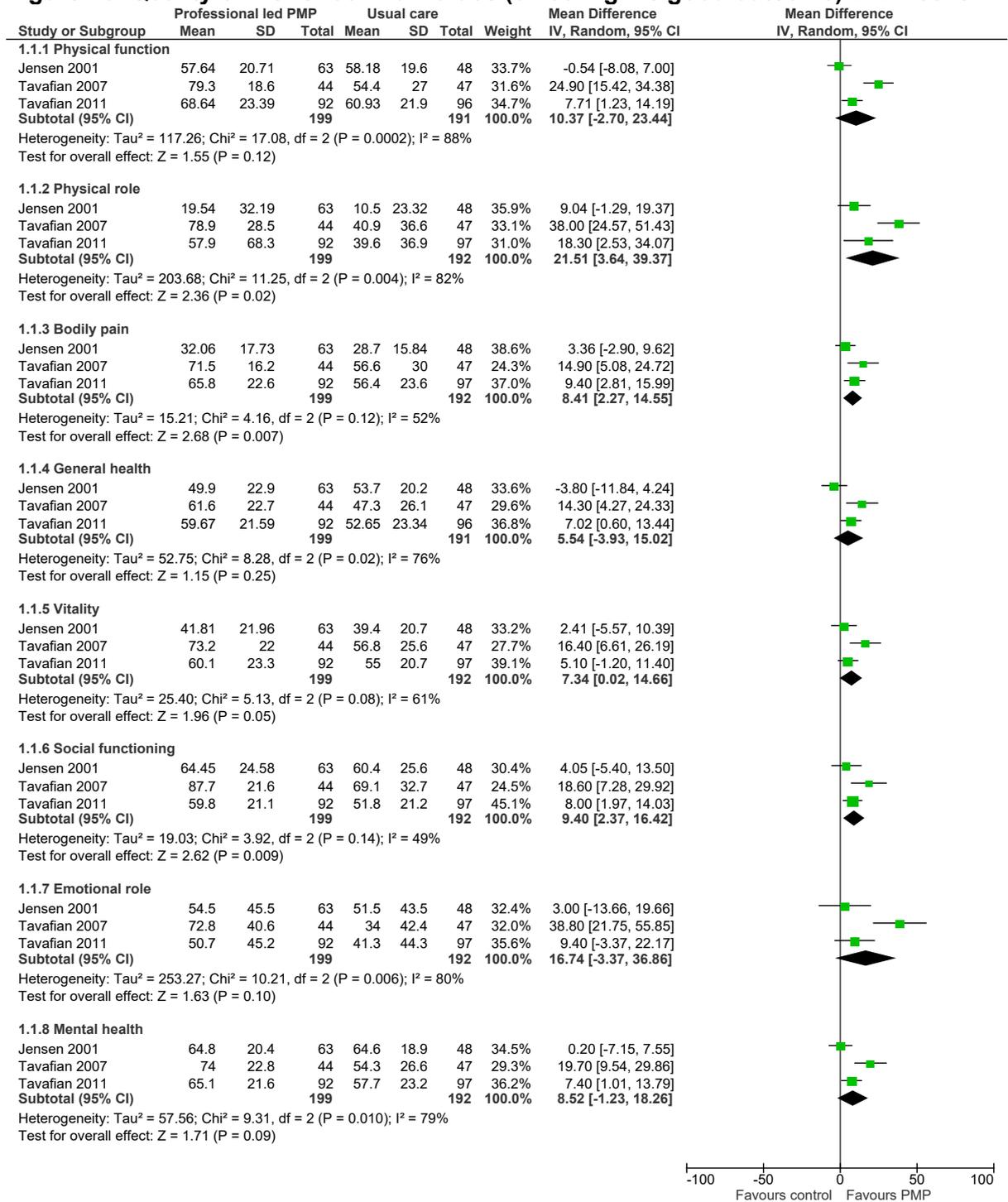
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**Figure 9: Quality of life: SF12 Mental component final values (0-100, high is good outcome) >12 weeks**



11

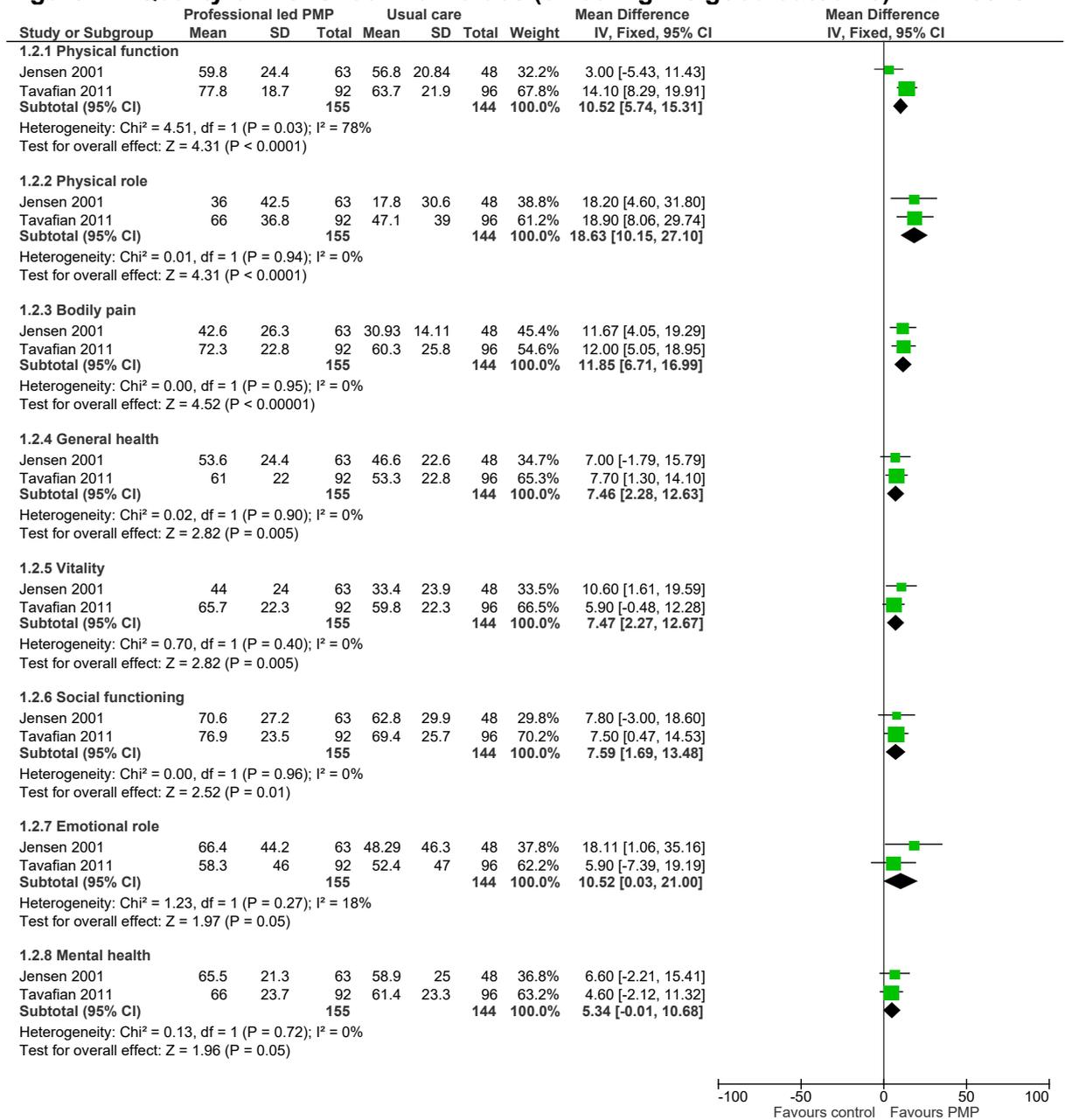
**Figure 10: Quality of life: SF36 final values (0-100 high is good outcome) ≤12 weeks**



1 Source/Note: Random effects has been applied where there was unexplained heterogeneity

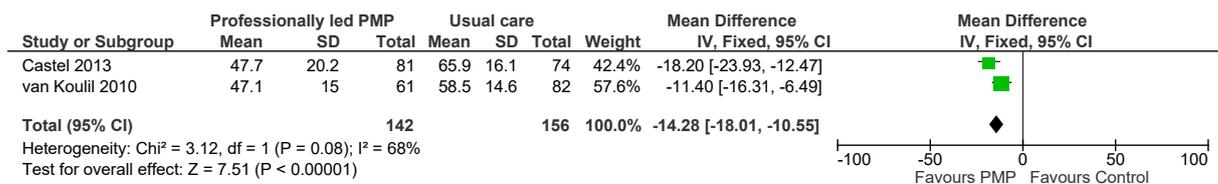
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**Figure 11: Quality of life: SF36 final values (0-100 high is good outcome) >12 weeks**



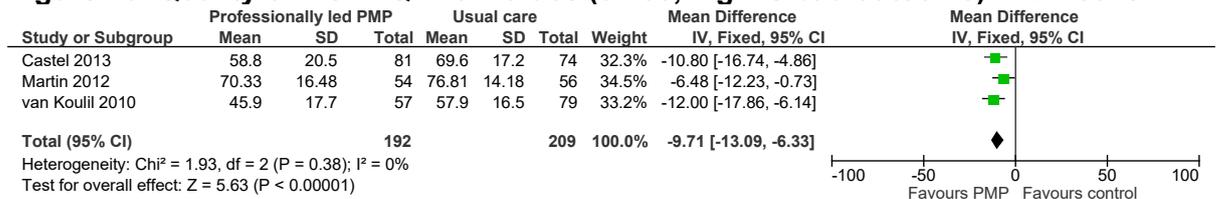
1

**Figure 12: Quality of life: FIQ final values (0-100, high is bad outcome) ≤12 weeks**



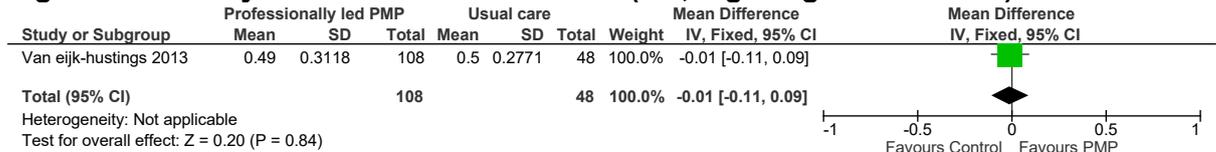
2

**Figure 13: Quality of life: FIQ final values (0-100, high is bad outcome) >12 weeks**



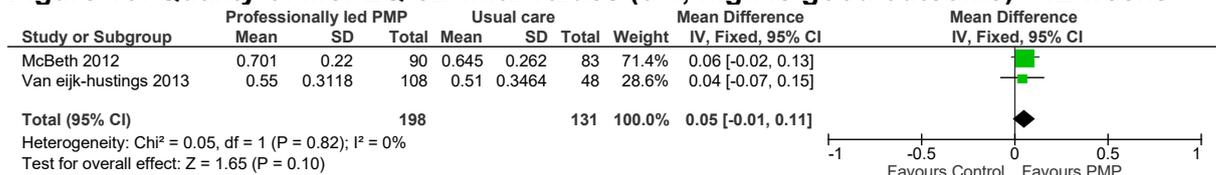
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**Figure 14: Quality of life: EQ-5D final values (0-1, high is good outcome) ≤12 weeks**



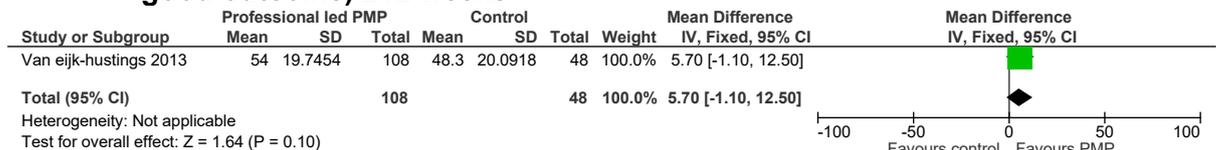
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**Figure 15: Quality of life: EQ-5D final values (0-1, high is good outcome) >12 weeks**



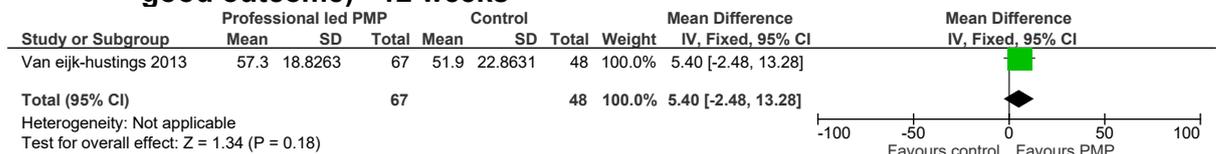
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**Figure 16: Quality of life: EQ-5D visual analogue scale final values (0-100, high is good outcome) ≤12 weeks**



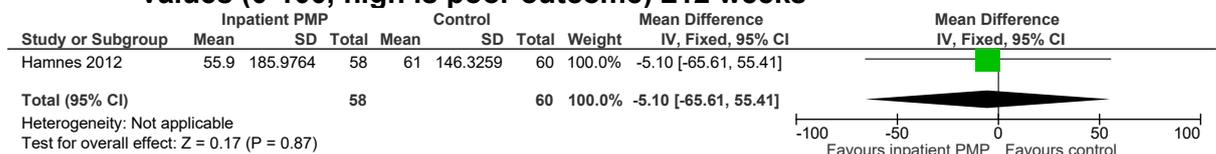
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**Figure 17: Quality of life: EQ-5D visual analogue scale final values (0-100, high is good outcome) >12 weeks**



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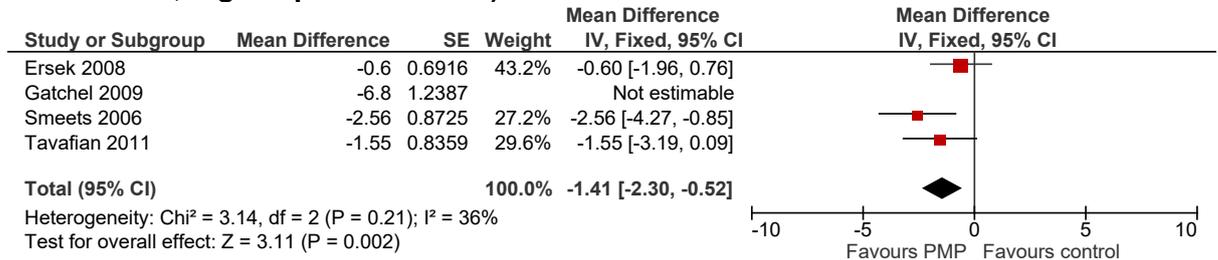
**Figure 18: INPATIENT PMP Quality of life: Fibromyalgia Impact Questionnaire final values (0-100, high is poor outcome) ≤12 weeks**



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2 **Physical function**

**Figure 19: Physical function: Roland Morris Disability Questionnaire final values (0-24, high is poor outcome) ≤12 weeks**



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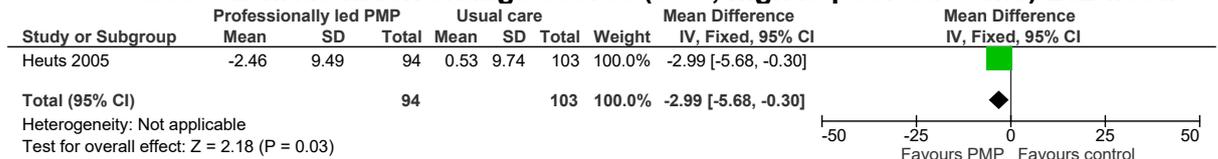
Source/Note: Sensitivity analysis has been performed (Gatchel 2009 removed as the population, intervention and control were considered to be significantly different from other studies and results were inconsistent).

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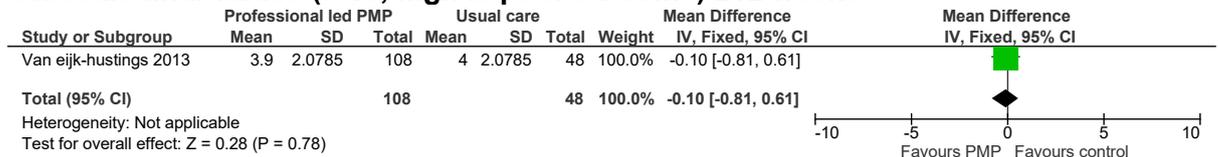
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**Figure 20: Physical function: Western Ontario and McMaster Universities Osteoarthritis Index change scores (0-68, high is poor outcome) ≤12 weeks**



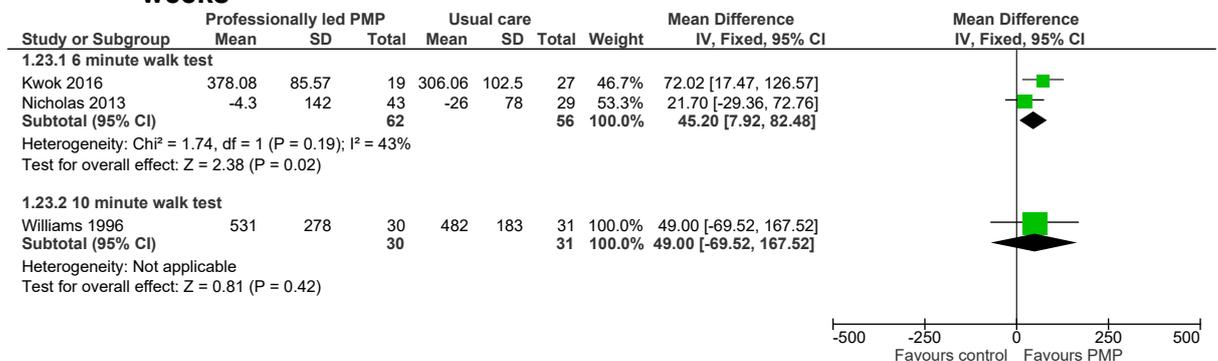
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**Figure 21: Physical function: Fibromyalgia Impact Questionnaire physical function subscale final values (0-10, high is poor outcome) ≤12 weeks**



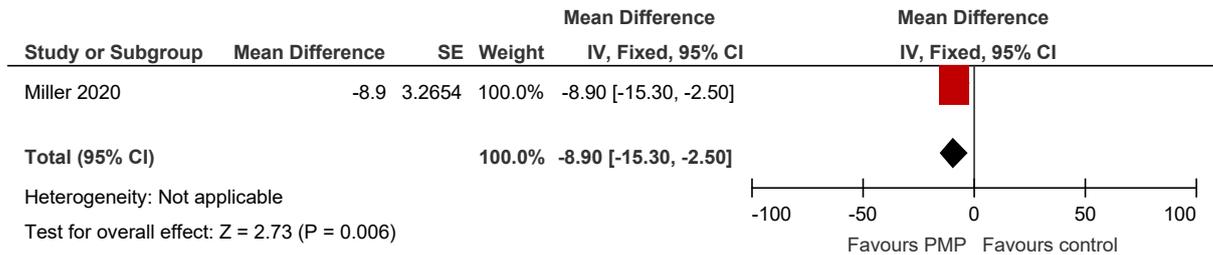
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**Figure 22: Physical function: metres walked final values and change scores ≤12 weeks**



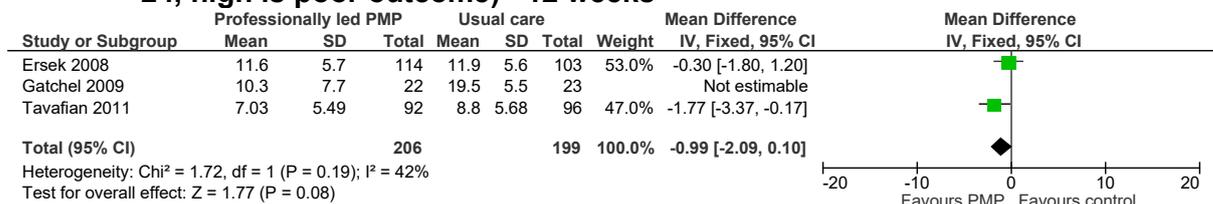
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**Figure 23: Physical function: Short musculoskeletal function assessment – dysfunction index final values (34-170, high is poor outcome) ≤12 weeks**



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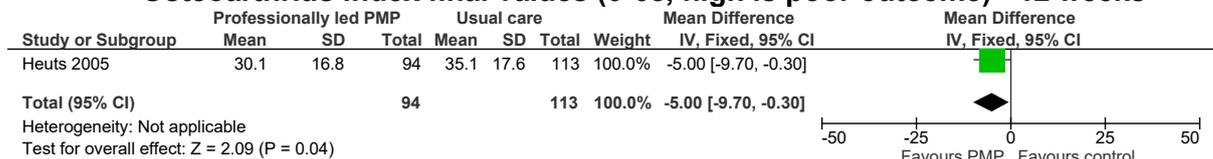
**Figure 24: Physical function: Roland Morris Disability Questionnaire final values (0-24, high is poor outcome) >12 weeks**



2 Source/Note: Sensitivity analysis has been performed (Gatchel 2009 removed as the population, intervention  
3 and control were considered to be significantly different from other studies and results were  
4 inconsistent).

