



Evidence Brief: Effectiveness of Models Used to Deliver Multimodal Care for Chronic Musculoskeletal Pain

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PREFACE

The VA Evidence-based Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted healthcare topics of particular importance to clinicians, managers, and policymakers as they work to improve the health and healthcare of Veterans. QUERI provides funding for four ESP Centers, and each Center has an active University affiliation. Center Directors are recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Centers. The ESP is governed by a Steering Committee comprised of participants from VHA Policy, Program, and Operations Offices, VISN leadership, field-based investigators, and others as designated appropriate by QUERI/HSR&D.

The ESP Centers generate evidence syntheses on important clinical practice topics. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The ESP disseminates these reports throughout VA and in the published literature; some evidence syntheses have informed the clinical guidelines of large professional organizations.

The ESP Coordinating Center (ESP CC), located in Portland, Oregon, was created in 2009 to expand the capacity of QUERI/HSR&D and is charged with oversight of national ESP program operations, program development and evaluation, and dissemination efforts. The ESP CC establishes standard operating procedures for the production of evidence synthesis reports; facilitates a national topic nomination, prioritization, and selection process; manages the research portfolio of each Center; facilitates editorial review processes; ensures methodological consistency and quality of products; produces “rapid response evidence briefs” at the request of VHA senior leadership; collaborates with HSR&D Center for Information Dissemination and Education Resources (CIDER) to develop a national dissemination strategy for all ESP products; and interfaces with stakeholders to effectively engage the program.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP CC Program Manager, at Nicole.Floyd@va.gov.

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EXECUTIVE SUMMARY

In Veterans, chronic pain may occur in up to 50% of those treated in primary care, and severe pain is more prevalent than in the general population. Chronic pain is a major public health challenge that is associated with serious physical and psychosocial impairment which costs the United States approximately \$635 billion annually. Pain is a complex condition involving dynamic interactions between biological, psychological, and social factors unique to each individual. For this reason, pain care needs to be individually tailored, involving multiple care approaches and collaboration between primary and specialty care clinicians. Pain management guidelines, including those for the VHA, advocate for multimodal pain care. The VHA National Pain Management Strategy utilizes a stepped care model of pain management involving primary care and patient aligned care teams (PACTs), secondary consultation, and tertiary interdisciplinary pain centers. However, barriers to effective implementation of guideline-concordant care still exist, including: limitations in service accessibility; provider time constraints leading to fragmentation of the care process; complexity of treatment decisions due to variability in patients' pain characteristics and multimorbidities; variability in patient education, activation, expectations, suspicion, and mistrust; provider training and burnout; and reimbursement limitations. Thus, there is a need to identify effective models of chronic pain care with system-based interventions aiming to improve the delivery of multimodal care.

Our objectives were to determine what multimodal care delivery models relieve chronic musculoskeletal pain and minimize unintended consequences, define key elements of and the resources required for these models, and identify patients who are most likely to benefit from these models.

This review found that 5 models coupling decision support —most commonly algorithm-guided treatment and/or stepped care — with proactive ongoing treatment monitoring have the best evidence from good-quality RCTs of providing clinically relevant improvement in pain intensity and pain-related function over 9 to 12 months (NNT range, 4.1 to 12.70), as well as variable improvement in other important core outcomes (Executive Summary Table). The strength of the evidence is generally low, however, as each intervention is only supported by a single study with imprecise findings. Findings from ESCAPE, SEACAP, SCAMP, and SCOPE are the most applicable to Veterans because they were studied in VAMC settings. We were unable to determine the patients who are most likely to benefit from these models due to under-reporting of key patient characteristics such as pain duration, opioid use at baseline and prevalence of common medical and mental health comorbidities. It is reasonable to consider wider implementation of one or more of these models across multiple VAMCs, with a clear plan for further evidence development to address shortcomings of previous research: (1) better characterization of patients' pain duration, opioid use at baseline, prevalence of common medical and mental health comorbidities, co-interventions, and usual care; (2) more rigorous

Background

The ESP Coordinating Center (ESP CC) is responding to a request from HSR&D for an evidence brief on the effectiveness of models used to deliver multimodal care for treating chronic musculoskeletal pain. Findings from an interim report were used to inform a November 2016 state-of-the-art (SOTA) conference and this expanded evidence brief will inform subsequent prioritization of clinical and research implementation objectives.

Methods

To identify studies, we searched MEDLINE[®] and CINAHL through October 2016, and other sources. We used prespecified criteria for study selection, data abstraction, and rating internal validity and strength of the evidence. See our PROSPERO protocol for our full methods.

evaluation of model fidelity; (3) assessment of a broader range of clinically-relevant core outcomes per IMMPACT recommendations; (4) longer-term follow-up; and (5) inclusion of potentially underserved populations, such as rural settings and racial/ethnic minorities.

