

Evidence-based Practice Center Technical Brief Protocol

Project Title: *Technical Brief - Multidisciplinary Pain Programs for Chronic Non-Cancer Pain*

I. Background and Objectives for the Technical Brief

Chronic non-cancer pain:

Chronic pain symptoms cause major medical and socioeconomic problems in industrialized countries and are the most common cause of long-term disability in middle aged people.¹ The total estimated healthcare costs to Americans are more than \$70 billion per year. Pain (of various types) is responsible for a half million lost workdays and costs more than \$150 billion annually in health care, disability, and related expenses in the United States.² The American Pain Society estimates that 9 percent of the United States adult population suffers from moderate to severe, non-cancer related chronic pain.³ However, epidemiological research has suggested that the prevalence of chronic pain varies, depending on how the survey questions are asked and how chronic pain is defined. Researchers have estimated that from 10 to 20 percent of adults report having chronic pain when defined as persistent pain lasting at least 3 months.² People who are 50 years of age and older are twice as likely to have been diagnosed with chronic pain when compared to people who are younger.² The 2000 U.S. Census projects that, by the year 2030, about 20 percent of the population will be 65 years of age or older. Chronic pain is not only prevalent, it is costly. Consequently, chronic pain management will gain greater public interest, and continued research in this field will be an important investment for the future health care of aging Americans.

Current medical practice as related to management of chronic pain:

Chronic pain is best understood via the biopsychosocial model, which emphasizes the complex and dynamic interaction between physiological, psychological, and social factors that serve to perpetuate and potentially worsen the pain experience. Chronic pain is a disease of the whole person. The traditional biomedical model promises a cure, or at least elimination of a significant amount of pain. Yet, there are currently no definitive cures for the most prevalent chronic pain syndromes, such as back pain, upper extremity pain disability, peripheral neuropathies, et cetera. The biopsychosocial model is more appropriate than the biomedical model for disease states for which the cause is not clearly defined.⁴ The biopsychosocial model, in contrast to the biomedical model, assumes that no one can “cure” patients of all the ills associated with their pain conditions. Rehabilitation, rather than cure, is viewed as the most appropriate therapeutic objective. The goal of chronic pain treatment has evolved from eliminating pain to managing pain to an extent that the patient’s independence is restored and overall quality of life improved.

Various treatment modalities have evolved to deal with the many aspects of chronic pain; these modalities include the following.⁵

- Pharmacologic treatment, such as nonsteroidal anti-inflammatory drugs (NSAIDs), antidepressants (primarily tricyclic compounds), anticonvulsants, ergotamine, antiemetics, serotonin receptor agonists, angiotensin-converting enzyme (ACE) inhibitors, inhibitors, β -blockers, calcium channel blockers, opioids, and sedative-hypnotics. One or more of these medications may be indicated, for example, for arthritic, neuropathic or headache pain.
- Physical therapy, including transcutaneous electronic nerve stimulation (TENS).
- Occupational therapy.
- Behavioral/psychological therapy, including: pharmacological treatment for depression and anxiety, stress management training, relaxation training, cognitive behavioral therapy, operant therapy, and biofeedback.

Source: www.effectivehealthcare.ahrq.gov

Published Online: July 28, 2010



- Vocational rehabilitation and disability management.
- Adjunctive treatment modalities, such as: trigger point injections, including muscle injections with botulinum toxin (Botox[®]); prolotherapy; nerve blockade procedures, such as sympathetic or epidural steroid injections; and acupuncture, and other complementary and alternative medical therapies.
- More invasive medical procedures, including: implantable infusion pumps or spinal stimulators, radiofrequency denervation, intradiscal electrothermal therapy, and spine surgery.

The multiplicity of treatment options has added complexity to health care decisionmaking for patients, providers, and payers. In addition, although there have long been guidelines and consensus opinion documents for treating acute and cancer pain, such guidance on therapy or combination of therapies for managing chronic noncancer pain has been lacking.²

Multidisciplinary pain programs (MPP) currently exist as an option for some patients. There is generally a medical, physical, and behavioral component of multidisciplinary care, and there is often a vocational component as well.⁵ Although multidisciplinary pain programs exist as an option for some patients, these programs have been decreasing since the 1990s after an initial proliferation in the 1980s. Third party payers felt these programs were expensive and offered limited clinical benefits; thus they refused to utilize them, causing many MPPs to close.²

The care of patients with chronic non-cancer pain represents an important variation in clinical care and an important controversy in what constitutes appropriate clinical care. The APS states that:

Pain is maintained by multiple mechanisms; and its proper management can vary on a case by case basis. Currently, only a relatively small subset of treatments is easily accessible and appropriately reimbursed. While this subset may be wholly appropriate for some cases, clinical pain services need to be able to offer broader resources in order to address the needs of patients in pain as a population.