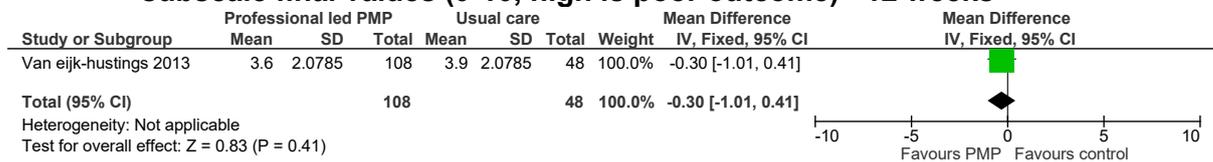
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**Figure 25: Physical function: Western Ontario and McMaster Universities Osteoarthritis Index final values (0-68, high is poor outcome) >12 weeks**



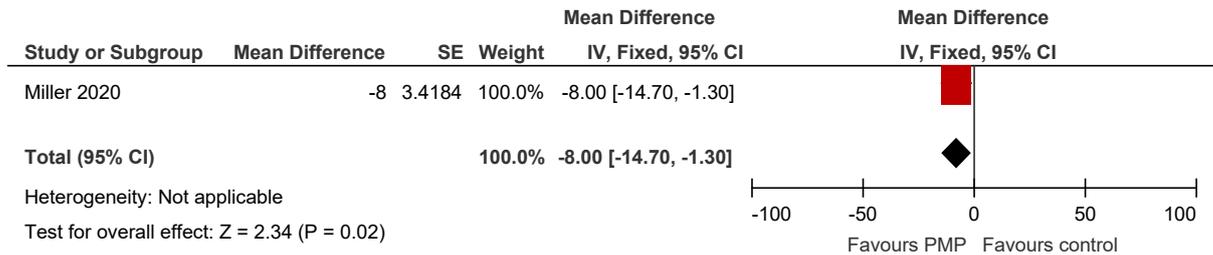
6

**Figure 26: Physical function: Fibromyalgia Impact Questionnaire physical function subscale final values (0-10, high is poor outcome) >12 weeks**



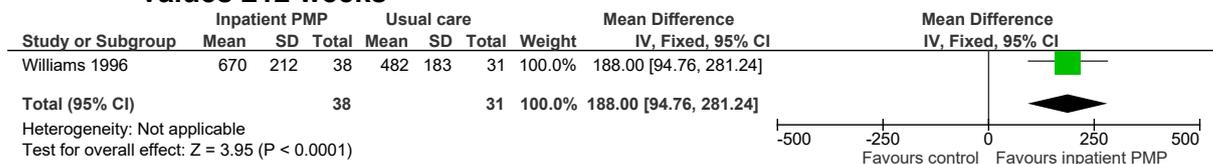
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**Figure 27: Physical function: Short musculoskeletal function assessment – dysfunction index final values (34-170, high is poor outcome) >12 weeks**



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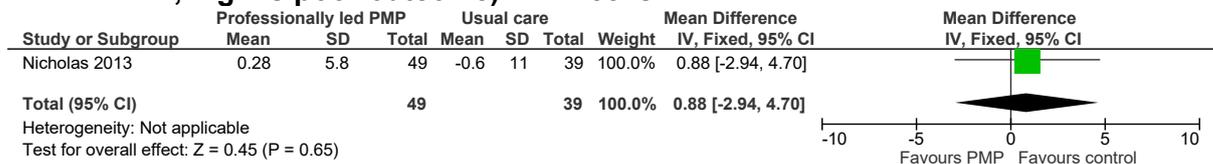
**Figure 28: INPATIENT PMP Physical function: metres walked in 10 minutes, final values ≤12 weeks**



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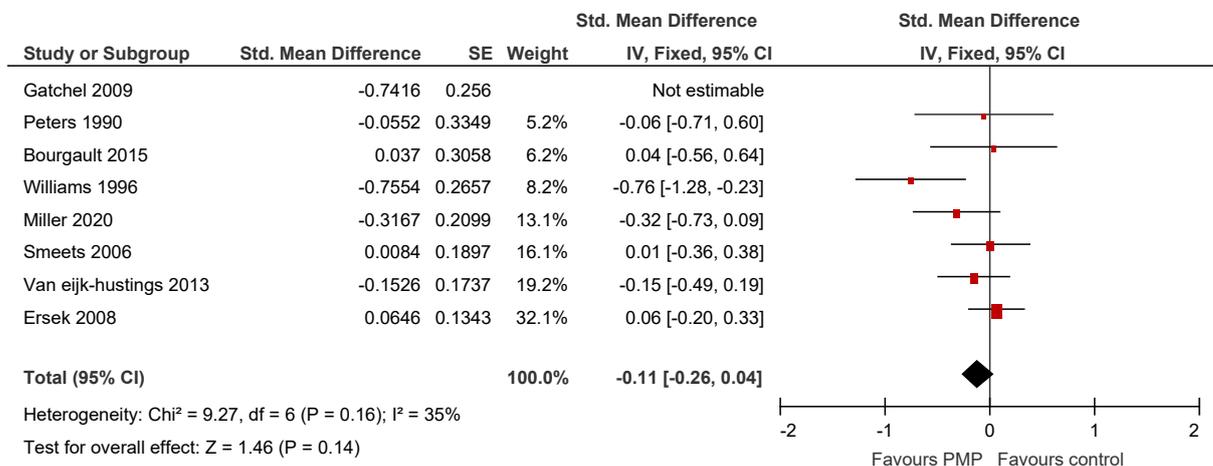
3 **Psychological distress**

**Figure 29: Psychological distress: Depression Anxiety Stress Scale change scores (0-42, high is poor outcome) ≤12 weeks**



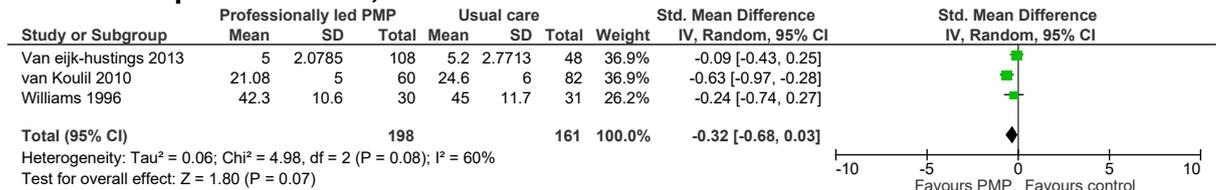
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**Figure 30: Psychological distress: Beck Depression Inventory final values (0-63), Geriatric Depression Scale (0-30), Patient health questionnaire depression (0-27) and Fibromyalgia Impact questionnaire depression subscale (0-10), high is poor outcome, final values ≤12 weeks**



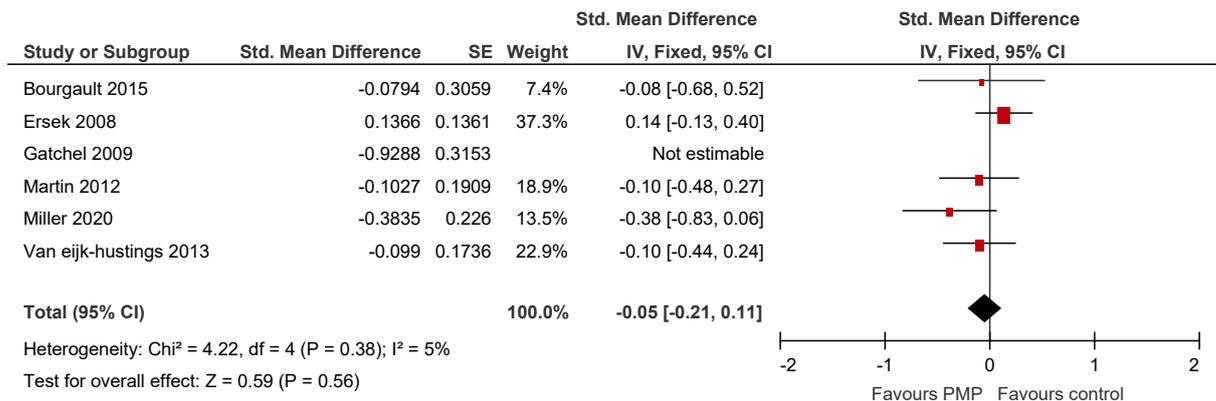
1 Source/Note: Sensitivity analysis has been performed (Gatchel 2009 removed as the population, intervention  
2 and control were considered to be significantly different from other studies and results were  
3 inconsistent).  
4

**Figure 31: Psychological distress: Fibromyalgia Impact Questionnaire anxiety subscale (0-10), Impact of Rheumatic Diseases on General Health and Lifestyle anxiety scale (10-40) and State-Trait Anxiety Inventory (20-80), high is poor outcome, final values ≤12 weeks**



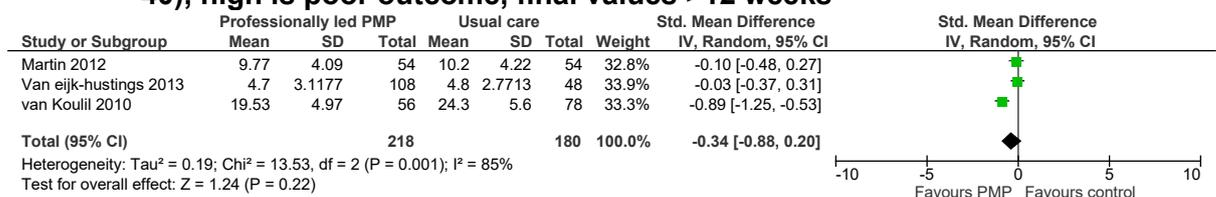
5 Source/Note: Random effects has been applied where there was unexplained heterogeneity  
6

**Figure 32: Psychological distress: Geriatric Depression Scale (0-30), Beck depression inventory (0-63), Hospital Anxiety and Depression Scale depression (0-21), Patient health questionnaire depression (0-27) and Fibromyalgia Impact Questionnaire depression subscale (0-10), high is poor outcome, final values >12 weeks**



7 Source/Note: Sensitivity analysis has been performed (Gatchel 2009 removed as the population, intervention  
8 and control were considered to be significantly different from other studies and results were  
9 inconsistent).  
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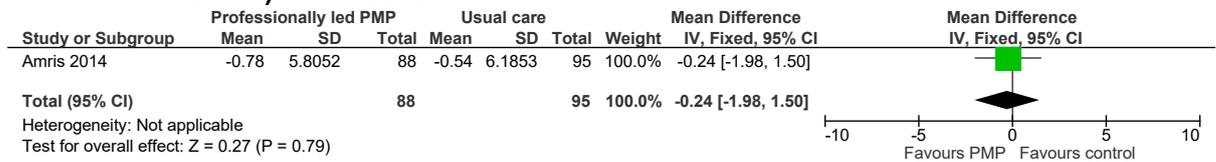
**Figure 33: Psychological distress: Hospital Anxiety and Depression scale anxiety (0-21), Fibromyalgia Impact Questionnaire anxiety subscale (0-10) and Impact of Rheumatic Diseases on General Health and Lifestyle anxiety scale (10-40), high is poor outcome, final values >12 weeks**



11 Source/Note: Random effects has been applied where there was unexplained heterogeneity

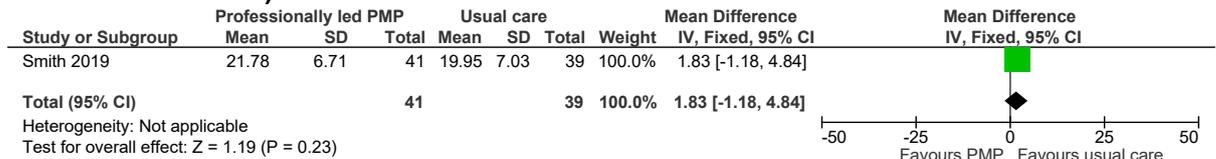
1

**Figure 34: Psychological distress GAD-10 anxiety change scores (0-10, high is poor outcome) >12 weeks**



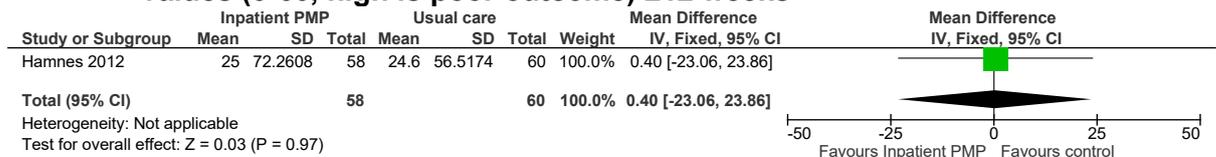
2

**Figure 35: Psychological Distress Kessler-10 final values (10-50, high is poor outcome) >12 weeks**



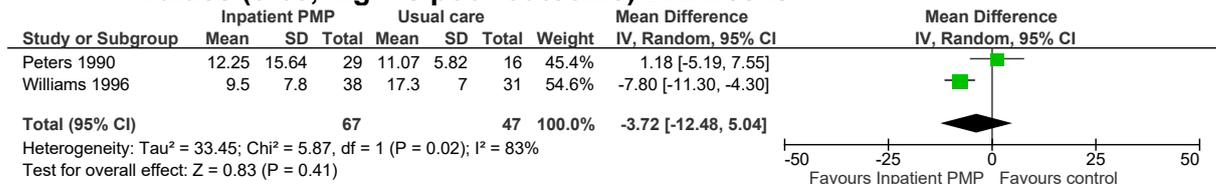
3

**Figure 36: INPATIENT PMP Psychological distress: General Health Questionnaire final values (0-60, high is poor outcome) ≤12 weeks**



4

**Figure 37: INPATIENT PMP Psychological distress: Beck Depression Inventory final values (0-63, high is poor outcome) ≤12 weeks**

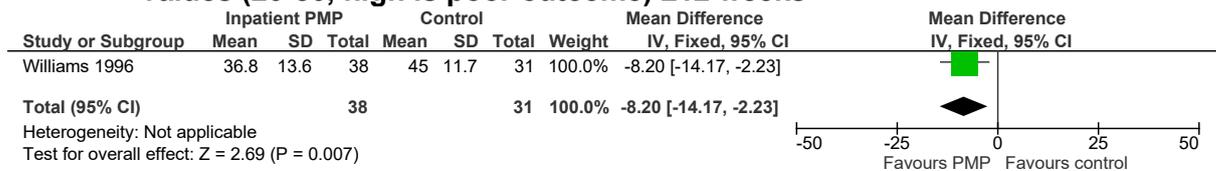


5

Source/Note: Random effects has been applied where there was unexplained heterogeneity

6

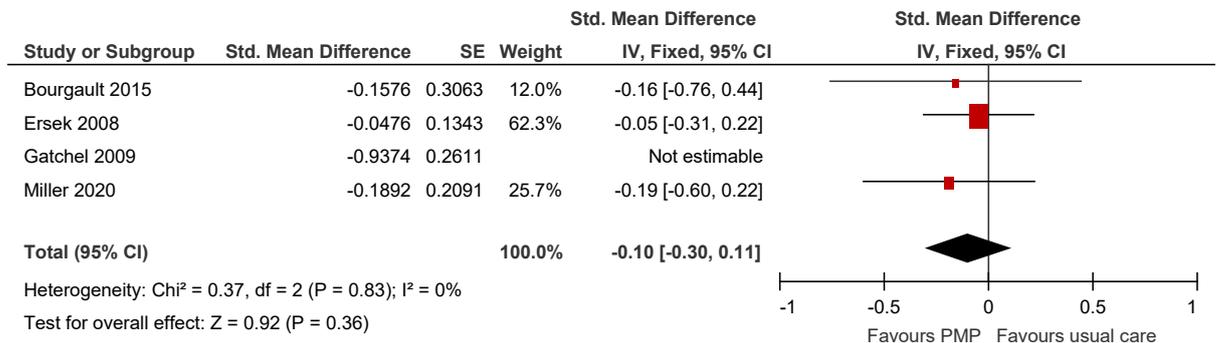
**Figure 38: INPATIENT PMP Psychological distress: State-Trait Anxiety Inventory final values (20-80, high is poor outcome) ≤12 weeks**



7

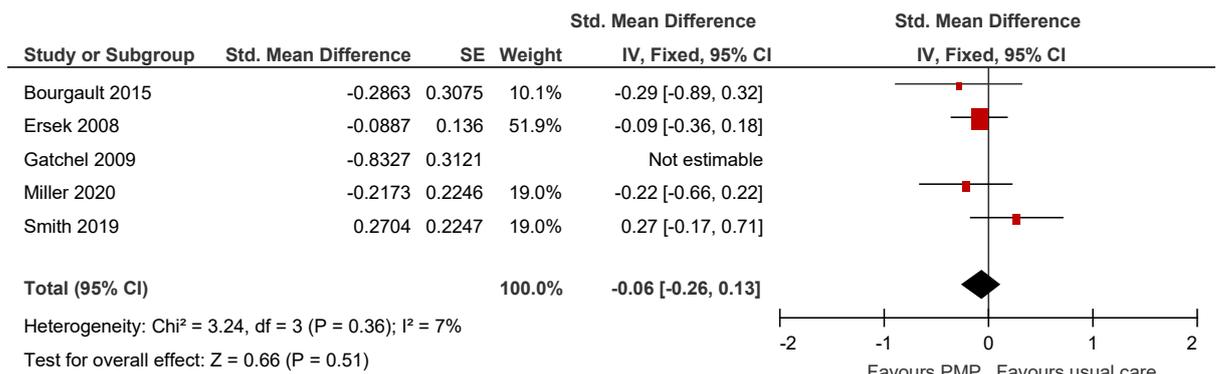
8 Pain interference

**Figure 39: Pain interference: Brief Pain Inventory interference (0-10) and PROMIS pain interference (8-40) scale final values (high is poor outcome) ≤12 weeks**



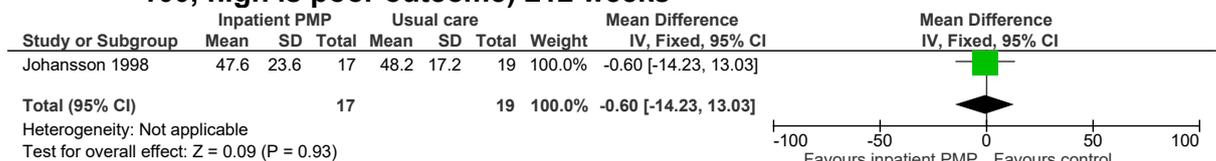
1 Source/Note: Sensitivity analysis has been performed (Gatchel 2009 removed as the population, intervention  
2 and control were considered to be significantly different from other studies and results were  
3 inconsistent).

**Figure 40: Pain interference: Brief Pain Inventory interference (0-10\_ and PROMIS pain interference (8-40) scale final values (high is poor outcome) >12 weeks**



4 Source/Note: Sensitivity analysis has been performed (Gatchel 2009 removed as the population, intervention  
5 and control were considered to be significantly different from other studies and results were  
6 inconsistent).

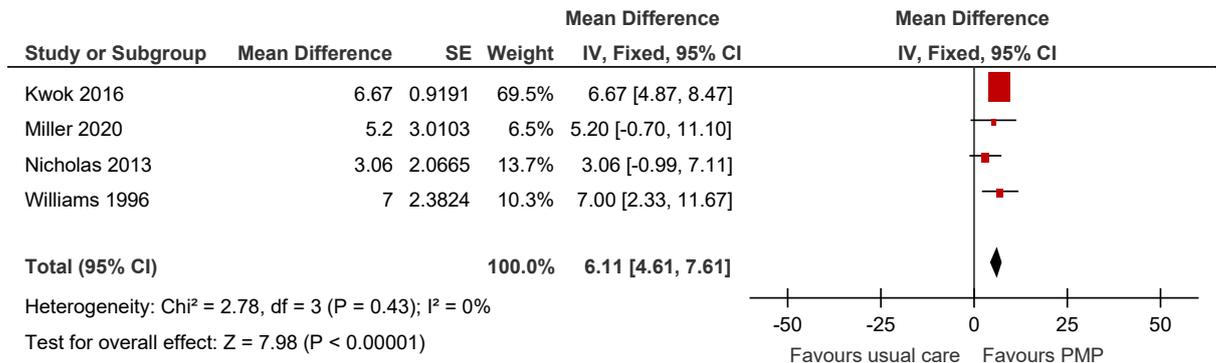
**Figure 41: INPATIENT PMP Pain interference: visual analogue scale final values (0-100, high is poor outcome) ≤12 weeks**



7

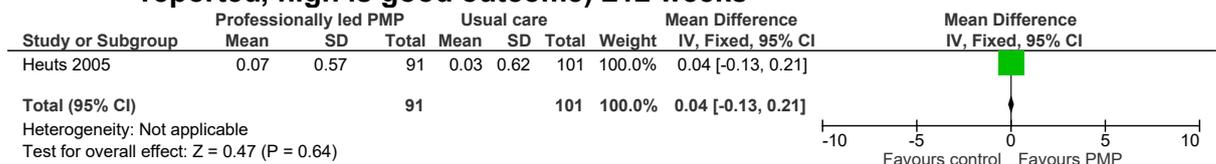
8 Pain self-efficacy

**Figure 42: Self-efficacy: Pain Self-Efficacy Questionnaire final values and change scores (0-60, high is good outcome) ≤12 weeks**



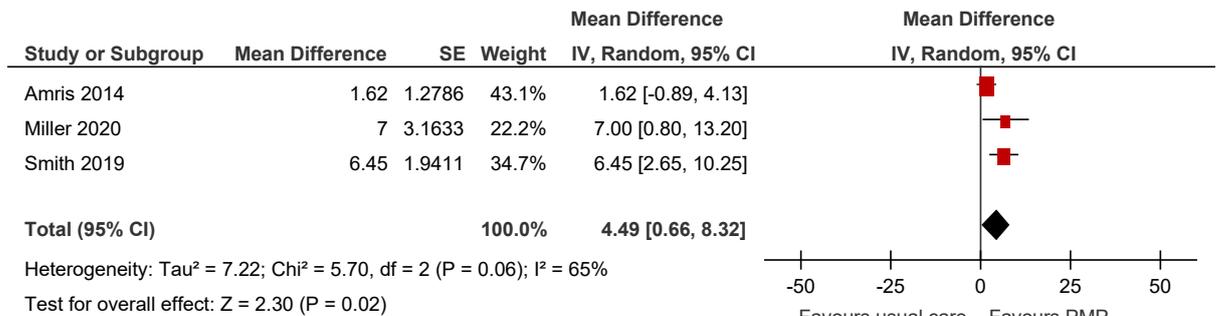
1

**Figure 43: Self-efficacy: Arthritis Self-Efficacy Scale change scores (scale not reported, high is good outcome) ≤12 weeks**



2

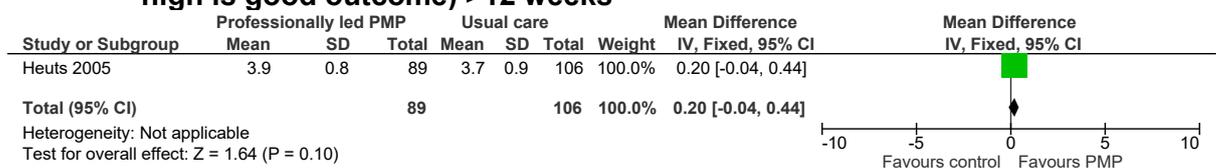
**Figure 44: Self-efficacy: Pain Self-Efficacy Questionnaire final values and change scores (0-60, high is good outcome) >12 weeks**



3 Source/Note: Random effects has been applied where there was unexplained heterogeneity

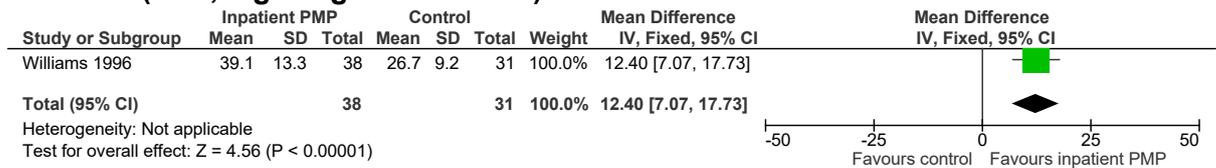
4

**Figure 45: Self-efficacy: Arthritis Self-Efficacy Scale final values (scale not reported, high is good outcome) >12 weeks**



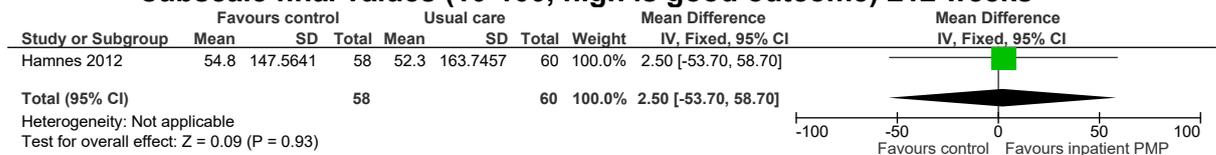
5

**Figure 46: INPATIENT PMP Self-efficacy: Pain Self-Efficacy Questionnaire final values (0-60, high is good outcome) ≤12 weeks**



1

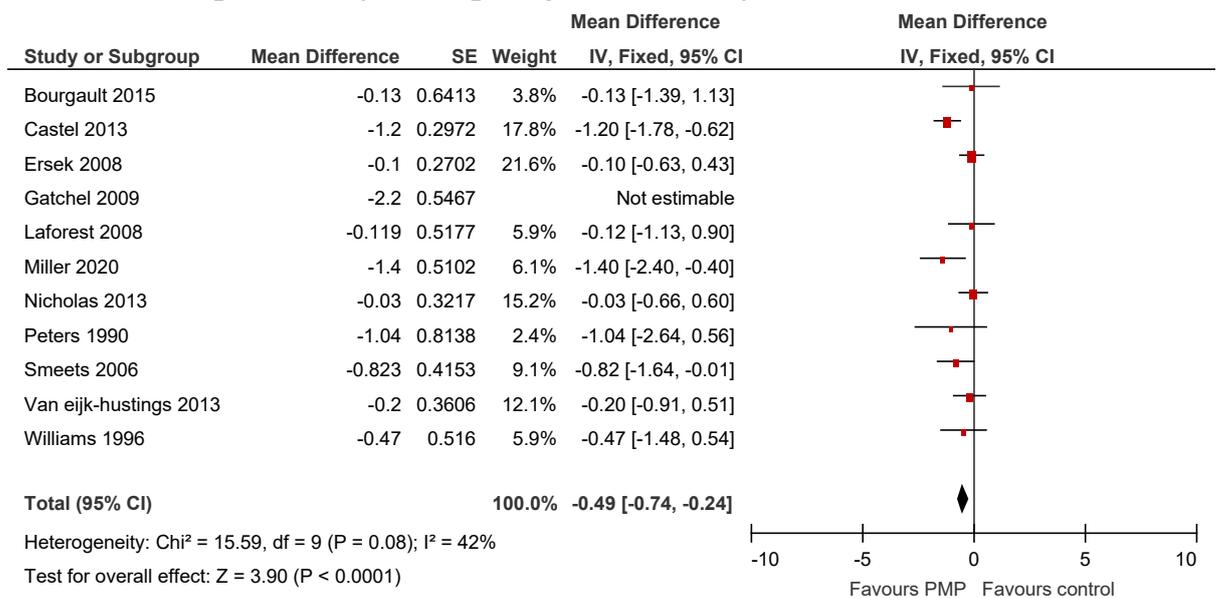
**Figure 47: INPATIENT PMP Self-efficacy: Arthritis Self-Efficacy Scale pain subscale final values (10-100, high is good outcome) ≤12 weeks**



2

3 **Pain reduction**

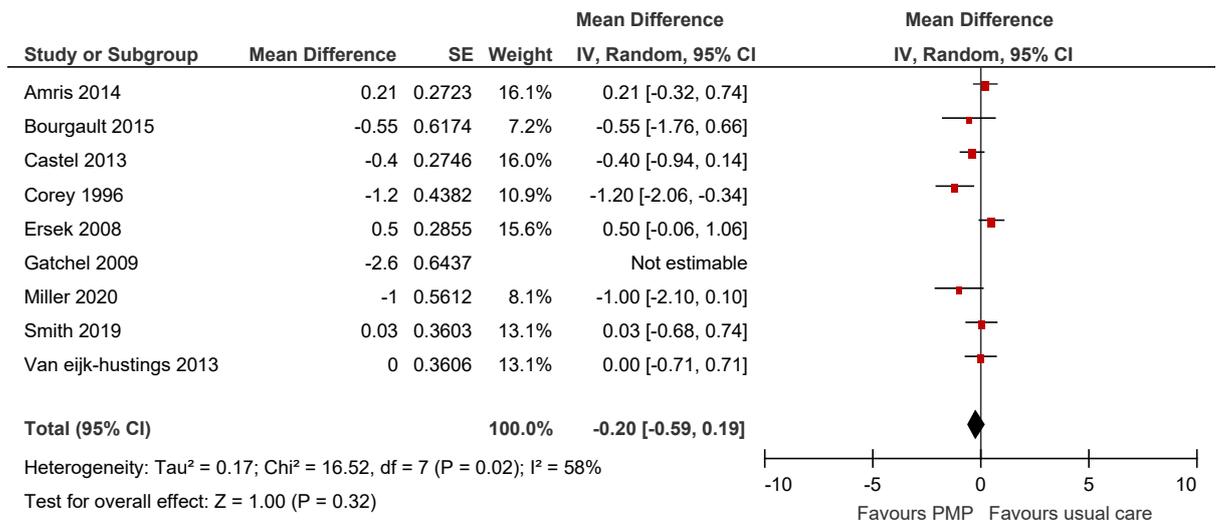
**Figure 48: Pain reduction: numeric rating scale/visual analogue scale final values and change scores (0-10, high is poor outcome) ≤12 weeks**



4 *Source/Note: Sensitivity analysis has been performed (Gatchel 2009 removed as the population, intervention*  
 5 *and control were considered to be significantly different from other studies and results were*  
 6 *inconsistent).*

7

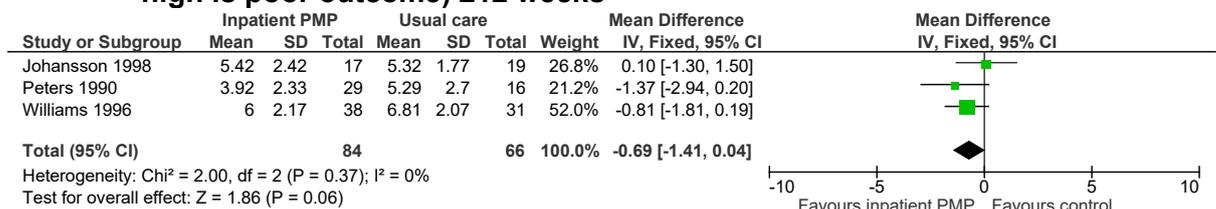
**Figure 49: Pain reduction: numeric rating scale/visual analogue scale final values and change scores (0-10, high is poor outcome) >12 weeks**



1 Source/Note: Sensitivity analysis has been performed (Gatchel 2009 removed as the population, intervention  
2 and control were considered to be significantly different from other studies and results were  
3 inconsistent).

4

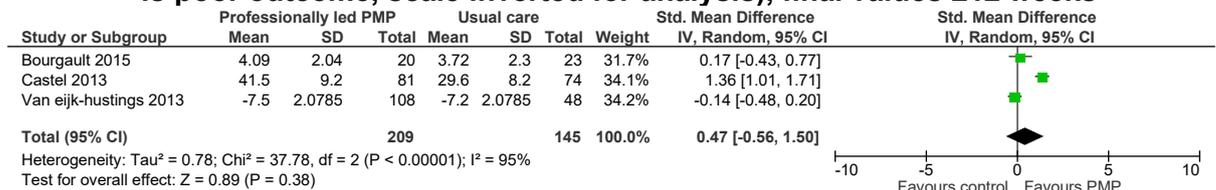
**Figure 50: INPATIENT PMP Pain reduction: visual analogue scale final values (0-10, high is poor outcome) ≤12 weeks**



5

6 Sleep

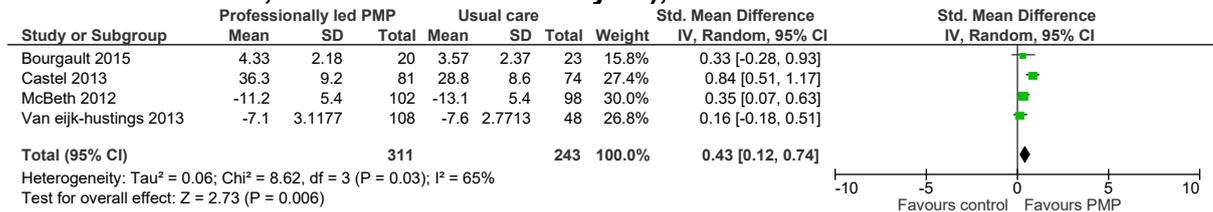
**Figure 51: Sleep: Chronic Pain Sleep Index (0-10, high is good outcome), Medical Outcomes study Sleep scale (12-71, high is good outcome) and Fibromyalgia Impact Questionnaire unrefreshed sleep subscale (0-10, high is poor outcome, scale inverted for analysis), final values ≤12 weeks**



7 Source/Note: Random effects has been applied where there was unexplained heterogeneity

8

**Figure 52: Sleep: Chronic Pain Sleep Index (0-10, high is good outcome), Medical Outcomes study Sleep scale (12-71, high is good outcome), Sleep Scale (0-20, high is poor outcome, scale inverted for analysis) and Fibromyalgia Impact Questionnaire unrefreshed sleep subscale (0-10, high is poor outcome, scale inverted for analysis), final values >12 weeks**



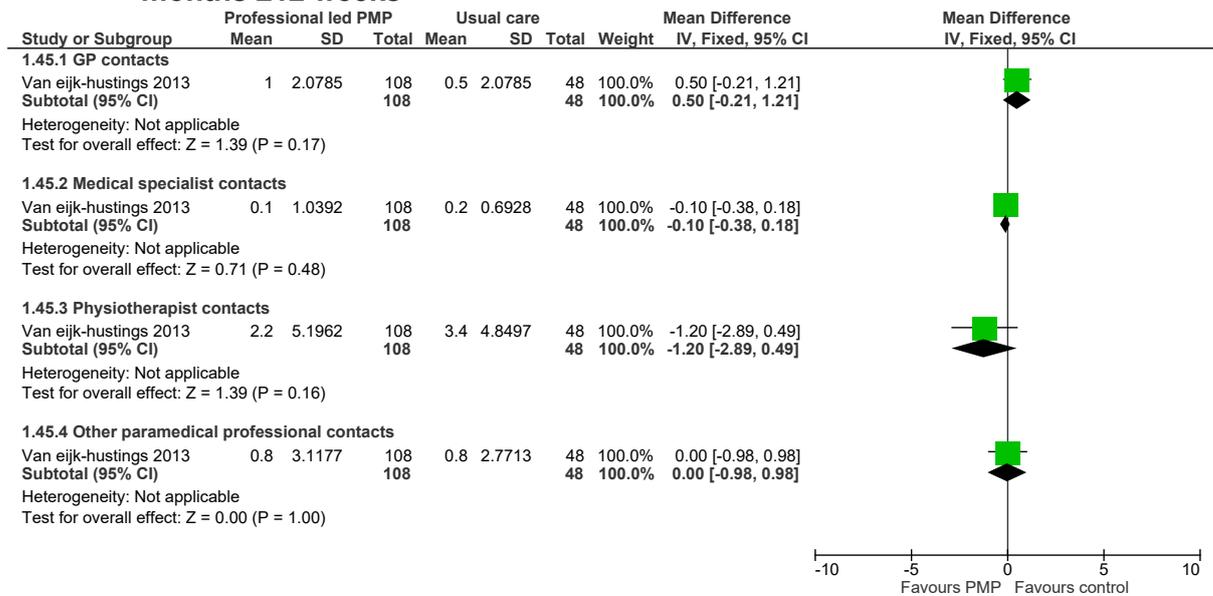
1 Source/Note: Random effects has been applied where there was unexplained heterogeneity