Specifically, greater access to and augmented reimbursement for multidisciplinary pain care is needed. Such approaches include (but are not limited to): psychological and behavioral approaches targeting pain and function, physical and occupational rehabilitation, interventional approaches, traditional medical approaches, and long-term care coordination.

Despite great scientific strides in the past decade, we are far from accomplishing a satisfactory impact on this enormous world-wide health problem. Too many people suffer daily, severe pain. Much more needs to be done to meet these challenges and to increase public awareness of them.⁶

Objective of technical brief:

The objective of this Technical Brief is to present the “lay of the land” and describe what types of MPPs (i.e., what combination of components) have been studied and, in each case, what was the comparison treatment (if there was a comparison treatment). We will describe the study population, including a focus on whether treated groups had failed prior therapy and how the comparison treatment group (if any) relates to the study treatment group. We will lay out the variation in outcomes assessed, and we will assess variation in how each outcome was measured. We will integrate information obtained from the published literature, grey literature, and key informants and by doing so will provide a structure for improved research on MPPs in the future.

II. Guiding Questions

The questions below will guide the data collection for this technical brief. Question 1 will lay the groundwork for the review by examining MPPs in the context of comprehensive pain programs in general. Multidisciplinary and interdisciplinary treatment models are part of a continuum of medical care ranging from unimodal patient care to completely integrative care. Models of patient care in order of increasing comprehensiveness and collaboration include: unimodal, parallel, collaborative, coordinated, multidisciplinary, interdisciplinary, and integrative approaches. The interdisciplinary approach to pain management is an extension of a more general multidisciplinary approach; both models address the multifactorial causes of pain.⁷ Question 2 will provide important background information on contextual factors affecting MPPs – such as reimbursement, current availability of such programs, and availability of practice guidelines. These are issues that contribute to variation in how chronic pain is managed. With the background provided by Questions 1 and 2, Question 3 will focus our investigation on the current evidence evaluating MPPs, using a specific operational definition of MPP. The variation across studies in how MPP is defined has contributed to confusion in this area of research; thus, a consistent operational definition of MPP is fundamental to this review. Given a consistent definition of MPP, we will then describe: what populations were studied, the detailed components of the treatment program, and the health outcomes and harms that were measured in these studies. For studies in which a comparison treatment group was used, it will be particularly important to describe how the comparison group relates to the study treatment group with regard to any prior pain therapy. After reviewing the evidence to obtain a “lay of the land” for this body of literature, in Question 4 we will explore the implications of further diffusion of MPPs, identify ethical issues, key areas of uncertainty and implications for research.

1. The existing technology:

What different types of comprehensive approaches to chronic pain management have been proposed or used in clinical practice?

- A. What are the theoretical advantages/disadvantages of these approaches when compared to current practice?
- B. What are the potential safety issues?

2. The context in which the technology is used:

- A. How widely available are multidisciplinary pain programs (MPPs); how widely are they used?
- B. What kind of staffing and what type of training is required or desirable?
- C. What is the role of accreditation with MPPs?
- D. What are other important contextual issues? (e.g. third-party payment, carve outs)

3. The current evidence of the technology:

In studies examining the effectiveness of MPPs (defined as including medical, behavioral, physical reconditioning, and educational components) for adults with chronic non-cancer pain:

- A. What chronic pain populations (excluding patients with cancer) were included in studies of MPP?
 1. Patients with what clinical conditions were included?
 2. Had the patients already failed standard pain treatment? If so, what kind? Or were patients in the process of obtaining standard treatment for pain?
 3. How did the comparison group, if any, relate to the treatment group (e.g., on what characteristics were they matched)?