2

3

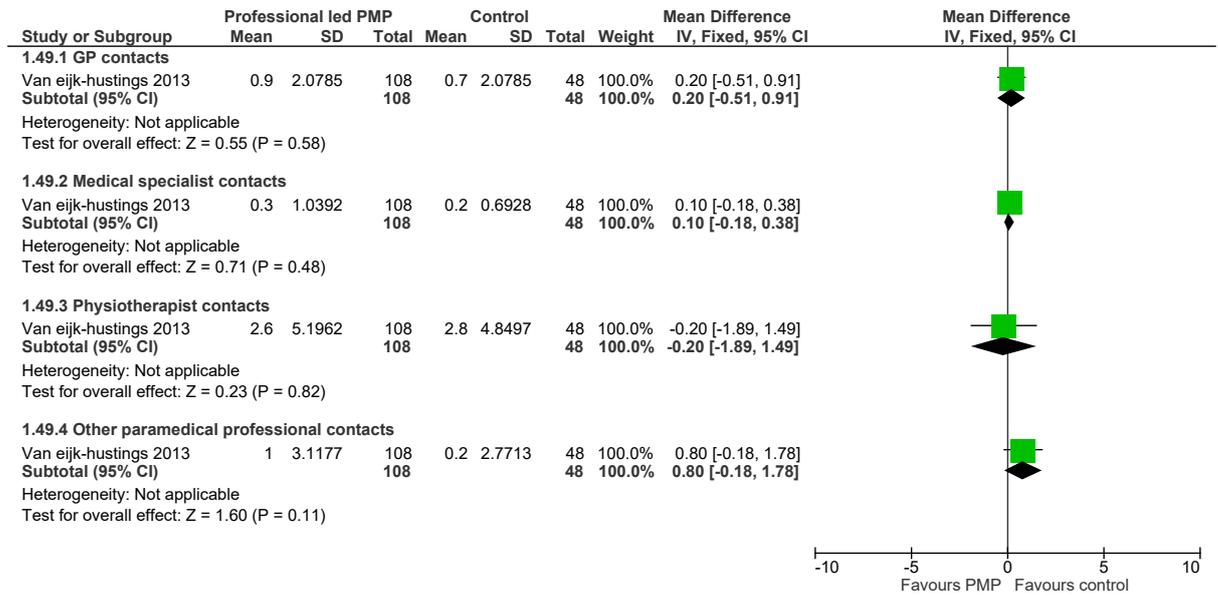
4 Use of healthcare services

**Figure 53: Use of healthcare services: Mean number of contacts within previous 2 months ≤12 weeks**



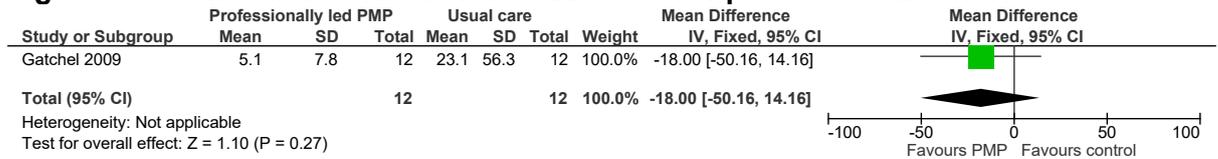
5

**Figure 54: Use of healthcare services: Mean number of contacts within previous 2 months >12 weeks**



1

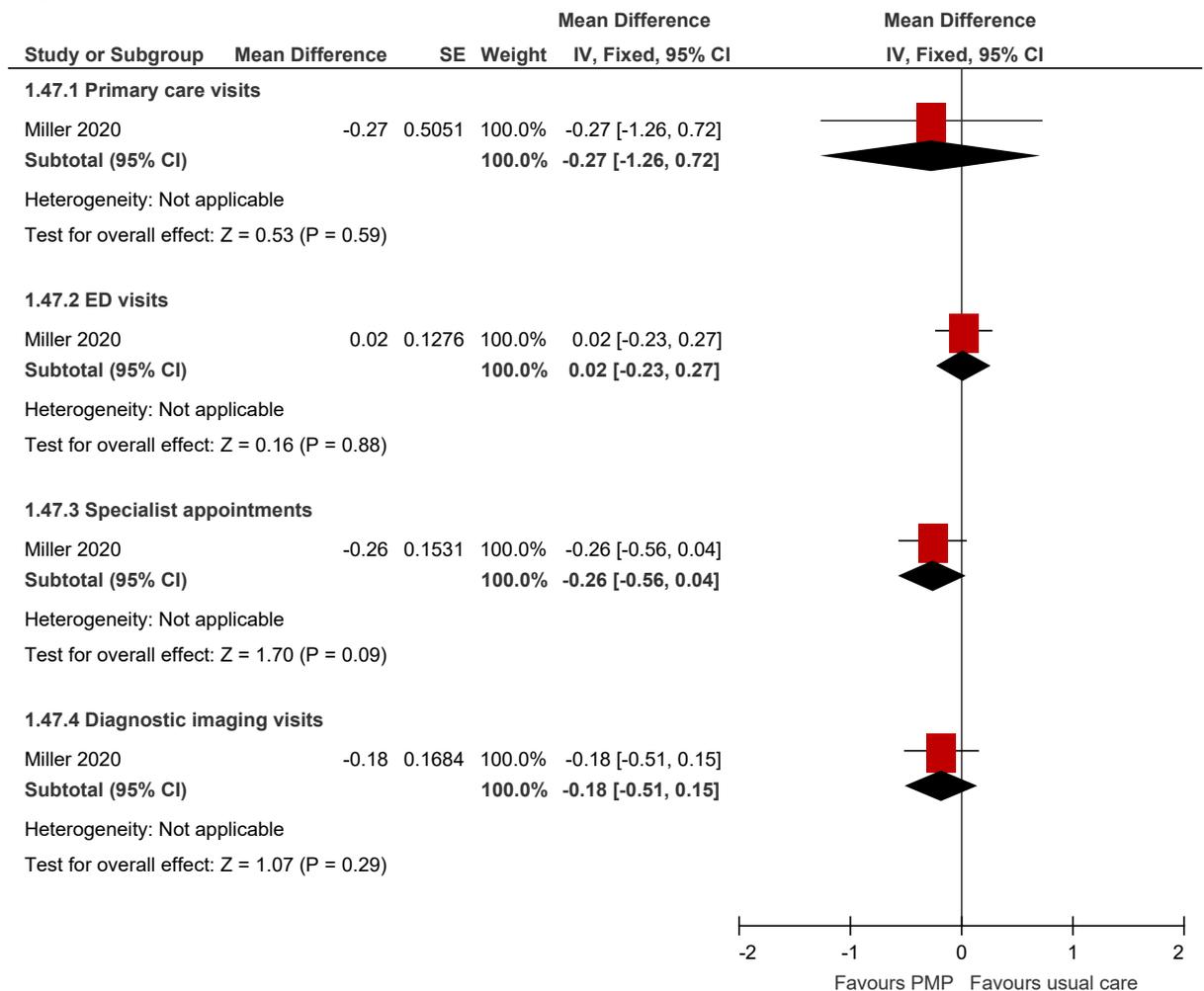
**Figure 55: Mean number of MD and/or ED visits for pain care >12 weeks**



2

3

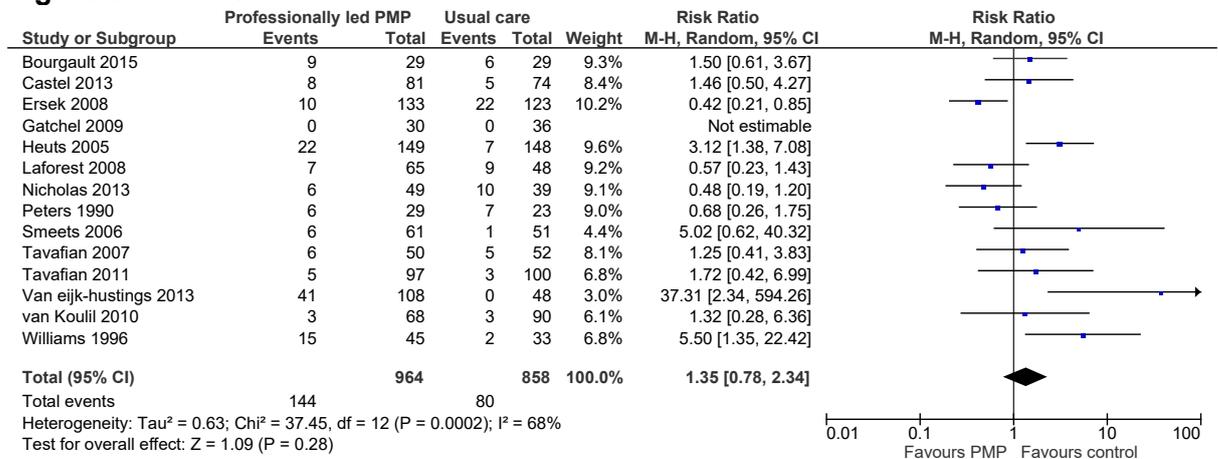
**Figure 56: Mean number of visits within the previous week >12 weeks**



1

2 **Discontinuation of study for any cause**

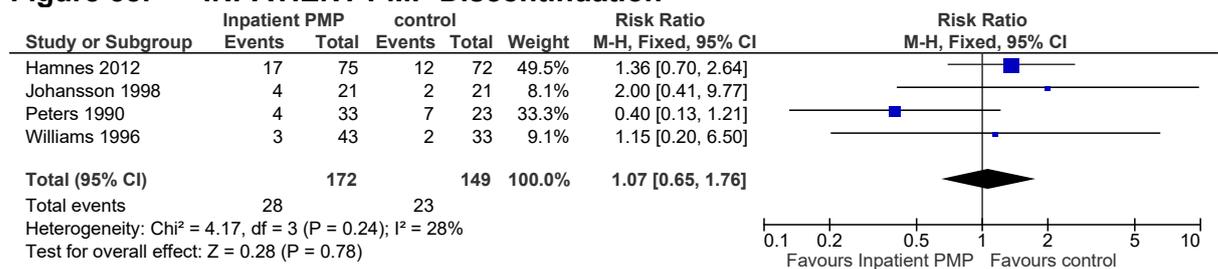
**Figure 57: Discontinuation**



3 *Source/Note: Random effects has been applied where there was unexplained heterogeneity*

4

**Figure 58: INPATIENT PMP Discontinuation**



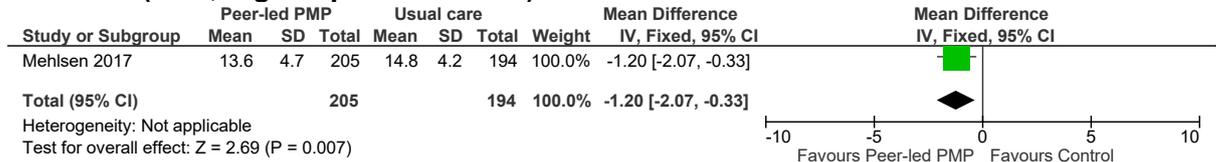
1

2

## E.2 Peer led pain management programmes

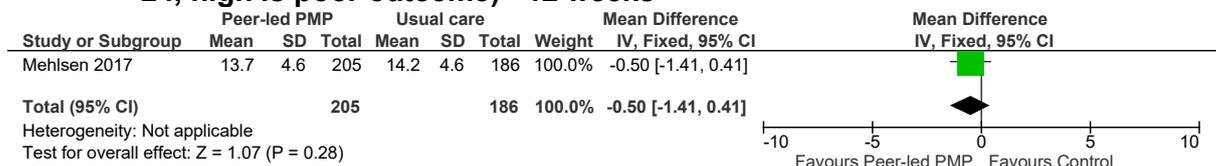
### 2 Physical function

**Figure 59: Physical function: Roland Morris Disability Questionnaire final values (0-24, high is poor outcome) ≤12 weeks**



### 3

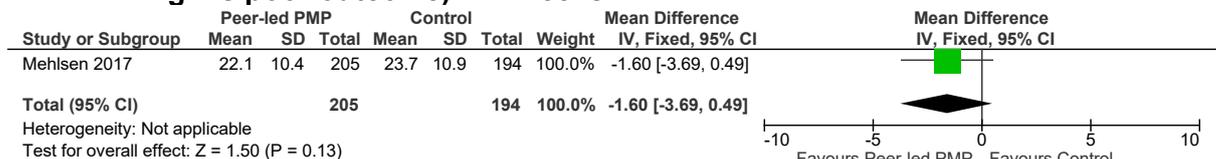
**Figure 60: Physical function: Roland Morris Disability Questionnaire final values (0-24, high is poor outcome) >12 weeks**



### 4

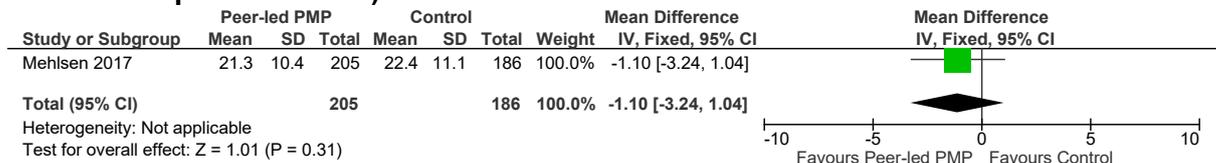
### 5 Psychological distress

**Figure 61: Psychological distress: Pain Catastrophising Scale final values (0-52, high is poor outcome) ≤12 weeks**



### 6

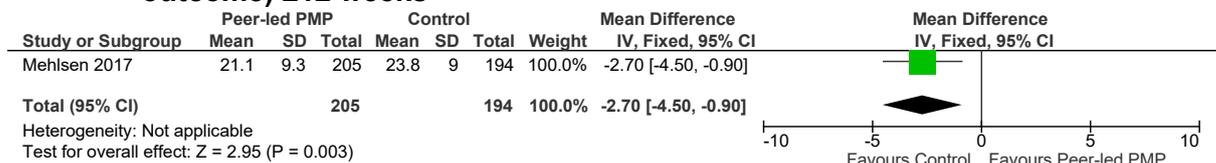
**Figure 62: Psychological distress: Pain Catastrophising Scale final values (0-52, high is poor outcome) >12 weeks**



### 7

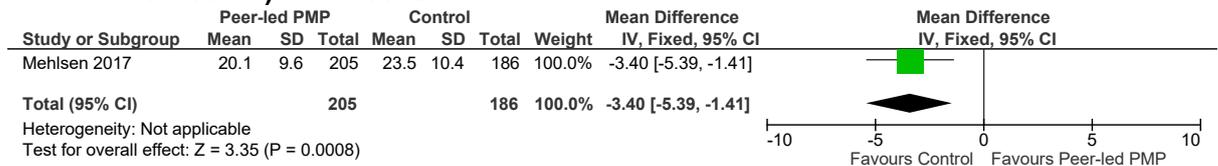
### 8 Self-efficacy

**Figure 63: Self-efficacy: Arthritis Self Efficacy Scale final values (5-50, high is good outcome) ≤12 weeks**



1

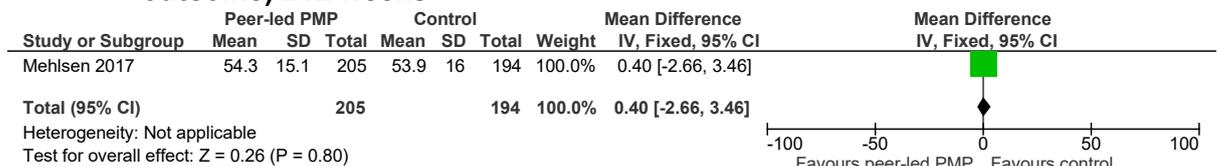
**Figure 64: Self-efficacy: Arthritis Self Efficacy Scale final values (5-50, high is good outcome) >12 weeks**



2

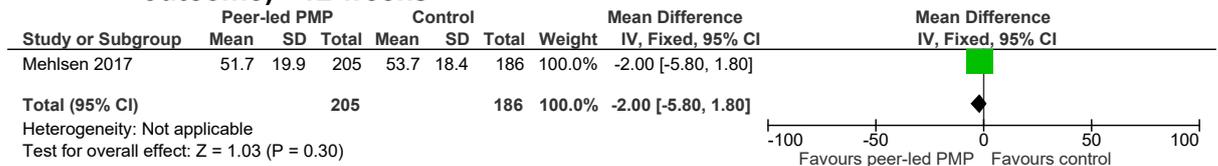
3 **Pain reduction**

**Figure 65: Pain reduction: visual analogue scale final values (0-100, high is poor outcome) ≤12 weeks**



4

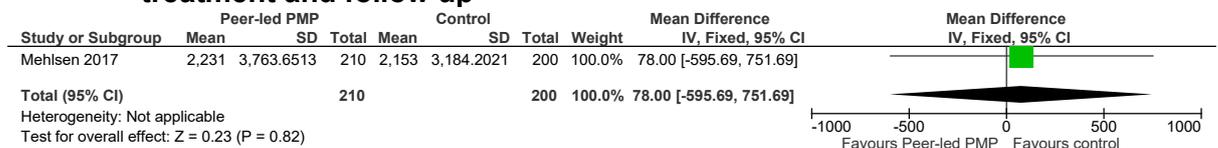
**Figure 66: Pain reduction: visual analogue scale final values (0-100, high is poor outcome) >12 weeks**



5

6 **Use of healthcare services**

**Figure 67: Use of healthcare services: Total healthcare costs in Euros during treatment and follow up**



7

# Appendix F: GRADE tables

**Table 8: Clinical evidence profile: Professional led or combination of professional and peer led pain management programmes versus standard care/waiting list**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Professionally led pain management programme	Control	Relative (95% CI)	Absolute		
<b>Quality of life (follow-up 7 weeks; measured with: SF36 Physical component final values (high is good outcome) =&lt;12 weeks; range of scores: 0-100; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	19	27	-	MD 6.02 higher (2.09 to 9.95 higher)	⊕⊕⊕⊕ MODERATE	CRITICAL
<b>Quality of life (follow-up 11 weeks; measured with: SF12 Physical component final values (high is good outcome) =&lt;12 weeks; range of scores: 0-100; Better indicated by higher values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	20	23	-	MD 1.14 higher (4.63 lower to 6.91 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Quality of life (follow-up 7 weeks; measured with: SF36 Mental component final values (high is good outcome) =&lt;12 weeks; range of scores: 0-100; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	19	27	-	MD 3.81 higher (3.02 lower to 10.64 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Quality of life (follow-up 11 weeks; measured with: SF12 Mental component final values (high is good outcome) =&lt;12 weeks; range of scores: 0-100; Better indicated by higher values)</b>												

1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	20	23	-	MD 1.67 higher (4.23 lower to 7.57 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Quality of life (follow-up 6 months; measured with: SF36 Physical component final values and change scores (high is good outcome) &gt;12 weeks; range of scores: 0-100; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	84	86	-	MD 0.57 higher (0.94 lower to 2.08 higher)	⊕⊕⊕○ MODERATE	CRITICAL
<b>Quality of life (follow-up 6 months; measured with: SF12 Physical component final values (high is good outcome) &gt;12 weeks; range of scores: 0-100; Better indicated by higher values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	20	23	-	MD 1.84 higher (3.24 lower to 6.92 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Quality of life (follow-up 6 months; measured with: SF36 Mental component final values and change scores (high is good outcome) &gt;12 weeks; range of scores: 0-100; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	84	86	-	MD 1.14 higher (1.48 lower to 3.76 higher)	⊕⊕○○ LOW	CRITICAL
<b>Quality of life (follow-up 6 months; measured with: SF12 Mental component final values (high is good outcome) &gt;12 weeks; range of scores: 0-100; Better indicated by higher values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	20	23	-	MD 3.16 higher (2.93 lower to 9.25 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Quality of life (follow-up 1-3 months; measured with: SF36 Physical function final values (high is good outcome) =&lt;12 weeks; range of scores: 0-100; Better indicated by higher values)</b>												
3	randomised trials	serious <sup>1</sup>	very serious <sup>3</sup>	no serious indirectness	serious <sup>2</sup>	none	199	191	-	MD 10.37 higher (2.70 lower to 23.44 higher)	⊕○○○ VERY LOW	CRITICAL