4. What other inclusion/exclusion criteria (e.g., psychological or physical comorbidities, worker compensation status, third-party litigation status, active chemical dependency, etc.) were used?
 5. What patient characteristics (those not controlled by inclusion/exclusion criteria) have been tested for interactions with MPP that affect outcomes?
- B. Within a broad operational definition of an MPP requiring four components (medical, behavioral, physical reconditioning, and educational), what models (combinations of specific components) of an MPP for patients with chronic non-cancer pain have been studied with regard to effectiveness?
1. With what alternative treatment was the MPP compared?
 2. What structure and process variables in MPPs that potentially affect outcomes have been tested in studies of MPPs? Examples include length of treatment (length of each session, sessions per week, number of weeks), group versus one-on-one sessions, in-patient versus out-patient treatment, pain medications, discipline of person who provided treatment, degree of coordination of services, staff turnover, emphasis of the program, and source of referrals to the MPP.
- C. What outcomes were assessed (short-term and long-term)?
1. How were they measured?
 2. When were they measured?
 3. What patient characteristics (those not controlled by inclusion/exclusion criteria) have been tested for interactions with MPP that affect outcomes?
- D. What are the potential safety issues and harms that may be associated with an MPP? (i.e. what safety issues might occur as a result of *combining* different therapies, over and above the safety issues related to each individual therapy)?
- E. Other important study factors:
1. What was the study design?
 2. What was the sample size?
 3. How many patients were lost to follow-up (or dropped out)?
 4. In what setting (in-patient or out-patient) was the study done?
 5. In what country was the study done?
 6. What was the funding source for the study?

4. The Issues:

What are the implications of further diffusion of MPPs, given the state of the evidence?

- A. What key decisional uncertainties face practitioners, payers, and patients?
- B. What are the implications for equity (e.g. geographic equity)?
- C. What do key decision-makers (patients, physicians, payers) need to know?
- D. What are specific needs to make research in this area effective (e.g., design, definition of pain program, outcome assessment tools, etc.)?

Source: www.effectivehealthcare.ahrq.gov

Published Online: July 28, 2010

III. Methods

1. Data Collection Strategy:

Three research processes, including discussions with key informants, a search of the grey literature, and a published literature search, will be utilized to collect data related to the four guiding questions.

A. Discussions with Key Informants

We have identified relevant key informants for this technical brief, ensuring both balanced viewpoints and efficient data collection. Included are subject experts as well as end users of MPPs, including consumers, a patient advocate (director of a consumer organization, American Chronic Pain Association), practicing clinicians, MPP Medical Directors, Pharmacy & Therapeutics Committee member, professional association leaders (American Pain Society), and a public purchaser of healthcare. The table below provides examples of the types of questions that will be used in Key Informant discussions.

Key Informant Group	Potential Questions
Third party payer (payer)	1. How do payers impact patient access to MPPs? 2. How do payers impact the therapy components of MPPs? 3. What information about MPPs is most needed by payers? 4. What kinds of research would be most useful? What outcomes? 5. Is the managed care practice of separating out certain components of an MPP (e.g., PT or psychological services) increasing? If so, why? 6. What do payers view as the advantages/disadvantages of MPPs? 7. Is third party reimbursement for MPP becoming more or less restrictive? 8. What therapies for chronic pain, if any, are more likely to be reimbursed?

Key Informant Group	Potential Questions
Pain content experts, researchers, pain program medical directors	<ol style="list-style-type: none"> 1. What are the geographic challenges to patients accessing MPPs? 2. What is your sense about MPPs increasing or decreasing in number? 3. Have MPPs become less available in recent years? (based on what?) 4. Is the managed care practice of separating out certain components of an MPP (e.g., PT or psychological services) increasing? If so, why? <ol style="list-style-type: none"> a. What is the impact of this practice on patients? b. What is the impact of this practice on MPPs? 5. How do payers impact the therapy components of MPPs? 6. What is the main MPP “critique” received from patients who “drop out”? 7. What type of staffing is necessary for an MPP? 8. What type of staff training? 9. What role, if any, do accreditation programs have with MPPs? (e.g. AAPM) 10. Should “interdisciplinary” be the standard (versus multi)? Why, why not? 11. Are community physicians generally aware of MPPs? 12. In what ways, should the referral process to MPP be improved? 13. Grey literature: which professional organizations are important to consult regarding: <ul style="list-style-type: none"> • Consensus statements • Abstracts • Preliminary study findings 14. Review/comment on indicators/exclusion criteria for literature search 15. Review/comment on definitions/examples of each of 4 MPP components 16. What types of research needed most? What outcomes? What designs? When should patient outcomes be measured (length of follow-up)? 17. What criteria are used to decide to refer patients to MPPs? 18. Have MPPs changed in content since their proliferation in the 1980’s? If so, in what way(s)?
Patients/patient advocates	<ol style="list-style-type: none"> 1. What has been your experience with MPP (or that of other patients)? 2. What were your expectations; were they met? Why or why not? 3. What information do patients need to know when seeking care at MPP? 4. What do you view as the advantages/disadvantages of MPP? 5. How did you learn about MPP? What approaches had already been tried? 6. What was your experience (or other patients) with reimbursement? 7. In what way(s), if any, did MPP improve your ability to function?