Quality of life (follow-up 1-3 months; measured with: SF36 Physical role final values (high is good outcome) =<12 weeks ; range of scores: 0-100; Better indicated by higher values)												
3	randomised trials	serious <sup>1</sup>	very serious <sup>3</sup>	no serious indirectness	no serious imprecision	none	199	192	-	MD 21.51 higher (3.64 to 39.37 higher)	⊕000 VERY LOW	CRITICAL
Quality of life (follow-up 1-3 months; measured with: SF36 Bodily pain final values (high is good outcome) =<12 weeks ; range of scores: 0-100; Better indicated by higher values)												
3	randomised trials	serious <sup>1</sup>	serious <sup>3</sup>	no serious indirectness	serious <sup>2</sup>	none	199	192	-	MD 8.41 higher (2.27 to 14.55 higher)	⊕000 VERY LOW	CRITICAL
Quality of life (follow-up 1-3 months; measured with: SF36 General health final values (high is good outcome) =<12 weeks ; range of scores: 0-100; Better indicated by higher values)												
3	randomised trials	serious <sup>1</sup>	serious <sup>3</sup>	no serious indirectness	very serious <sup>2</sup>	none	199	191	-	MD 5.54 higher (3.93 to 15.02 higher)	⊕000 VERY LOW	CRITICAL
Quality of life (follow-up 1-3 months; measured with: SF36 Vitality final values (high is good outcome) =<12 weeks ; range of scores: 0-100; Better indicated by higher values)												
3	randomised trials	serious <sup>1</sup>	serious <sup>3</sup>	no serious indirectness	serious <sup>2</sup>	none	199	192	-	MD 7.34 higher (0.02 to 14.66 higher)	⊕000 VERY LOW	CRITICAL
Quality of life (follow-up 1-3 months; measured with: SF36 Social functioning final values (high is good outcome) =<12 weeks ; range of scores: 0-100; Better indicated by higher values)												
3	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	199	192	-	MD 9.4 higher (2.37 to 16.42 higher)	⊕⊕00 LOW	CRITICAL
Quality of life (follow-up 1-3 months; measured with: SF36 Emotional role final values (high is good outcome) =<12 weeks ; range of scores: 0-100; Better indicated by higher values)												
3	randomised trials	serious <sup>1</sup>	very serious <sup>3</sup>	no serious indirectness	serious <sup>2</sup>	none	199	192	-	MD 16.74 higher (3.37 lower to 36.86 higher)	⊕000 VERY LOW	CRITICAL

<b>Quality of life (follow-up 1-3 months; measured with: SF36 Mental health final values (high is good outcome) =&lt;12 weeks ; range of scores: 0-100; Better indicated by higher values)</b>												
3	randomised trials	serious <sup>1</sup>	serious <sup>3</sup>	no serious indirectness	serious <sup>2</sup>	none	199	192	-	MD 8.52 higher (1.23 lower to 18.26 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Quality of life (follow-up 6-19 months; measured with: SF36 Physical function final values (high is good outcome) &gt;12 weeks ; range of scores: 0-100; Better indicated by higher values)</b>												
2	randomised trials	serious <sup>1</sup>	serious <sup>3</sup>	no serious indirectness	no serious imprecision	none	155	144	-	MD 10.52 higher (5.74 to 15.31 higher)	⊕⊕○○ LOW	CRITICAL
<b>Quality of life (follow-up 6-19 months; measured with: SF36 Physical function role values (high is good outcome) &gt;12 weeks ; range of scores: 0-100; Better indicated by higher values)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	155	144	-	MD 18.63 higher (10.15 to 27.10 higher)	⊕⊕⊕○ MODERATE	CRITICAL
<b>Quality of life (follow-up 6-19 months; measured with: SF36 Bodily pain final values (high is good outcome) &gt;12 weeks ; range of scores: 0-100; Better indicated by higher values)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	155	144	-	MD 11.85 higher (6.71 to 16.99 higher)	⊕⊕⊕○ MODERATE	CRITICAL
<b>Quality of life (follow-up 6-19 months; measured with: SF36 General health final values (high is good outcome) &gt;12 weeks ; range of scores: 0-100; Better indicated by higher values)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	155	144	-	MD 7.46 higher (2.28 to 12.63 higher)	⊕⊕⊕○ MODERATE	CRITICAL
<b>Quality of life (follow-up 6-19 months; measured with: SF36 Vitality final values (high is good outcome) &gt;12 weeks ; range of scores: 0-100; Better indicated by higher values)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	155	144	-	MD 7.47 higher (2.27 lower to 12.67 higher)	⊕⊕⊕○ MODERATE	CRITICAL

Quality of life (follow-up 6-19 months; measured with: SF36 Social functioning final values (high is good outcome) >12 weeks ; range of scores: 0-100; Better indicated by higher values)												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	155	144	-	MD 7.59 higher (1.69 to 13.48 higher)	⊕⊕⊕⊕ LOW	CRITICAL
Quality of life (follow-up 6-19 months; measured with: SF36 Emotional role final values (high is good outcome) >12 weeks ; range of scores: 0-100; Better indicated by higher values)												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	155	144	-	MD 10.52 higher (0.03 to 21 higher)	⊕⊕⊕⊕ LOW	CRITICAL
Quality of life (follow-up 6-19 months; measured with: SF36 Mental health final values (high is good outcome) >12 weeks ; range of scores: 0-100; Better indicated by higher values)												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	155	144	-	MD 5.34 higher (0.01 lower to 10.68 higher)	⊕⊕⊕⊕ LOW	CRITICAL
Quality of life (follow-up 10 weeks; measured with: FIQ final values (high is poor outcome) =<12 weeks; range of scores: 0-100; Better indicated by lower values)												
2	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	142	156	-	MD 14.28 lower (18.01 to 10.55 lower)	⊕⊕⊕⊕ LOW	CRITICAL
Quality of life (follow-up 6 months; measured with: FIQ final values (high is poor outcome) >12 weeks; range of scores: 0-100; Better indicated by lower values)												
3	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	192	209	-	MD 9.71 lower (13.09 to 6.33 lower)	⊕⊕⊕⊕ LOW	CRITICAL
Quality of life (follow-up 3 months; measured with: EQ-5D final values (high is good outcome) =<12 weeks; range of scores: 0-1; Better indicated by higher values)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	108	48	-	MD 0.01 higher (0.11 lower to 0.09 higher)	⊕⊕⊕⊕ MODERATE	CRITICAL
Quality of life (follow-up 9-21 months; measured with: EQ-5D final values (high is good outcome) >12 weeks; range of scores: 0-1; Better indicated by higher values)												

2	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious indirectness	none	198	131	-	MD 0.05 higher (0.01 lower to 0.11 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Quality of life (follow-up 3 months; measured with: EQ-5D VAS (high is good outcome), final values =&lt;12 weeks; range of scores: 0-100; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	108	48	-	MD 5.7 higher (1.1 lower to 12.5 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Quality of life (follow-up 21 months; measured with: EQ-5D VAS (high is good outcome), final values &gt;12 weeks; range of scores: 0-100; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	67	48	-	MD 5.4 higher (2.48 lower to 13.28 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Quality of life (inpatient PMP) (follow-up 4 weeks; measured with: FIQ (high is poor outcome) final values =&lt;12 weeks; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	58	60	-	MD 5.1 lower (65.61 lower to 55.41 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Physical function (follow-up 7-12 weeks; measured with: Roland Morris Disability Questionnaire (high is poor outcome), final values =&lt;12 weeks; range of scores: 0-24; Better indicated by lower values)</b>												
3	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	270	248	-	MD 1.41 lower (2.3 to 0.52 lower)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Physical function (follow-up 3 months; measured with: Western Ontario and McMaster Universities Osteoarthritis Index (high is poor outcome) change scores =&lt;12 weeks; range of scores: 0-68; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	94	103	-	MD 2.99 lower (5.68 to 0.3 lower)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Physical function (follow-up 3 months; measured with: Fibromyalgia Impact Questionnaire physical function subscale final values (high is poor outcome) =&lt;12 weeks; range of scores: 0-10; Better indicated by lower values)</b>												

1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	108	48	-	MD 0.1 lower (0.81 lower to 0.61 higher)	⊕⊕⊕○ MODERATE	CRITICAL
<b>Physical function (follow-up 7-8 weeks; measured with: 6 minute walk test final values and change scores =&lt;12 weeks ; Better indicated by higher values)</b>												
2	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	62	56	-	MD 45.2 higher (7.92 to 82.48 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Physical function (follow-up 8 weeks; measured with: 10 minute walk test final values and change scores =&lt;12 weeks ; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	30	31	-	MD 49 higher (69.52 lower to 167.52 higher)	⊕⊕○○ LOW	CRITICAL
<b>Physical function (follow-up 7 weeks; measured with: Short musculoskeletal function assessment – dysfunction index final values =&lt;12 weeks ; range of scores: 34-170; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	45	47	-	MD 8.9 lower (15.3 to 2.5 lower)	⊕⊕○○ LOW	CRITICAL
<b>Physical function (follow-up 6-12 months; measured with: Roland Morris Disability Questionnaire final values (high is poor outcome) &gt;12 weeks; range of scores: 0-24; Better indicated by lower values)</b>												
2	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	206	199	-	MD 0.99 lower (2.09 lower to 0.1 higher)	⊕⊕○○ LOW	CRITICAL
<b>Physical function (follow-up 21 months; measured with: Western Ontario and McMaster Universities Osteoarthritis Index final values (high is poor outcome) &gt;12 weeks; range of scores: 0-68; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	94	113	-	MD 5 lower (9.7 to 0.3 lower)	⊕○○○ VERY LOW	CRITICAL
<b>Physical function (follow-up 21 months; measured with: Fibromyalgia Impact Questionnaire physical function subscale final values (high is poor outcome) &gt;12 weeks; range of scores: 0-10; Better indicated by lower values)</b>												

1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	108	48	-	MD 0.3 lower (1.01 lower to 0.41 higher)	⊕⊕⊕⊕ MODERATE	CRITICAL
<b>Physical function (follow-up 18 weeks; measured with: Short musculoskeletal function assessment – dysfunction index final values &gt;12 weeks ; range of scores: 34-170; Better indicatd by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	38	42	-	MD 8 lower (14.7 to 1.3 lower)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Physical function (inpatient PMP) (follow-up 8 weeks; measured with: 10 minute walk test, final values =&lt;12 weeks; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	38	31	-	MD 188 higher (94.76 to 281.24 higher)	⊕⊕⊕⊕ MODERATE	CRITICAL
<b>Psychological distress (follow-up 8 weeks; measured with: Depression Anxiety Stress Scale change scores (high is poor outcome) =&lt; 12 weeks; range of scores: 0-42; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	49	39	-	MD 0.88 higher (2.94 lower to 4.7 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Psychological distress (follow-up 7-12 weeks; measured with: Beck Depression Inventory (0-63), Geriatric Depression Scale (0-30), Patient health questionnaire depression (0-27) and Fibromyalgia Impact questionnaire depression subscale (0-10), final values =&lt;12 weeks; Better indicated by lower values)</b>												
7	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	-	-	-	SMD 0.11 lower (0.26 lower to 0.04 higher)	⊕⊕⊕⊕ MODERATE	CRITICAL
<b>Psychological distress (follow-up 8-12 weeks; measured with: FIQ anxiety subscale 0-10, Impact of Rheumatic Diseases on General Health and Lifestyle anxiety scale 10-40 and State-Trait Anxiety Inventory 20-80 (high is poor outcome), final values =&lt;12 weeks; Better indicated by lower values)</b>												
3	randomised trials	serious <sup>1</sup>	serious <sup>3</sup>	no serious indirectness	serious <sup>2</sup>	none	198	161	-	SMD 0.32 lower (0.68 lower to 0.03 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL

<b>Psychological distress (follow-up 4.5-21 months; measured with: Geriatric Depression Scale 0-30, Beck depression inventory 0-63, Hospital Anxiety and Depression Scale depression 0-21, Fibromyalgia Impact Questionnaire depression subscale 0-10, Patient health questionnaire depression 0-27 (high is poor outcome), final values &gt;12 weeks; Better indicated by lower values)</b>												
5	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	334	272	-	SMD 0.05 lower (0.21 lower to 0.11 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Psychological distress (follow-up 6-21 months; measured with: Hospital Anxiety and Depression scale anxiety 0-21, FIQ anxiety subscale 0-10 and Impact of Rheumatic Diseases on Health and Lifestyle anxiety scale 10-40 (high is poor outcome) final values &gt;12 weeks; Better indicated by lower values)</b>												
3	randomised trials	serious <sup>1</sup>	very serious <sup>3</sup>	no serious indirectness	serious <sup>2</sup>	none	218	180	-	SMD 0.34 lower (0.88 lower to 0.2 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Psychological distress (follow-up 6 months; measured with: Generalised Anxiety Disorder-10 anxiety change scores (high is poor outcome) &gt;12 weeks; range of scores: 0-10; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	88	95	-	MD 0.24 lower (1.98 lower to 1.5 higher)	⊕⊕⊕⊕ MODERATE	CRITICAL
<b>Psychological distress (follow-up 28 weeks; measured with: Kessler-10 psychological distress scale final values (high is poor outcome) &gt;12 weeks; range of scores: 10-50; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	41	39	-	MD 1.83 higher (1.18 lower to 4.84 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Psychological distress (inpatient PMP) (follow-up 4 weeks; measured with: General Health Questionnaire (high is poor outcome) final values =&lt;12 weeks; range of scores: 0-60; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	58	60	-	MD 0.4 higher (23.06 lower to 23.86 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Psychological distress (inpatient PMP) (follow-up 4-8 weeks; measured with: Beck Depression Inventory (high is poor outcome) final values =&lt;12 weeks; range of scores: 0-63; Better indicated by lower values)</b>												

2	randomised trials	serious <sup>1</sup>	very serious <sup>3</sup>	no serious indirectness	serious <sup>2</sup>	none	67	47	-	MD 3.72 lower (12.48 lower to 5.04 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Psychological distress (inpatient PMP) (follow-up 8 weeks; measured with: State-Trait Anxiety Inventory (high is poor outcome), final values =&lt;12 weeks; range of scores: 20-80; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	38	31	-	MD 8.2 lower (14.17 to 2.23 lower)	⊕⊕○○ LOW	CRITICAL
<b>Pain interference (follow-up 7-11 weeks; measured with: Brief Pain Inventory interference scale 0-10 and PROMIS pain interference 8-40 final values (high is poor outcome) =&lt;12 weeks; Better indicated by lower values)</b>												
3	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	188	171	-	SMD 0.1 lower (0.3 lower to 0.11 higher)	⊕⊕○○ LOW	CRITICAL
<b>Pain interference (follow-up 4.5-12 months; measured with: Brief Pain Inventory interference scale 0-10 and PROMIS pain interference 8-40 final values (high is bad outcome) &gt;12 weeks; Better indicated by lower values)</b>												
4	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	213	207	-	SMD 0.06 lower (0.26 lower to 0.13 higher)	⊕⊕○○ LOW	CRITICAL
<b>Pain interference (inpatient PMP) (follow-up 8 weeks; measured with: VAS (high is poor outcome) final values =&lt;12 weeks; range of scores: 0-100; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	17	19	-	MD 0.6 lower (14.23 lower to 13.03 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Self-efficacy (follow-up 7-8 weeks; measured with: Pain Self-Efficacy Questionnaire final values and change scores (high is good outcome) =&lt;12 weeks; range of scores: 0-60; Better indicated by higher values)</b>												
4	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	137	134	-	MD 6.11 higher (4.61 to 7.61 higher)	⊕⊕○○ LOW	CRITICAL
<b>Self efficacy (follow-up 3 months; measured with: Arthritis self efficacy scale change scores (high is good outcome) =&lt;12 weeks; Better indicated by higher values)</b>												

1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	91	101	-	MD 0.04 higher (0.13 lower to 0.21 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Self-efficacy (follow-up 4.5-7 months; measured with: Pain Self-Efficacy Questionnaire final values and change scores (high is good outcome) &gt;12 weeks; range of scores: 0-60; Better indicated by higher values)</b>												
3	randomised trials	serious <sup>1</sup>	serious <sup>3</sup>	no serious indirectness	serious <sup>2</sup>	none	163	167	-	MD 4.49 higher (0.66 to 8.32 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Self efficacy (follow-up 21 months; measured with: Arthritis Self Efficacy Scale final values (high is good outcome) &gt;12 weeks; Better indicated by higher values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	89	106	-	MD 0.2 higher (0.04 lower to 0.44 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Self-efficacy (inpatient PMP) (follow-up 8 weeks; measured with: Pain Self-Efficacy Questionnaire (high is good outcome), final values =&lt;12 weeks; range of scores: 0-60; Better indicated by higher values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	38	31	-	MD 12.4 higher (7.07 to 17.73 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Self-efficacy (inpatient PMP) (follow-up 4 weeks; measured with: Arthritis Self-Efficacy Scale pain subscale (high is good outcome) final values =&lt;12 weeks; range of scores: 10-100; Better indicated by higher values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	58	60	-	MD 2.5 higher (53.7 lower to 58.7 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Pain reduction (follow-up 7-12 weeks; measured with: Numeric Rating Scale and Visual Analogue Scale 0 final values and change scores (high is poor outcome) =&lt;12 weeks; range of scores: 0-10; Better indicated by lower values)</b>												
10	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	579	456	-	MD 0.49 lower (0.74 to 0.24 lower)	⊕⊕⊕⊕ LOW	IMPORTANT

<b>Pain reduction (follow-up 4.5-27 months; measured with: Numeric Rating Scale and Visual Analogue Scale final values and change scores (high is poor outcome) &gt;12 weeks; range of scores: 0-10; Better indicated by lower values)</b>												
8	randomised trials	very serious <sup>1</sup>	serious <sup>3</sup>	no serious indirectness	no serious imprecision	none	560	479	-	MD 0.2 lower (0.59 lower to 0.19 higher)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Pain reduction (inpatient PMP) (follow-up 4-8 weeks; measured with: Visual Analogue Scale (high is bad outcome) final values =&lt;12 weeks; range of scores: 0-10; Better indicated by lower values)</b>												
3	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	84	66	-	MD 0.69 lower (1.41 lower to 0.04 higher)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Sleep (follow-up 11-12 weeks; measured with: Chronic Pain Sleep Index 0-10 (high is good outcome), Medical Outcomes study Sleep scale (12-71, high is good outcome) and Fibromyalgia Impact Questionnaire unrefreshed sleep subscale 0-10 (high is poor outcome, scale inverted for analysis) =&lt;12 weeks; Better indicated by higher values)</b>												
3	randomised trials	serious <sup>1</sup>	very serious <sup>3</sup>	no serious indirectness	very serious <sup>2</sup>	none	209	145	-	SMD 0.47 higher (0.56 lower to 1.5 higher)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Sleep (follow-up 6-21 months; measured with: Chronic Pain Sleep Index 0-10 (high is good outcome), Medical Outcomes study Sleep scale (12-71, high is good outcome), Sleep Scale 0-20 (high is poor outcome, scale inverted for analysis) and Fibromyalgia Impact Questionnaire unrefreshed sleep subscale 0-10 (high is poor outcome, scale inverted for analysis), final values &gt;12 weeks; Better indicated by higher values)</b>												
4	randomised trials	serious <sup>1</sup>	serious <sup>3</sup>	no serious indirectness	serious <sup>2</sup>	none	311	243	-	SMD 0.43 higher (0.12 to 0.74 higher)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Use of healthcare services (follow-up 3 months; measured with: Mean number of GP contacts within previous 2 months =&lt;12 weeks ; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	108	48	-	MD 0.5 higher (0.21 lower to 1.21 higher)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Use of healthcare services (follow-up 3 months; measured with: Mean number of medical specialist contacts within previous 2 months =&lt;12 weeks ; Better indicated by lower values)</b>												