B. Grey Literature Search

We will conduct a grey literature search utilizing the advice of key informants to identify professional societies from which to obtain the following: professional society consensus statements, meeting abstracts, and/or preliminary study findings. These professional societies may include, for example, American Pain Society, American Chronic Pain Association, and/or International Association of the Study of Pain. We will also utilize the internet (e.g., LexisNexis and Google Scholar) to obtain, for example, information on availability and other issues and controversies regarding MPPs. We will survey enrolling and ongoing clinical trials through ClinicalTrials.gov. In addition, we will search government websites (e.g., Medicare and/or Veterans Administration) for current coverage and/or payment policies. We may also try to obtain coverage information for some major private insurers.

C. Published Literature Search

Criteria for Inclusion/Exclusion of Studies in the Review

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Published Online: July 28, 2010

The two primary criteria that will be used for inclusion/exclusion of studies pertain to population (i.e., adults with chronic non-cancer pain) and treatment (multidisciplinary pain program defined as including at least four components – medical, behavioral, physical reconditioning, and educational). We will include studies of any sample size, any design (RCT, controlled clinical trial, uncontrolled observational trial, and case reports/series) and studies that report any clinical outcome (e.g., quality of life, functioning, disability, and pain).

Studies will be excluded based on the following exclusion criteria:

1. Patients with cancer
2. Patients with acute pain (e.g. pain less than 3 months and post-surgical pain)
3. Patients who are ages 18 years or younger
4. MPP studied does not include all four components: medical, behavioral, physical reconditioning, and educational. Among the studies that are excluded by this criteria, we will identify pain programs that meet two or three components (but not all four components) and have a rehabilitation focus. Since we are employing a rather stringent definition of MPP, it is important to identify the loss in studies that may occur as a result by accounting for those with a less stringent definition of MPP.

The table below displays various indicators/examples of how each component may be evident in the literature. In other words, there are many variations within each of the four required components of MPP. We will seek input from Key Informants to further refine this table that will be used in inclusion/exclusion decisions for the review. The indicators listed are based on three sources from the literature.^{1,4-5}

Components of MPP	Examples and Indicators of Each Component
Medical Therapy	<ul style="list-style-type: none"> • Responsible for patient's physical well-being • Manage medications • Educational component may be included with medical (but research study must explicitly state this) e.g., neurophysiology education
Behavioral Therapy	<ul style="list-style-type: none"> • Responsible for psychosocial aspects of patients' care • Cognitive Behavioral Therapy (CBT) • Operant Behavioral Therapy (OBT) • Stress management training • Relaxation, progressive muscle relaxation • Applied relaxation • Biofeedback • Behavioral therapy • Comorbidity diagnosis & treatment • Help patient unlearn maladaptive responses to pain • Problem solving • Individual or group psychotherapy • Educational component is often included with behavioral (but research study must explicitly state this)

Components of MPP	Examples and Indicators of Each Component
Physical Reconditioning	<ul style="list-style-type: none"> • Physical Therapy (PT) or Occupational Therapy (OT) • Upper extremity, ergonomic assessment and problem solving, work activities, leisure activities, ADLs. • Graduated activity exposure (pacing) enabling patients to control exacerbations in pain by learning to regulate the activity and, once a regime of paced activity is established, to gradually increase their activity level • Graded therapeutic exercises to safely increase functioning (e.g. flexibility, range of motion, posture, body mechanics, ambulation, gait training, core strength/stability, cardiovascular fitness, increasing upper and lower extremity strength & endurance • Passive modes (e.g. ultrasound, electrical stimulation, massage) are generally avoided in MPP and focus is teaching patients independent management of pain • Stretching & strengthening emphasized • Job analysis & reconditioning • Aerobic exercises • Exercise therapy • Hydrotherapy, swimming • Educational component is often included with Physical Reconditioning (but research study must explicitly state this), e.g. back education
Education	<ul style="list-style-type: none"> • Improved self management is the focus • Educational component is sometimes integrated with one or more other component - (e.g., by psychologist with behavioral component or by nurse with medical component or by PT with physical reconditioning component) • Back education • Home exercise training • Ergonomic training • Neurophysiology education provided by a physician or nurse

Searching for the Evidence: Literature Search Strategies for Identification of Relevant Studies to Answer the Guiding Questions