1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	108	48	-	MD 0.1 lower (0.38 lower to 0.18 higher)	⊕⊕○○ LOW	IMPORTANT
<b>Use of healthcare services (follow-up 3 months; measured with: Mean number of physiotherapist contacts within previous 2 months) =&lt;12 weeks ; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	108	48	-	MD 1.2 lower (2.89 lower to 0.49 higher)	⊕⊕○○ LOW	IMPORTANT
<b>Use of healthcare services (follow-up 3 months; measured with: Mean number of other paramedical professional contacts within previous 2 months =&lt;12 weeks ; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	108	48	-	MD 0 higher (0.98 lower to 0.98 higher)	⊕⊕⊕○ MODERATE	IMPORTANT
<b>Use of healthcare services (follow-up 21 months; measured with: Mean number of GP contacts within previous 2 months &gt;12 weeks ; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	108	48	-	MD 0.2 higher (0.51 lower to 0.91 higher)	⊕⊕⊕○ MODERATE	IMPORTANT
<b>Use of healthcare services (follow-up 21 months; measured with: Mean number of medical specialist contacts within previous 2 months &gt;12 weeks ; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	108	48	-	MD 0.1 higher (0.18 lower to 0.38 higher)	⊕⊕○○ LOW	IMPORTANT
<b>Use of healthcare services (follow-up 21 months; measured with: Mean number of physiotherapist contacts within previous 2 months &gt;12 weeks; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	108	48	-	MD 0.2 lower (1.89 lower to 1.49 higher)	⊕⊕⊕○ MODERATE	IMPORTANT
<b>Use of healthcare services (follow-up 21 months; measured with: Mean number of other paramedical professional contacts within previous 2 months &gt;12 weeks ; Better indicated by lower values)</b>												

1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	108	48	-	MD 0.8 higher (0.18 lower to 1.78 higher)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Use of healthcare services (follow-up 12 months; measured with: Mean number of MD and/or ED visits for pain care &gt;12 weeks; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	12	12	-	MD 18 lower (50.16 lower to 14.16 higher)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Use of healthcare services (follow up 18 weeks; measured with: mean number of primary care visits during the previous week &gt;12 weeks; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	38	42	-	MD 2.7 lower (1.26 lower to 0.72 higher)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Use of healthcare services (follow up 18 weeks; measured with: mean number of emergency department visits during the previous week &gt;12 weeks; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	38	42	-	MD 0.02 higher (0.23 lower to 0.27 higher)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Use of healthcare services (follow up 18 weeks; measured with: mean number of specialist appointment visits during the previous week &gt;12 weeks; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	38	42	-	MD 0.26 lower (0.56 lower to 0.04 higher)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Use of healthcare services (follow up 18 weeks; measured with: mean number of diagnostic imaging visits during the previous week &gt;12 weeks; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	38	42	-	MD 0.18 lower (0.51 lower to 0.15 higher)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Discontinuation (follow-up 7-12 weeks; assessed with: Discontinuation)</b>												

13	randomised trials	serious <sup>1</sup>	serious <sup>3</sup>	serious <sup>4</sup>	very serious <sup>2</sup>	none	144/964 (14.9%)	6.1%	RR 1.35 (0.78 to 2.34)	21 more per 1000 (from 13 fewer to 82 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Discontinuation (inpatient PMP) (follow-up 4-8 weeks; assessed with: Discontinuation for any reason)</b>												
4	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>4</sup>	very serious <sup>2</sup>	none	28/172 (16.3%)	13.1%	RR 1.07 (0.65 to 1.76)	9 more per 1000 (from 46 fewer to 100 more)	⊕○○○ VERY LOW	IMPORTANT

- 1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
- 2 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs
- 3 Downgraded by 1 or 2 increments because heterogeneity, I<sup>2</sup>=50%, p=0.04, unexplained by subgroup analysis
- 4 Downgraded by 1 or 2 increments because the majority of the evidence had indirect outcomes

**6 Table 9: Clinical evidence profile: Peer led pain management programmes versus standard care/waiting list**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Peer-led pain management programmes	Usual care	Relative (95% CI)	Absolute		
<b>Physical function (follow-up 6 weeks; measured with: Roland Morris Disability Questionnaire final values (high is bad outcome) ≤12 weeks; range of scores: 0-24; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	205	194	-	MD 1.2 lower (2.07 to 0.33 lower)	⊕⊕⊕○ MODERATE	CRITICAL
<b>Physical function (follow-up 5 months; measured with: Roland Morris Disability Questionnaire final values (high is bad outcome) &gt;12 weeks; range of scores: 0-24; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	205	186	-	MD 0.5 lower (1.41 lower to 0.41 higher)	⊕⊕⊕○ MODERATE	CRITICAL

<b>Psychological distress (follow-up 6 weeks; measured with: Pain catastrophising scale (high is bad outcome) final values ≤12 weeks; range of scores: 0-52; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	205	194	-	MD 1.6 lower (3.69 lower to 0.49 higher)	⊕⊕⊕○ MODERATE	CRITICAL
<b>Psychological distress (follow-up 5 months; measured with: Pain catastrophising scale (high is bad outcome) final values &gt;12 weeks; range of scores: 0-52; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	205	186	-	MD 1.1 lower (3.24 lower to 1.04 higher)	⊕⊕⊕○ MODERATE	CRITICAL
<b>Self-efficacy (follow-up 6 weeks; measured with: Arthritis Self Efficacy Scale (high is good outcome) final values ≤12 weeks; range of scores: 5-50; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	205	194	-	MD 2.7 lower (4.5 to 0.9 lower)	⊕⊕○○ LOW	CRITICAL
<b>Self-efficacy (follow-up 5 months; measured with: Arthritis Self Efficacy Scale (high is good outcome) final values &gt;12 weeks; range of scores: 5-50; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	205	186	-	MD 3.4 lower (5.39 to 1.41 lower)	⊕⊕○○ LOW	CRITICAL
<b>Pain reduction (follow-up 6 weeks; measured with: Visual Analogue Scale (high is poor outcome) final values ≤12 weeks; range of scores: 0-10; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	205	194	-	MD 0.4 higher (2.66 lower to 3.46 higher)	⊕⊕⊕○ MODERATE	IMPORTANT
<b>Pain reduction (follow-up 5 months; measured with: Visual Analogue Scale (high is poor outcome) final values &gt;12 weeks; range of scores: 0-10; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	205	186	-	MD 0.2 lower (0.58 lower to 0.18 higher)	⊕⊕⊕○ MODERATE	IMPORTANT
<b>Use of healthcare services (follow-up 5 months; measured with: Total healthcare costs in Euros; Better indicated by lower values)</b>												

1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	210	200	-	MD 96 higher (551.65 lower to 743.65 higher)	⊕⊕⊕○ MODERATE	IMPORTANT
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1 1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

2  
3 2 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

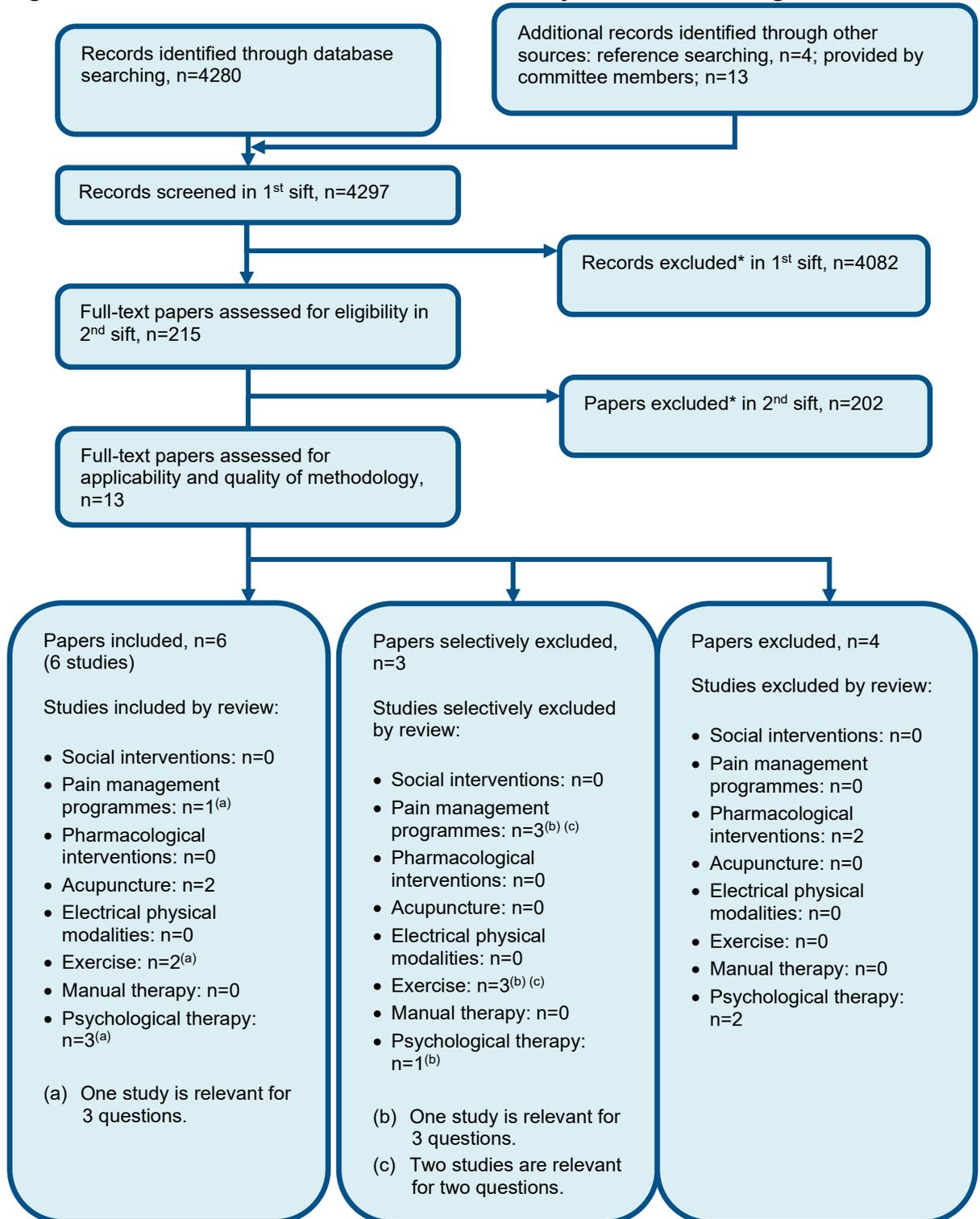
4

5

# 1 Appendix G: Health economic evidence selection

## 2

**Figure 68: Flow chart of health economic study selection for the guideline**



\* Non-relevant population, intervention, comparison, design or setting; non-English language

# Appendix H: Health economic evidence tables

1  
2

Study	Beasley (2015) <sup>24</sup>																																						
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness																																			
<p><b>Economic analysis:</b> CUA (health outcome: QALYs )</p> <p><b>Study design:</b> Within-trial analysis (RCT – clinical results in same paper)</p> <p><b>Approach to analysis:</b> Analysis of individual data for EQ-5D (adjusted for baseline differences in utility) and resource use. Unit costs applied.</p> <p><b>Perspective:</b> UK NHS</p> <p><b>Follow-up:</b> 30 months*</p> <p><b>Treatment effect duration:</b><sup>(a)</sup> 6 months</p> <p><b>Discounting:</b> Costs: 3.5%; Outcomes: 3.5%</p>	<p><b>Population:</b> People aged 25 years and over with chronic widespread pain according to the definition in the American College of Rheumatology (ACR) 1990 criteria for fibromyalgia, for which they have consulted their general practitioner in the previous year.</p> <p><b>Patient characteristics:</b> N = 442 (in all four arms) Age: 56.3 Male: 30.5%</p> <p><b>Intervention 1:</b> Treatment as usual (from GP – precise care delivered not recorded)</p> <p><b>Intervention 2:</b> Telephone-delivered cognitive behaviour therapy (TCBT): initial assessment (45-60mins) followed by 7 weekly sessions (30-45mins each), 1 session at three months, and 1 session at 6 months. Intervention delivered by 4 therapists accredited by the British</p>	<p><b>Incremental costs (mean per patient):</b></p> <p>Intervention 1 is the reference.</p> <p><u>Complete cases</u> Intervention 1: £0 Intervention 2: £574 Intervention 3: £1,924 Intervention 4: £1,778</p> <p><u>Multiple imputations</u> Intervention 1: £0 Intervention 2: £554 Intervention 3: £1,256 Intervention 4: £1,453</p> <p><b>Currency &amp; cost year:</b> 2010 UK pounds</p>	<p><b>Incremental QALYs (mean per patient):</b></p> <p>Intervention 1 is the reference.</p> <p><u>Complete cases</u> Intervention 1: 0 Intervention 2: 0.097 Intervention 3: 0.025 Intervention 4: 0.047</p> <p><u>Multiple imputations</u> Intervention 1: 0 Intervention 2: 0.140 Intervention 3: 0.071 Intervention 4: 0.096</p>	<p><b>ICER:</b> <b>Full incremental analysis (complete cases, adjusted) (pa):</b></p> <table border="1"> <thead> <tr> <th>Int</th> <th>Inc cost</th> <th>Inc QALY</th> <th>ICER</th> <th>ICER (ruled out dominated options)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>£0</td> <td>£0</td> <td>Reference</td> <td>-</td> </tr> <tr> <td>2</td> <td>£574</td> <td>0.097</td> <td>£5,917</td> <td>£5,917</td> </tr> <tr> <td>3</td> <td>£1,924</td> <td>0.025</td> <td>£76,960</td> <td>Dominated</td> </tr> <tr> <td>4</td> <td>£1,778</td> <td>0.047</td> <td>£37,830</td> <td>Dominated</td> </tr> </tbody> </table> <p>Probability Intervention 2 cost effective (£20K threshold): approx. 75% (read off graph)</p> <p><b>Full incremental analysis (multiple imputations, adjusted) (pa):</b></p> <table border="1"> <thead> <tr> <th>Int</th> <th>Inc cost</th> <th>Inc QALY</th> <th>ICER</th> <th>ICER (ruled out dominated)</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Int	Inc cost	Inc QALY	ICER	ICER (ruled out dominated options)	1	£0	£0	Reference	-	2	£574	0.097	£5,917	£5,917	3	£1,924	0.025	£76,960	Dominated	4	£1,778	0.047	£37,830	Dominated	Int	Inc cost	Inc QALY	ICER	ICER (ruled out dominated)					
Int	Inc cost	Inc QALY	ICER	ICER (ruled out dominated options)																																			
1	£0	£0	Reference	-																																			
2	£574	0.097	£5,917	£5,917																																			
3	£1,924	0.025	£76,960	Dominated																																			
4	£1,778	0.047	£37,830	Dominated																																			
Int	Inc cost	Inc QALY	ICER	ICER (ruled out dominated)																																			

				options )
1	£0	0	Reference	-
2	£554	0.140	£3,957	£3,957
3	£1,256	0.071	£17,690	Dominated
4	£1,453	0.096	£15,135	Dominated

Probability Intervention 2 cost effective (£20K/30K threshold): NR

**Analysis of uncertainty:** Used non-parametric bootstrapping. Multiple imputation was also used to assess the sensitivity of findings to missing data.

**Cost components incorporated:**

- Intervention costs (for exercise this includes gym membership)
- Routine health service (GP, nurse, physio, community visits, outpatient, inpatient, admission, primary care).

Association for Behaviour and Cognitive Psychotherapies. Therapists conducted a patient-centred assessment, developed shared understanding and formulation of the participants' problem(s) and identified two to three patient-defined goals. Patients also received a self-management CBT manual that included: behavioural activation, cognitive restructuring, unhelpful thinking and lifestyle changes.

**Intervention 3:**

Exercise therapy: leisure-facility-and-gym-based exercise program consistent with American College of Sport Medicine (ACSM) guidelines for improving cardiorespiratory fitness. Following an induction sessions, patients were offered 6 fitness instructor-led monthly appointments. Experienced fitness instructors delivered the intervention following a 1-day training session on exercise prescription for people with CWP. The specific exercises are negotiated between fitness instructor and patient, and can be changed while maintaining goal of improving cardio-respiratory fitness. Initial intensity was low to moderate, patients were free to engage in additional exercises to those prescribed. Recommended session duration was 20-60 mins,

	<p>patients were advised to attend at least twice a week and engage in 'everyday' activities on non-gym days.</p> <p><b>Intervention 4:</b> Combination of Interventions 2 and 3.</p> <ul style="list-style-type: none"> <li>•</li> </ul>			
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**Data sources**

\*The follow up is 24 months post treatment, and given that the exercise and CBT interventions were about 6 months in length then that equates to a 30 month follow up.

Analyses were adjusted for age, sex, baseline pain score, baseline psychological distress score, study centre, and baseline scores of outcome of interest (e.g. EQ-5D).

**Health outcomes:** Resource use was reported to 3 months post treatment, and at months 18-24 post treatment. Linear interpolation between reported health service costs at 3 and 24 months post treatment was used to impute an average cost per quarter for the 5 quarters not covered by data collection (i.e. months 3-6, 6-9, 9-12, 12-15 and 15-18 post treatment). **Quality-of-life weights:** EQ-5D UK tariff. QALYs calculated using patient response to EQ-5D at 24 months post-treatment. Additional QALYs accrued between 3 and 24 months post treatment were calculated for each person assuming a linear change in utility. **Cost sources:** Cost sources were the same as those used for the original McBeth 2012 economic evaluation that this paper is also based on, which are PSSRU 2010, and NHS reference costs 2008/9. TCBT delivered by 4 therapists accredited by the British Association for Behaviour and Cognitive Psychotherapies. Exercise delivered by experienced fitness instructors.

**Comments**

**Source of funding:** Arthritis Research UK. **Limitations:** Participation in study based on self-reported symptoms and recruited through primary care, may not necessarily be representative of general population with chronic widespread pain caused by fibromyalgia. Treatment as usual not defined, usual care provided by GP was not restricted and may not be the same across all participants in that group. Within-study analysis which may not reflect full body of evidence. **Other:** Analyses were adjusted for: age, sex, baseline pain on CPG (chronic pain grade) scale, baseline GHQ (general health questionnaire) score and study centre.