We will conduct a literature scan of MEDLINE®, the Cochrane Central Register of Controlled Trials, SCOPUS and Web of Science as well as the Cochrane Database of Systematic Reviews, from 1985 until May 2010. The search will be restricted to publications in English, which has been shown to be a reasonable strategy in reviews focused on conventional medicine.⁸ In addition, a manual search of references from reports of studies or review articles will be conducted. A preliminary search strategy, including proposed search terms, is listed in Appendix 1. We will also conduct a grey literature search for abstracts and studies in process, as stated previously. The articles will be scanned initially to (a) identify relevant narrative articles dealing with the broader issues in Question 1 (background regarding MPPs) and Question 2 (context), and (b) to assess all abstracts against inclusion criteria related to population and MPP (as operationally defined for this review). All articles meeting the two criteria of population and MPP will then be reviewed in detail and data points related to all Question 3 sub-questions will be abstracted to the five tables presented in Appendix 2.

The literature search may be updated concurrent with the peer review process, based on input from the peer reviewers. Additional relevant data obtained via the updated literature search will be incorporated into the final report.

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Published Online: July 28, 2010

2. Data Organization and Presentation

A. Information Management

Data from the published literature will be abstracted using a standardized data abstraction tool shown in Appendix 2. One reviewer will collect the data and will assess the evidence against the inclusion/exclusion criteria. In addition, the following information will be obtained from each study, where applicable: author, year of publication, source of study funding, study design characteristics, study population (including study inclusion and exclusion criteria), duration of patient followup, outcomes assessed (specific measures used, as well as timing of assessment) and other information.

Data from the published literature will be integrated with information from the grey literature and key informant discussions. Responses to Questions 1 and 2 will be formed with information from published narrative reviews, information in the grey literature, and from key informant discussions. Responses to Question 3 will be based primarily on peer-reviewed, published literature and may be combined with some information gleaned from the grey literature (e.g., information from ongoing studies). Although Question 3 will be based primarily on published literature, grey literature and key informant discussions will also be helpful in order to answer the guiding questions and develop a conceptual framework. For example, they may help identify patient characteristics that may have a role in effect modification of the MPP on outcomes, even though these characteristics have not been tested in studies of MPP. Responses to Question 4 will be formed by key informant discussions along with information used to address Questions 1-3.

B. Data Presentation

Information relevant to Questions 1 and 2 will be summarized in narrative form.

Information related to Question 3 sub-questions will be summarized using the five tables shown in Appendix 2. The tables will present a summary of the state of research for studies examining the effectiveness of MPP (defined as including medical, behavioral, physical reconditioning, and educational components) for adults with chronic non-cancer pain with regard to the following:

- A. Study Population: Relationship to MPP and Comparison Groups
- B. Multidisciplinary Pain Programs – Components, Definitions, and Structure/Process Variables
- C. Outcomes Assessed (Measures and Timing) and Patient Characteristic Interacted with Treatment
- D. Potential Safety Issues or Harms
- E. General study factors (design, sample size, country, funding source)

Information related to Question 4 will be presented narratively in combination with an Evidence Map. The Evidence Map will be generated based on information pertaining to Questions 1-3 collected via all three research processes (key informant discussions, grey literature search, and published literature search). In addition to the Evidence Map, a conceptual framework and a structure utilizing the PICO format (i.e. Population, Intervention, Comparison treatment, Outcomes) will be proposed to guide future MPP research.

IV. References

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V. Definition of Terms

Multidisciplinary Pain Program (MPP): The multidisciplinary model of chronic pain treatment is based on the biopsychosocial model. This model emphasizes the complex and dynamic interaction between physiological, psychological, and social factors that serve to perpetuate and potentially worsen the pain experience. In contrast to the biomedical model, which emphasizes cure or at least elimination of a significant amount of pain, the goal of multidisciplinary pain programs is to restore the patient's independence and overall quality of life (i.e., rehabilitation). An MPP includes the following four components: education, medical treatment, behavioral therapy, and physical reconditioning.

Partial Multidisciplinary Pain Program (Partial MPP): A Partial MPP includes two or three, but not all four of the following components of an MPP: education, medical treatment, behavioral therapy, and physical reconditioning. In addition, the Partial MPP must be fundamentally rehabilitation in focus, i.e. the goal of the program is to restore the patient's independence and overall quality of life.