**Overall applicability:**<sup>(b)</sup> Directly applicable      **Overall quality:**<sup>(c)</sup> Potentially serious limitations

- 1 Abbreviations: 95% CI: 95% confidence interval; CUA: cost-utility analysis; da: deterministic analysis; EQ-5D: Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health],
- 2 negative values mean worse than death); ICER: incremental cost-effectiveness ratio; NR: not reported; pa: probabilistic analysis; QALYs: quality-adjusted life years
- 3 (a) For studies where the time horizon is longer than the treatment duration, an assumption needs to be made about the continuation of the study effect. For example, does a
- 4 difference in utility between groups during treatment continue beyond the end of treatment and if so for how long.
- 5 (b) Directly applicable / Partially applicable / Not applicable
- 6 (c) Minor limitations / Potentially serious limitations / Very serious limitations

# 1 Appendix I: Excluded studies

## I.1 Excluded clinical studies

3 **Table 10: Studies excluded from the clinical review**

Study	Exclusion reason
Abbasi 2012 <sup>1</sup>	Incorrect interventions (lack of applicability)
Aggarwal 2019 <sup>2</sup>	Systematic review with different PICO
Ahles 2006 <sup>3</sup>	Incorrect interventions: pharmacological
Akhter 2014 <sup>4</sup>	Incorrect interventions. no psychological component
Alaranta, 1994 <sup>5</sup>	Inappropriate comparison (control group received massage, electrical therapies, traction, etc.)
Alexandre, 2001 <sup>6</sup>	No relevant outcomes
Alp, 2007 <sup>7</sup>	Not review population (osteoporosis)
Amorim 2019 <sup>8</sup>	Incorrect interventions (insufficient psychological component)
Andersen 2015 <sup>10</sup>	Incorrect interventions (insufficient psychological component)
Andersen 2016 <sup>11</sup>	Incorrect interventions (insufficient psychological component)
Andersson 2012 <sup>12</sup>	Incorrect interventions
Angeles 2013 <sup>13</sup>	Incorrect study design (non-randomised pilot study)
Angst 2009 <sup>14</sup>	Incorrect study design (cohort study)
Aragones 2016 <sup>15</sup>	Study protocol
Ariza-Mateos 2020 <sup>16</sup>	Incorrect intervention (insufficient physical component)
Asenlof 2005 <sup>17</sup>	Inappropriate comparison (exercise)
Astin 2003 <sup>18</sup>	Inappropriate comparison (education in weekly groups)
Bair 2015 <sup>19</sup>	Incorrect interventions
Bandemer-greulich 2008 <sup>20</sup>	Article not in English
Bao 2015 <sup>21</sup>	Article not in English
Barefoot 2012 <sup>22</sup>	Incorrect interventions
Basler 1997 <sup>23</sup>	Incorrect interventions (insufficient physical component)
Becker 2000 <sup>25</sup>	Unclear intervention (one or more components received so unclear how many received both a psychological and physical component)
Becker 2001 <sup>26</sup>	Article not in English
Beltran-Alacreu 2015 <sup>27</sup>	Inappropriate comparison (manual therapy and education)
Bendix 1995 <sup>29</sup>	Inappropriate comparison
Bendix 1996 <sup>30</sup>	No useable outcomes
Bendix 1997 <sup>28</sup>	Incorrect interventions
Bennell 2012 <sup>31</sup>	Study protocol
Bennell 2017 <sup>32</sup>	Incorrect interventions: Coping skills.
Berglund 2018 <sup>33</sup>	Incorrect population (1/3 did not have chronic pain)
Bergstrom 2012 <sup>34</sup>	No relevant outcomes
Bergstrom 2014 <sup>35</sup>	Incorrect study design (nonrandomised)
Bernaards, 2006 <sup>36</sup>	Study protocol
Bernstein 2004 <sup>37</sup>	Thesis, not available
Berwick, 1989 <sup>38</sup>	Incorrect interventions (no physical component)

Study	Exclusion reason
Bjornsdottir 2016 <sup>39</sup>	Incorrect interventions: no physical element except motor control training
Blake 2016 <sup>40</sup>	Incorrect interventions: CBT only
Bliokas 2007 <sup>41</sup>	Incorrect interventions
Brage 2015 <sup>43</sup>	Inappropriate comparison: Education
Brodsky 2019 <sup>44</sup>	Incorrect interventions (insufficient psychological component)
Bronfort 2001 <sup>45</sup>	Incorrect interventions
Brown 2013 <sup>46</sup>	Incorrect interventions (insufficient physical component)
Brunahl 2018 <sup>47</sup>	Study protocol
Buckelew 1998 <sup>49</sup>	Incorrect interventions (not a PMP)
Buchser 1999 <sup>48</sup>	Incorrect interventions: hypnosis
Buhrman 2013 <sup>50</sup>	Incorrect interventions
Burckhardt 1994 <sup>51</sup>	Incorrect interventions (not a PMP; education + exercise interventions)
Burns 2005 <sup>52</sup>	Incorrect study design: observational
Burton 2015 <sup>53</sup>	Systematic review with different PICO
Busch 2011 <sup>54</sup>	No relevant outcomes
Cabak 2017 <sup>55</sup>	Very low intensity programme while participants waited for rehabilitation programme; only relevant outcome reported is quality of life, but unclear measure
Calner 2017 <sup>56</sup>	Inappropriate comparison: the same intervention with an add-on
Campello 2012 <sup>57</sup>	Incorrect population (not chronic)
Carbonell-baeza 2011 <sup>59</sup>	Incorrect study design: not randomised
Carbonell-baeza 2011 <sup>58</sup>	Incorrect study design: not randomised
Cardosa 2012 <sup>60</sup>	Incorrect study design (observational)
Carlson 2001 <sup>61</sup>	Incorrect interventions
Carnes 2012 <sup>63</sup>	Systematic review with different PICO
Carnes 2013 <sup>62</sup>	Incorrect study design (mixed methods; systematic review with different PICO, qualitative study, observational feasibility study)
Carnes 2013 <sup>64</sup>	Study protocol
Carron 1981 <sup>65</sup>	Book result; non-randomised study
Casanueva-Fernandez 2012 <sup>66</sup>	Inappropriate comparison
Castel 2012 <sup>67</sup>	Incorrect interventions (no physical component)
Cedraschi 2004 <sup>69</sup>	Incorrect interventions Inappropriate comparison
Chelimsky 2013 <sup>70</sup>	Incorrect interventions
Cheng 2017 <sup>71</sup>	Study protocol
Chiauzzi 2010 <sup>72</sup>	Self-management website
Choi 2016 <sup>73</sup>	Incorrect population
Clarke-jenssen 2014 <sup>74</sup>	Incorrect interventions
Cooper 2013 <sup>76</sup>	Systematic review with different PICO
Cooper 2014 <sup>75</sup>	Not review population
Courtenay 2008 <sup>78</sup>	Systematic review with different PICO
Crockett 1986 <sup>79</sup>	Incorrect interventions
Cunningham 2011 <sup>80</sup>	Study protocol
Currie 2000 <sup>81</sup>	Incorrect intervention
Da silva 2018 <sup>82</sup>	Results unextractable

Study	Exclusion reason
Daly-eichenhardt 2016 <sup>83</sup>	Incorrect study design: observational study
Damush 2003 <sup>85</sup>	Not guideline condition
Damush 2016 <sup>84</sup>	Incorrect study design (follow-up study)
Davis 2015 <sup>86</sup>	Incorrect interventions
Dear 2018 <sup>92</sup>	Incorrect interventions
De bruijn-kofman 1997 <sup>87</sup>	Incorrect interventions
De heer 2013 <sup>88</sup>	Study protocol
De seze 2017 <sup>89</sup>	Article not in English
De wit 2001 <sup>91</sup>	Incorrect interventions
De wit 2001 <sup>90</sup>	Incorrect interventions
Debar 2018 <sup>93</sup>	Study protocol
Deckert 2016 <sup>94</sup>	Systematic review with different PICO
Dekker 2016 <sup>95</sup>	Study protocol
Delgado 2014 <sup>96</sup>	Systematic review with different PICO
Demoulin 2010 <sup>97</sup>	Incorrect study design (non randomised)
Dobscha 2008 <sup>98</sup>	Baseline results only
Dobscha 2009 <sup>99</sup>	Incorrect interventions
Dobson 2014 <sup>100</sup>	Study protocol
Dragioti 2019 <sup>101</sup>	Systematic review with different PICO
Du 2011 <sup>102</sup>	Not review population
Dworkin 2002 <sup>103</sup>	Unclear comparison
Elbers 2018 <sup>104</sup>	Systematic review with different PICO
Ersek 2003 <sup>107</sup>	Incorrect study design
Ersek 2004 <sup>105</sup>	Study protocol
Fedoroff 2014 <sup>108</sup>	Incorrect study type (not randomised study)
Ferwerda 2017 <sup>109</sup>	Incorrect interventions
Feuerstein 1993 <sup>110</sup>	Incorrect interventions
Field 2014 <sup>111</sup>	Not review population
Flor 1992 <sup>112</sup>	Incorrect interventions
Fontaine 2010 <sup>113</sup>	Incorrect interventions (no psychological component) and comparator (control group received group education, Q&A and social support)
Forbes 2020 <sup>114</sup>	Incorrect intervention
Foster 2007 <sup>115</sup>	Incorrect interventions
Friedrich 2005 <sup>116</sup>	Inappropriate comparison
Frost 1995 <sup>117</sup>	Incorrect comparator (back school)
Galdas 2015 <sup>118</sup>	Not review population
Ganderton 2016 <sup>119</sup>	Study protocol
Gardiner 2017 <sup>120</sup>	Study protocol
Garland 2013 <sup>121</sup>	Incorrect interventions
Garschagen 2015 <sup>122</sup>	Not review population
Garza-villarreal 2017 <sup>123</sup>	Incorrect interventions
Gaskell 2016 <sup>124</sup>	Incorrect interventions
Gaskell 2017 <sup>125</sup>	Incorrect interventions
Gastfriend 2011 <sup>126</sup>	Incorrect interventions
Gaston-johansson 1996 <sup>127</sup>	Incorrect interventions

Study	Exclusion reason
Gatchel 2003 <sup>130</sup>	Not guideline condition. Acute pain
Gatchel 2006 <sup>129</sup>	Systematic review with different PICO
Gater 2015 <sup>131</sup>	Not review population
Gatt 2016 <sup>132</sup>	Not review population
Gatti 2016 <sup>133</sup>	Not review population
Gausel 2019 <sup>134</sup>	Incorrect intervention (no psychological component)
Gavish 2015 <sup>135</sup>	Incorrect interventions
Gaw 1975 <sup>136</sup>	Incorrect interventions
Gay 2007 <sup>137</sup>	Incorrect interventions
Gaynor 2007 <sup>138</sup>	Incorrect interventions
Geisser 2010 <sup>139</sup>	Incorrect study design
Geissner 1994 <sup>140</sup>	Not guideline condition
Geraets, 2006 <sup>141</sup>	Incorrect interventions (no psychological component)
Geraets, 2005 <sup>142</sup>	Incorrect interventions (no psychological component)
Giannotti 2014 <sup>143</sup>	Incorrect interventions (no psychological component)
Giusti 2017 <sup>144</sup>	Systematic review with different PICO
Glombiewski, 2010 <sup>145</sup>	Incorrect interventions (no physical component; biofeedback only)
Glomsrod, 2001 <sup>146</sup>	Unclear population (at least one episode of LBP in the previous year)
Goldthorpe 2017 <sup>147</sup>	Incorrect interventions
Gowans 1999 <sup>148</sup>	Not guideline condition. Not review population. No extractable data
Greco, 2004 <sup>149</sup>	Incorrect interventions (no physical component)
Greenberg 2019 <sup>150</sup>	Incorrect study design (non-randomised)
Greitemann 2006 <sup>151</sup>	Incorrect interventions
Guarino 2018 <sup>152</sup>	Inappropriate comparison
Gustavsson 2011 <sup>153</sup>	Inappropriate comparison
Haas 2005 <sup>154</sup>	Incorrect interventions (no physical component)
Haines 2008 <sup>155</sup>	Incorrect interventions: patient education
Haldorsen, 1998 <sup>156</sup>	Incorrect population (sick-listed for 8 weeks - 6 months and average duration not reported)
Hammond 2006 <sup>157</sup>	Inappropriate comparison: Relaxation sessions
Haugmark 2018 <sup>159</sup>	Study protocol
Hauser 2009 <sup>160</sup>	Systematic review with different PICO
Heapy 2015 <sup>161</sup>	Incorrect study design
Heapy 2017 <sup>162</sup>	Incorrect study design
Helstrom 2018 <sup>163</sup>	Incorrect interventions (telephone based; no physical component)
Heymans, 2006 <sup>165</sup>	Incorrect interventions (no psychological component)
Hirase 2018 <sup>166</sup>	Incorrect interventions
Hofmann 2013 <sup>167</sup>	Study protocol
Hopman-Rock, 2000 <sup>168</sup>	Incorrect interventions (education only 'psychological' component)
Hsu 2010 <sup>169</sup>	Incorrect interventions
Hudson 2010 <sup>170</sup>	Inappropriate comparison: educational advice and manual therapy
Hurley 2007 <sup>172</sup>	Incorrect interventions (insufficient psychological component)
Hurley 2012 <sup>171</sup>	Incorrect interventions (insufficient psychological component)
Hutting 2013 <sup>174</sup>	Not review population
Ibrahim 2019 <sup>175</sup>	Study protocol

Study	Exclusion reason
Itz 2016 <sup>176</sup>	Incorrect study design
Janke 2011 <sup>177</sup>	No relevant outcomes
Jaracz 2016 <sup>178</sup>	Incorrect study design
Jarrell 2005 <sup>179</sup>	Incorrect study design
Jatoi 2017 <sup>180</sup>	Incorrect interventions
Jawahar 2013 <sup>182</sup>	Not review population
Jawahar 2014 <sup>181</sup>	Not review population
Jay 2014 <sup>184</sup>	Incorrect interventions
Jay 2016 <sup>183</sup>	Incorrect study design
Jensen, 2005 <sup>185</sup>	No relevant outcomes
Johnson 2007 <sup>188</sup>	Incorrect interventions (insufficient information on programme content; further details given in an appendix which was not available)
Johnston 2010 <sup>189</sup>	Incorrect interventions
Jongen 2017 <sup>190</sup>	Incorrect interventions
Kaapa 2006 <sup>191</sup>	Inappropriate comparison
Kahan 2014 <sup>192</sup>	Incorrect study design
Kanai 2017 <sup>193</sup>	Incorrect interventions
Keays 2016 <sup>194</sup>	Incorrect study design
Keel 1998 <sup>195</sup>	Inappropriate comparison (relaxation sessions led by psychiatrist and physio)
Keller 1997	Incorrect intervention (insufficient psychological component)
Kenny 2004 <sup>196</sup>	Incorrect study design
Khan 2014 <sup>197</sup>	Inappropriate comparison
Kim 2015 <sup>198</sup>	Inappropriate comparison
King 2002 <sup>199</sup>	Incorrect intervention (not a PMP; education + exercise interventions)
Kitahara 2006 <sup>200</sup>	Incorrect study design
Kole-Snijders 1999 <sup>201</sup>	No extractable outcomes and incorrect intervention
Koutantji 1999 <sup>202</sup>	Conference abstract
Kroenke 2019 <sup>203</sup>	Incorrect interventions; inappropriate comparison
La Cour 2015	Incorrect intervention (insufficient physical component)
Lamb 2010 <sup>208</sup>	Incorrect interventions
Lamb 2010 <sup>207</sup>	Incorrect interventions
Lamb 2010 <sup>206</sup>	Article not in English
Lambeek 2010 <sup>209</sup>	Incorrect interventions (insufficient psychological component)
Lambeek 2010 <sup>210</sup>	Incorrect interventions (insufficient psychological component)
Lang 2003 <sup>211</sup>	Incorrect study design (non-randomised)
Lange 2011 <sup>212</sup>	Article not in English
Lasser 2016 <sup>213</sup>	Not review population
Lefort 1998 <sup>214</sup>	Incorrect interventions
Lera 2009 <sup>216</sup>	Inappropriate comparison
Lemstra 2005 <sup>215</sup>	Incorrect interventions: 'old' back school vs 'new' back school
Liedl 2011 <sup>217</sup>	Not review population (traumatised refugees with PTSD and chronic pain)
Linden 2014 <sup>219</sup>	Inappropriate comparison. inpatient treatment + CBT vs. inpatient treatment + occupational therapy

Study	Exclusion reason
Lindell, 2008 <sup>218</sup>	Not review population (subacute and chronic pain and proportions not reported)
Linton 1984 <sup>221</sup>	Incorrect interventions
Linton, 2005 <sup>220</sup>	Incorrect interventions (CBT + physical therapy intervention; not a PMP)
Lonn, 1999 <sup>222</sup>	Incorrect interventions (no psychological component)
Lopez 2020 <sup>223</sup>	Inappropriate comparison
Luedtke 2015 <sup>224</sup>	Inappropriate comparison
Lugo 2016 <sup>225</sup>	Incorrect interventions
Mangels 2009 <sup>226</sup>	Inappropriate comparison
Mannerkorpi 2009 <sup>227</sup>	Inappropriate comparison (education programme)
Mannerkorpi 2000 <sup>228</sup>	Incorrect intervention (not a PMP)
Marques 2014 <sup>229</sup>	Incorrect interventions
Marquina 2012 <sup>230</sup>	Incorrect interventions
Mars 2013 <sup>231</sup>	Incorrect interventions
Marta 2010 <sup>232</sup>	Incorrect interventions
Martin 2000 <sup>233</sup>	No relevant outcomes
Martin 2013 <sup>234</sup>	Not review population: no cited papers relevant
Martin 2014 <sup>235</sup>	Incorrect interventions
Mazzuca, 2004 <sup>239</sup>	Incorrect interventions (no psychological component)
Mcdonough 2008 <sup>241</sup>	Incorrect interventions
Mcknight 2010 <sup>242</sup>	Not review population
Mecklenburg 2018 <sup>243</sup>	Incorrect intervention: not led by peer or professional. No psychological component as 'CBT' is educational reading only. <a href="https://www.hingehealth.com/careers">https://www.hingehealth.com/careers</a>
Meng 2011 <sup>245</sup>	Not review population
Merlin 2018 <sup>246</sup>	Incorrect interventions. no physical component
Millegan 2019 <sup>247</sup>	Incorrect study design (non-randomised)
Milosavljevic 2015 <sup>249</sup>	Inappropriate comparison
Mishra, 2000 <sup>250</sup>	Not review population (pain, clicking, popping, or locking of the jaw or have received a past diagnosis of TMD)
Mitchell 1994 <sup>251</sup>	No relevant outcomes
Moffett 1999 <sup>252</sup>	Incorrect interventions
Monticone 2014 <sup>254</sup>	Inappropriate comparison
Monticone 2017 <sup>253</sup>	Inappropriate comparison
Moore 2000 <sup>256</sup>	Incorrect interventions
Moore 2019 <sup>255</sup>	Not review population
Moseley 2002 <sup>257</sup>	Incorrect interventions: Physio and exercise education only
Nazzal 2013 <sup>259</sup>	Inappropriate comparison
Nct 2017 <sup>260</sup>	Citation only
Nct 2018 <sup>261</sup>	Citation only
Nevedal 2013 <sup>262</sup>	Incorrect study design (nonrandomised study)
Nicholas 2017 <sup>264</sup>	Inappropriate comparison
Nielssen 2019 <sup>266</sup>	Secondary analysis of an excluded study
Nielssen 2019 <sup>265</sup>	Incorrect intervention (insufficient physical component)
Nordin 2016 <sup>267</sup>	Inappropriate comparison
Norrefalk 2008 <sup>268</sup>	Incorrect study design (non-randomised)