APPENDIX 1

Preliminary Search Strategy

Concept Analysis

Three concepts in order of importance: 1) pain, 2) chronic and 3) multidisciplinary treatment

		Concepts		
		pain	chronic	multidisciplinary treatment
Search terms: (MeSH) and text words	Set A	Pain (MeSH) pain.tx neuralgia.tx	chronic.tx intractable.tw. refractory.tw. persistent.tw.	Patient Care Team (MeSH) multidisciplinar\$.tw interdisciplinar\$.tw multiprofessional\$.tw multimod\$.tw
	Set B	Pain clinics (MeSH) "pain clinic".tx "pain clinics".tx		
MPP Literature Set = A + B				

Ovid MEDLINE(R) Search Strategy:

Database: Ovid MEDLINE(R) <1950 to May Week 4 2010>

Search Strategy:

-
- 1 exp *Pain/
 - 2 pain\$.tw.
 - 3 neuralg\$.tw.
 - 4 1 or 2 or 3
 - 5 chronic.tw.
 - 6 sustain\$.tw.
 - 7 intractable.tw.
 - 8 refractory.tw.
 - 9 persistent.tw.
 - 10 5 or 6 or 7 or 8 or 9
 - 11 4 and 10
 - 12 *Patient Care Team/
 - 13 multidisciplinar\$.tw.
 - 14 interdisciplinar\$.tw.
 - 15 multiprofessional\$.tw.
 - 16 multimod\$.tw.
 - 17 12 or 13 or 14 or 15 or 16
 - 18 11 and 17
 - 19 exp *Pain Clinics/
 - 20 "pain clinics".tw.

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Published Online: July 28, 2010



- 21 "pain clinic".tw.
- 22 19 or 20 or 21
- 23 18 or 22
- 24 exp Neoplasms/
25 cancer.tw.
- 26 24 or 25
- 27 23 not 26
- 28 exp Pain, Postoperative/
29 (post and (operative or surgical)).mp. [mp=title, original title, abstract, name of substance
word, subject heading word, unique identifier]
- 30 28 or 29
- 31 27 not 30
- 32 limit 31 to (English language and humans)
- 33 limit 32 to "all child (0 to 18 years)"
- 34 limit 33 to "all adult (19 plus years)"
- 35 32 not 33
- 36 34 or 35
- 37 limit 36 to (addresses or bibliography or biography or dictionary or directory or in vitro or
interactive tutorial or lectures or legal cases or legislation or news or newspaper article or
patient education handout or periodical index or portraits)
- 38 36 not 37
- 39 "chest pain clinic".tw.
- 40 38 not 39
- 41 limit 40 to yr="1985 -Current"
- 42 pediatric.mp. or exp Pediatrics/
43 41 not 42

APPENDIX 2

Data Abstraction Form and Presentation of Data for Question 3: Evidence on Multidisciplinary Pain Programs

Table 3A. Study Population and Relationship to MPP and Comparison groups

Study	MPP Population (duration of pain, failed standard therapy*, in process of obtaining standard therapy, not reported)	Comparison population (duration of pain, failed standard therapy*, in process of obtaining standard therapy, not reported)	Clinical Conditions	Other Inclusion and Exclusion Criteria	MPP Therapy	Comparison Therapy (if any)
Author, year, title						
Author, year, title						
Author, year, title						

*If failed standard care, specify what therapy was tried & what failed

Table 3B. Multidisciplinary Pain Programs – Components, Definitions, Structure/Process Variables

Study	MPP1: Components and Definitions	MPP2 Components and Definitions	Comparison Treatment 1 Components and Definitions	Comparison Treatment 2 Components and Definitions	Structure and Process Variables Tested	Concurrent Therapy
Author, year, title						
Author, year, title						
Author, year, title						

Table 3C. Outcomes Assessed (Measures and Timing) and Patient Characteristics Interacted with Therapy

Study	Outcome 1 (measure & timing)	Outcome 2 (measure & timing)	Outcome 3 (measure & timing)	Patient Characteristics Tested	MPP Therapy	Comparison Therapy
Author, year, title						
Author, year, title						
Author, year, title						

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Published Online: July 28, 2010

Table 3D. Potential Safety Issues or Harms

Study	Safety Issues or Harms Assessed	MPP Therapy	Comparison Therapy
Author, year, title			
Author, year, title			
Author, year, title			

Table 3E. General Study Factors

Study	Design (RCT, CCT, Uncontrolled Observational, Case Report/Case Series)	Number Per Group	Country	Funding Source for Study	Number of Patients Lost to Follow-up	Setting (In-patient, Out-patient)
Author, year, title						
Author, year, title						
Author, year, title						