Study	Exclusion reason
Olason 2004 <sup>269</sup>	Incorrect study design
Olason 2018 <sup>270</sup>	Incorrect interventions
Oldenmenger 2011 <sup>271</sup>	Incorrect interventions
Oliver 2001 <sup>272</sup>	Systematic review with different PICO
Paganini 2019 <sup>273</sup>	Incorrect interventions
Paolucci 2016 <sup>274</sup>	Incorrect interventions
Parker 2016 <sup>275</sup>	Incorrect interventions (lack of applicability)
Patrick 2000 <sup>276</sup>	Unavailable thesis
Patrick 2004 <sup>277</sup>	Incorrect study design (non-randomised)
Perez-Aranda 2019 <sup>278</sup>	Incorrect interventions
Peters 1991 <sup>279</sup>	Inappropriate comparison
Petrozzi 2019 <sup>281</sup>	Incorrect comparator (manual therapy plus exercise)
Philips 1987 <sup>282</sup>	Incorrect interventions (CBT; education only)
Pieper 2018 <sup>283</sup>	Incorrect interventions
Pimm 2019 <sup>284</sup>	Incorrect study design (non-randomised)
Pires 2015 <sup>285</sup>	Inappropriate comparison
Pradhan 2007 <sup>286</sup>	Not review population (rheumatoid arthritis; no mention of pain)
Redondo 2004 <sup>287</sup>	Inappropriate comparison (physical exercise vs. CBT)
Ribeiro, 2008 <sup>288</sup>	Incorrect interventions (no psychological component)
Richards 2002 <sup>289</sup>	Inappropriate comparison (exercise)
Richardson 2014 <sup>290</sup>	Not review population
Riddle 2012 <sup>291</sup>	Not review population
Ris 2016 <sup>292</sup>	Inappropriate comparison
Rizzo 2018 <sup>293</sup>	Inappropriate comparison. Incorrect interventions
Ronzi 2017 <sup>294</sup>	Inappropriate comparison
Ruehlman 2012 <sup>295</sup>	Incorrect interventions (computer education software)
Santaella da fonseca lopes da sousa 2009 <sup>296</sup>	Incorrect interventions
Scascighini 2008 <sup>297</sup>	Systematic review with different PICO
Schmidt 2011 <sup>298</sup>	Incorrect intervention (insufficient physical component)
Schultz 2018 <sup>299</sup>	Inappropriate comparison
Schweikert 2006 <sup>300</sup>	Inappropriate comparison
Sephton 2007 <sup>301</sup>	Incorrect intervention (insufficient physical component)
Skouen 2002 <sup>303</sup>	No relevant outcomes
Skouen 2006 <sup>302</sup>	No relevant outcomes
Smeets 2009 <sup>304</sup>	Inappropriate comparison
Soukup, 1999 <sup>309</sup>	Incorrect interventions (no psychological component)
Spinhoven 2004 <sup>310</sup>	Post-hoc analysis of Kole-Snijnders
Steiner 2013 <sup>311</sup>	Incorrect study design (non-randomised)
Storro 2004 <sup>312</sup>	No relevant outcomes
Stowell 2007 <sup>313</sup>	Not guideline population (acute pain of jaw)
Strong 1998 <sup>314</sup>	Inappropriate comparison
Subramanian 1988 <sup>315</sup>	Incorrect interventions; Incorrect study design (non-randomised)
Taimela 2000 <sup>316</sup>	Inappropriate comparison (insufficient psychological component)
Takai 2015 <sup>317</sup>	Systematic review with different PICO
Taylor 2016 <sup>320</sup>	Incorrect interventions (insufficient physical component)

Study	Exclusion reason
Taylor 2018 <sup>322</sup>	Incorrect interventions
Taylor 2016 <sup>321</sup>	Unpublished
Theadom 2015 <sup>323</sup>	Systematic review with different PICO
Thielke 2015 <sup>324</sup>	Incorrect interventions (no physical component)
Tierce-hazard 2014 <sup>325</sup>	Commentary
Toomey 2015 <sup>326</sup>	Incorrect interventions
Triano 1995 <sup>327</sup>	Inappropriate comparison
Tse 2012 <sup>329</sup>	Unclear population (duration of pain not specified)
Tse 2013 <sup>328</sup>	Incorrect study design: quasi RCT
Tse 2014 <sup>331</sup>	Study protocol
Tse 2016 <sup>330</sup>	Incorrect study design: quasi RCT
Turner 1990 <sup>334</sup>	Incorrect interventions
Turner 2018 <sup>333</sup>	Inappropriate comparison
Turner-stokes 2003 <sup>332</sup>	Inappropriate comparison (group v individual PMP)
Van der maas 2015 <sup>335</sup>	Incorrect interventions
Van koulil 2011 <sup>338</sup>	No relevant outcomes
van Santen, 2002 <sup>340</sup>	Incorrect interventions (not a PMP)
Verra 2018 <sup>341</sup>	Inappropriate comparison (tailored PMP vs standard PMP)
Vlaeyen 1995 <sup>342</sup>	Inappropriate comparison
Vlaeyen 1996 <sup>343</sup>	Incorrect interventions (insufficient detail on exercise component)
Von Korff 2005 <sup>344</sup>	Incorrect interventions (2 outpatient consultations; not a PMP)
Wells-federman 2002 <sup>346</sup>	Incorrect study design (non-randomised)
Weissbecker, 2002 <sup>345</sup>	No relevant outcomes
Wilson 2015 <sup>349</sup>	Incorrect interventions (no physical component)
Wilson 2017 <sup>348</sup>	Incorrect study design (literature review)
Wippert 2020 <sup>350</sup>	Unclear population (unclear pain duration)
Wong 2011 <sup>351</sup>	Incorrect interventions
Wylde 2014 <sup>352</sup>	No relevant outcomes
Yip 2007 <sup>353</sup>	Incorrect interventions (insufficient psychological component)
Yip 2008 <sup>354</sup>	Incorrect interventions (insufficient psychological component)
Zale 2018 <sup>355</sup>	Incorrect interventions
Zhang 2014 <sup>357</sup>	Inappropriate comparison
Zhang 2019 <sup>356</sup>	Systematic review with different PICO

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## 1.2 Excluded health economic studies

3 **Table 11: Studies excluded from the health economic review**

Reference	Reason for exclusion
McBeth 2012 <sup>240</sup>	This study was assessed as partially applicable with potentially serious limitations. However, other available evidence was of greater applicability and methodological quality and therefore this study was selectively excluded. This is the same study as the included economic evaluation but has shorter follow up period.

Reference	Reason for exclusion
Van Eijk-Hustings 2016 <sup>336</sup>	This study was assessed as partially applicable with potentially serious limitations. It has methodological limitations as it is a cost comparison study, based on an RCT included in the clinical review but also using additional data as it takes a period from diagnosis to after the interventions (which includes before the interventions) and compares costs across the interventions. So slightly odd methodology and unclear that the resource use would only be related to the post intervention period.
Van Eijk-Hustings 2013 <sup>337</sup>	This study was assessed as partially applicable with potentially serious limitations. However, other available evidence was of greater applicability as this was a cost consequences analysis that reported only costs and QoL separately.

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## 2 **Appendix J: Research recommendations**

### J.1 **Pain management programmes**

4 **Research question: What are the optimum characteristics of a clinically and cost**  
5 **effective pain management programme for people aged 16 years and over with**  
6 **chronic pain?**

7 **Why this is important:**

8 A review of pain management programmes raises the difficulty of defining what a pain  
9 management programme is. For the guideline evidence review, the committee made  
10 distinctions between different components of programmes and agreed that any definition has  
11 to work clinically. Agreement was reached to define a pain management programme as any  
12 intervention that has two or more components including a physical and a psychological  
13 component with some interaction/coordination between the two delivered by trained people.

14 Evidence from many studies identified showed a very small improvement in quality of life with  
15 pain management programmes led by professionals compared with usual care or waiting list  
16 controls. However, benefits to quality of life were not consistent across studies. Quality of life  
17 includes physical function and psychological distress, but there were no benefits observed  
18 for these outcomes considered singly.

19 Complexity of patient needs, and programme differences, means that it was not possible to  
20 identify what treatment (with programme variables including condition being treated, duration,  
21 content, intensity, structure and aims) is most effective. The studies included in the review  
22 varied widely from recruiting people with low levels of distress and disability to those with  
23 more complex needs. The committee acknowledged that due to the individual nature of each  
24 chronic pain experience, it is likely that pain management programme format may need to be  
25 tailored to subgroups of people.

26 The evidence on cost of pain management programmes was very weak so the committee  
27 could not comment on this but they did discuss the relative cost compared with  
28 pharmacological interventions and considered them to be at least as favourable.

29 The committee decided to make a research recommendation to determine what makes some  
30 programmes more effective than others; to investigate the variance already existing in this  
31 field. The committee acknowledge it is complex to combine and analyse for sources of  
32 variance, including heterogeneity of subjects, but methods such as comparative meta-

1 analysis, or re-analysis of existing data from all relevant existing trials could provide useful  
2 data to inform future guidance.

3 **Criteria for selecting high-priority research recommendations:**

<b>PICO question</b>	Population: Adults (aged >16) with Chronic Pain Intervention(s): Pain Management Programmes Comparison: Usual Care Outcome(s): Follow IMMPACT recommendations
<b>Importance to patients or the population</b>	Complexity of patient needs, and programme differences, means that it is difficult to identify what programme variables, including condition being treated, duration, content, intensity, structure and aims, is best for a particular patient. If this could be determined, it would have the potential to improve quality of life for people with chronic primary pain.
<b>Relevance to NICE guidance</b>	This research will reduce the existing uncertainty regarding the effectiveness and cost-effectiveness of pain management programmes and hopefully enable future guidelines to make recommendations on pain management programmes.
<b>Relevance to the NHS</b>	Clear recommendations for <u>or against</u> pain management programmes will offer clinicians guidance on best care for chronic pain. Pain management programmes can require considerable resource and therefore ensuring only the most effective programmes are used would be an important way of making best use of this resource. A recommendation is likely to require staff training and venues to host programmes.
<b>National priorities</b>	Yes
<b>Current evidence base</b>	Evidence from many studies identified in the review in this guideline showed a very small improvement in quality of life with pain management programmes led by professionals compared with usual care or waiting list controls. However, benefits to quality of life were not consistent across studies. Quality of life includes physical function and psychological distress, but there were no benefits observed for these outcomes considered singly.  Plenty of research exists already on pain management programmes but the trials are usually small and it is complex to combine and analyse for sources of variance.
<b>Equality</b>	Pain management programmes tend to exclude participants where language or other conditions are present, for example homelessness, significant psychological co-morbidities etc. Research to explore ways to reduce access inequalities is needed.
<b>Study design</b>	Individual patient data meta-analysis, including meta-regression, reanalysing individual data from all relevant existing trials, or larger higher-powered trials. Long term follow up is required to demonstrate effectiveness beyond the duration of the programmes.
<b>Feasibility</b>	The methods mentioned above would require appropriate resource to enable them to answer the research recommendation, however an individual patient data meta-analysis is feasible if trial data from existing studies are available. Given the importance of this intervention in terms of potential clinical effectiveness as well as the unknown cost effectiveness, this research represents a high priority.
<b>Other comments</b>	The committee decided to make a research recommendation to determine what makes some programmes more effective than others – to investigate the variance already existing in this field. It is complex to combine and analyse for sources of variance, including heterogeneity of subjects, but methods such as comparative meta-analysis, or re-analysis of existing data from all relevant existing trials could provide useful data to inform future guidance.
<b>Importance</b>	High: the research is essential to inform future updates of key recommendations in the guideline.



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## Appendix K: MIDs for continuous outcomes

**Table 12: MID for continuous outcomes (0.5 x SD): Professional led pain or combination of professional and peer led management programmes vs. standard care/waiting list**

Outcomes	MID
Quality of life SF12 Physical component final values (high is good outcome) ≤12 weeks. Scale from: 0 to 100.	5.54
Quality of life SF12 Mental component final values (high is good outcome) ≤12 weeks. Scale from: 0 to 100.	5.64
Quality of life SF12 Physical component final values (high is good outcome) >12 weeks. Scale from: 0 to 100.	4.55
Quality of life SF12 Mental component final values (high is good outcome) >12 weeks. Scale from: 0 to 100.	4.88
Quality of life FIQ final values (high is poor outcome) ≤12 weeks. Scale from: 0 to 100.	7.68
Quality of life FIQ final values (high is poor outcome) >12 weeks. Scale from: 0 to 100.	8.25
Quality of life EQ-5D VAS (high is good outcome), final values ≤12 weeks. Scale from: 0 to 100.	10.05
Quality of life EQ-5D VAS (high is good outcome), final values >12 weeks. Scale from: 0 to 100.	11.43
Quality of life (inpatient PMP) FIQ (high is poor outcome) final values ≤12 weeks. Scale from: 0 to 100.	73.17
Physical function Roland Morris Disability Questionnaire (high is poor outcome), final values ≤12 weeks. Scale from: 0 to 24.	2.7
Physical function Western Ontario and McMaster Universities Osteoarthritis Index (high is poor outcome) change scores ≤12 weeks. Scale from: 0 to 68.	4.87
Physical function FIQ physical function subscale final values (high is poor outcome) ≤12 weeks. Scale from: 0 to 10.	1.04
Physical function 6 minute walk test final values and change scores ≤12 weeks	45.13
Physical function 10 minute walk test final values and change scores ≤12 weeks	91.5
Physical function Short musculoskeletal function assessment dysfunction index ≤12 weeks. Scale from: 34-170.	9.05

Outcomes	MID
Physical function Roland Morris Disability Questionnaire final values (high is poor outcome) >12 weeks. Scale from: 0 to 24.	2.8
Physical function Western Ontario and McMaster Universities Osteoarthritis Index final values (high is poor outcome) >12 weeks. Scale from: 0 to 68.	8.8
Physical function FIQ physical function subscale final values (high is poor outcome) >12 weeks. Scale from: 0 to 10.	1.04
Physical function Short musculoskeletal function assessment dysfunction index >12 weeks. Scale from: 34-170.	10.15
Physical function (inpatient PMP) 10 minute walk test, final values ≤12 weeks	91.5
Psychological distress Depression Anxiety Stress Scale change scores (high is poor outcome) ≤ 12 weeks. Scale from: 0 to 42.	5.5
Psychological distress BDI (0-63), Geriatric Depression Scale (0-30), Patient health questionnaire depression (0-27) and FIQ depression subscale (0-10), high is poor outcome, final values ≤12 weeks	0.5 (SMD)
Psychological distress FIQ anxiety subscale 0-10, Impact of Rheumatic Diseases on General Health and Lifestyle anxiety scale 10-40 and State-Trait Anxiety Inventory 20-80 (high is poor outcome), final values ≤12 weeks	5.85
Psychological distress Geriatric Depression Scale 0-30, BDI 0-63, HADS depression 0-21, FIQ depression subscale 0-10, Patient health questionnaire depression 0-27 (high is poor outcome), final values >12 weeks	0.5 (SMD)
Psychological distress HADS anxiety 0-21, FIQ anxiety subscale 0-10 and Impact of Rheumatic Diseases on Health and Lifestyle anxiety scale 10-40 (high is poor outcome) final values >12 weeks	0.5 (SMD)
Psychological distress GAD-10 anxiety change scores (high is poor outcome) >12 weeks. Scale from: 0 to 10.	3.09
Psychological distress Kessler-10 psychological distress scale final values (high is poor outcome) >12 weeks. Scale from 10 to 50.	3.52
Psychological distress (inpatient PMP) General Health Questionnaire (high is poor outcome) final values ≤12 weeks. Scale from: 0 to 60.	28.23
Psychological distress (inpatient PMP) BDI (high is poor outcome) final values ≤12 weeks. Scale from: 0 to 63.	3.21
Psychological distress (inpatient PMP) State-Trait Anxiety Inventory (high is poor outcome), final values ≤12 weeks. Scale from: 20 to 80.	5.85
Pain interference BPI interference scale 0-10 and PROMIS pain interference 8-40 final values (high is poor outcome) ≤12 weeks.	SMD 0.5

Outcomes	MID
Pain interference BPI interference scale 0-10 and PROMIS pain interference 8-40 final values (high is poor outcome) >12 weeks.	0.5
Pain interference (inpatient PMP) VAS (high is poor outcome) final values ≤12 weeks. Scale from: 0 to 100.	8.6
Self-efficacy Pain Self-Efficacy Questionnaire final values and change scores (high is good outcome) ≤12 weeks. Scale from: 0 to 60.	5.77
Self-efficacy Arthritis Self-Efficacy Scale change scores (high is good outcome) ≤12 weeks	0.31
Self-efficacy Pain Self-Efficacy Questionnaire final values and change scores (high is good outcome) >12 weeks. Scale from: 0 to 60.	5.75
Self-efficacy Arthritis Self Efficacy Scale final values (high is good outcome) >12 weeks	0.45
Self-efficacy (inpatient PMP) Pain Self-Efficacy Questionnaire (high is good outcome), final values ≤12 weeks. Scale from: 0 to 60.	4.6
Self-efficacy (inpatient PMP) Arthritis Self-Efficacy Scale pain subscale (high is good outcome) final values ≤12 weeks. Scale from: 10 to 100.	81.88
Pain reduction NRS and VAS final values and change scores (high is poor outcome) ≤12 weeks. Scale from: 0 to 10.	1.1
Pain reduction NRS and VAS final values and change scores (high is poor outcome) >12 weeks. Scale from: 0 to 10.	1.03
Pain reduction (inpatient PMP) VAS (high is bad outcome) final values ≤12 weeks. Scale from: 0 to 10.	1.04
Sleep Chronic Pain Sleep Index (0-10, high is good outcome), MOS Sleep scale (12-71, high is good outcome) and FIQ unrefreshed sleep subscale (0-10, high is poor outcome, scale inverted for analysis), final values ≤12 weeks	0.5 (SMD)
Sleep Chronic Pain Sleep Index (0-10, high is good outcome), MOS Sleep scale (12-71, high is good outcome), Sleep Scale (0-20, high is poor outcome, scale inverted for analysis) and FIQ unrefreshed sleep subscale (0-10, high is poor outcome, scale inverted for analysis), final values >12 weeks	0.5 (SMD)
Use of healthcare services Mean number of GP contacts within previous 2 months ≤12 weeks	1.04
Use of healthcare services Mean number of medical specialist contacts within previous 2 months ≤12 weeks	0.35
Use of healthcare services Mean number of physiotherapist contacts within previous 2 months ≤12 weeks	2.42
Use of healthcare services Mean number of other paramedical professional contacts within previous 2 months ≤12 weeks	1.39

Outcomes	MID
Use of healthcare services Mean number of GP contacts within previous 2 months >12 weeks	1.04
Use of healthcare services Mean number of medical specialist contacts within previous 2 months >12 weeks	0.35
Use of healthcare services Mean number of physiotherapist contacts within previous 2 months >12 weeks	2.42
Use of healthcare services Mean number of other paramedical professional contacts within previous 2 months >12 weeks	1.39
Use of healthcare services Mean number of MD and/or ED visits for pain care >12 weeks	28.15
Use of healthcare services Mean number of primary care visits within the previous week >12 weeks	1.95
Use of healthcare services Mean number of emergency department visits within the previous week >12 weeks	0.3
Use of healthcare services Mean number of specialist appointment visits within the previous week >12 weeks	0.5
Use of healthcare services Mean number of diagnostic imaging visits within the previous week >12 weeks	0.45

**Table 13: MIDs for continuous outcomes (0.5 x SD): Peer led pain management programmes vs. standard care/waiting list**

Outcomes	MID
Physical function Roland Morris Disability Questionnaire final values (high is bad outcome) ≤12 weeks. Scale from: 0 to 24.	2.1
Physical function Roland Morris Disability Questionnaire final values (high is bad outcome) >12 weeks. Scale from: 0 to 24.	2.3
Psychological distress Pain catastrophising scale (high is bad outcome) final values ≤12 weeks. Scale from: 0 to 52.	5.45
Psychological distress Pain catastrophising scale (high is bad outcome) final values >12 weeks. Scale from: 0 to 52.	5.55
Self-efficacy Arthritis Self Efficacy Scale (high is good outcome) final values ≤12 weeks. Scale from: 5 to 50.	4.5

<b>Outcomes</b>	<b>MID</b>
Self-efficacy Arthritis Self Efficacy Scale (high is good outcome) final values >12 weeks. Scale from: 5 to 50.	5.2
Pain reduction VAS (high is poor outcome) final values ≤12 weeks. Scale from: 0 to 10.	8
Pain reduction VAS (high is poor outcome) final values >12 weeks. Scale from: 0 to 10.	9.2
Use of healthcare services Total healthcare costs in Euros	1592.10