Executive Summary Table: Summary of Findings

| Intervention major components Best evidence quality, design, follow-up duration, and sample size | Clinically significant* improvement in: Pain Intensity or Pain-related Function (Intervention vs Control) | Statistically significant (P ≤ 0.05) improvement in other outcome |
|---|--|--|
| Computer-based assessment; telephone-based nurse-educator. 1 fair, 12m RCT ¹ of N=1066. | NR | QOL |
| Group multidisciplinary education sessions. 1 poor, 6m RCT ² of N=63. | NR | QOL |
| ESCAPE: Stepped care with analgesics and CBT, NCM. 1 good, 9m RCT ³ of N=241. | RMDQ: RR=1.52 (95% CI 1.22 to 1.99); NNT=7.5 | NR |
| Risk stratification, 5-hr weekly multidisciplinary sessions in rural setting. 1 poor, 18m RCT ⁴ of N=1905. | NR | NR |
| SEACAP: Collaborative care delivered by psychologist care manager. 1 good-quality, 12m RCT ⁵ of N=401. | RMDQ: 21.9% vs 14.0%, P=0.04 NNT=12.70 (95% CI 12.48 to 12.74) | Depression |
| Pharmacist-led pharmacological treatment optimization. 1 fair, 12m RCT ⁶ of N=325. | OMERACT-OARSI response as high improvement: 27% vs 28%; P=0.3 | Depression, anxiety |
| STarT Back: Prognostic screening with matched pathways. 1 fair, 12m RCT ⁷ of N=1573. | RMDQ: 65% vs 57%; OR=1.48 (95% CI 1.02 to 2.15); NNT=10.8 (95% CI 5.8 to 206) | QOL, depression |
| SCAMP: Stepped care with antidepressants and self-management delivered by a NCM. 1 good, 12m RCT ⁸ of N=250. | BPI: 41.5% vs 17.3%; RR=2.4 (95% CI 1.6 to 3.2); NNT=4.1 (95% CI 3.0 to 6.5) | QOL, depression, anxiety |
| SCOPE: Telecare collaborative management; algorithm-guided analgesic optimization; 1 good, 12m RCT ⁹ of N=250. | BPI: 51.7% vs 27.1%; RR=1.9 (95% CI 1.4 to 2.7); NNT=4.1 (95% CI 3.0 to 6.4) | QOL, depression, sleep |

*Patients with ≥ 30% reductions in pain and pain-related function unless otherwise noted

Abbreviations: m = month; RCT= randomized controlled trial; NR= not reported; QOL= quality of life; CBT = Cognitive Behavioral Therapy; NCM = nurse care managers; RMDQ = Roland-Morris Disability Questionnaire; NNT = Number Needed to Treat; OMERACT-OARSI = Outcome Measures in Rheumatology-Osteoarthritis Research Society International; OR= odds ratio; BPI = Brief Pain Inventory; RR= risk ratio; ESCAPE = Evaluation of Stepped Care for Chronic Pain; SEACAP = Study of the Effectiveness of A Collaborative Approach to Pain; STarT Back = stratified primary care management for low back pain ;SCAMP = Stepped Care for Affective Disorders and Musculoskeletal Pain; SCOPE = Stepped Care to Optimize Pain Care Effectiveness

EVIDENCE BRIEF

INTRODUCTION

PURPOSE

The ESP Coordinating Center (ESP CC) is responding to a request from HSR&D for an evidence brief on the effectiveness of models used to deliver multimodal care for treating chronic musculoskeletal pain. Findings from this evidence brief were used to inform a November 2016 state-of-the-art (SOTA) conference and subsequent clinical and research prioritization processes.

BACKGROUND

Chronic pain is typically defined as pain lasting more than a few months,¹⁰ although many patients experience pain for years or even decades.^{4,5} Chronic musculoskeletal pain is a major — and growing¹¹ — burden on today's Veteran population. Nearly 50% of Veterans receiving primary care endorse regular pain and have concerns about their pain.¹² Studies of Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn (OEF/OIF/OND) Veterans show that diseases of the musculoskeletal system are the most frequent diagnoses in cumulative reports of inpatient and outpatient encounters, even surpassing mental health conditions.¹³⁻¹⁵ Severe pain is more common in Veterans than in the general population.¹⁶ And this burden will grow; the prevalence of painful musculoskeletal conditions among Veterans increases each year after deployment.¹¹

A nationally representative survey of the US population estimated that 31% of adults report chronic pain when defined as pain lasting for at least 6 months, and that people over the age of 50 are twice as likely to have been diagnosed with chronic pain when compared to people who are younger.¹⁷ A 2011 report from the Institute of Medicine estimated that 100 million US adults suffer from chronic pain and that the total costs of their care due to medical treatment and lost productivity (*ie*, work days missed, number of annual hours worked, and hourly wages) are estimated at \$560 to \$635 billion per year, of which \$261 to \$300 billion are direct healthcare costs.¹⁸

Chronic pain is a complex condition involving dynamic interactions between biological, psychological, and social factors unique to each individual.³ Patients often have other comorbidities such as obesity, and are at increased risk for depression, PTSD, and suicide.¹⁹⁻²² Another complicating factor is that patients may have variable degrees of baseline self-management skills and may or may not be motivated or know how to address their pain outside of medication use.²³

To address this complexity, some pain management guidelines, including those for the VHA, recommend multimodal pain care,^{18,24-26} which is typically defined as the use of more than one type of therapy and can include more than one discipline when available ('multidisciplinary'). Common modalities include self-management, complementary and integrative health, pharmacological, psychological, physical or restorative therapy, procedural treatments, etcetera. The VHA National Pain Management Strategy recommends a stepped care model of pain management that emphasizes low-intensity interventions as "first step" or "tiers," followed by



the introduction of more intensive, multimodal, and multidisciplinary interventions as needed to maximize benefit.

Primary care providers (PCPs) are responsible for the majority of pain management.²⁷ However, PCPs face many system- and patient-level challenges in providing the recommended multimodal interventions.^{18,27,28} In their 2011 ‘Blueprint for Transforming Prevention, Care, Education and Research’, the Institute of Medicine’s Committee on Advancing Pain Research, Care and Education found that reimbursement limitations and short primary care visits often provide inadequate time and resources for complex treatment planning and coordination of multimodal care, monitoring, and patient education and activation activities.¹⁷ PCPs cited variability in patients’ duration of pain (years to decades), their stage of disease at presentation to primary care, and the presence of mental and physical comorbidities as factors that add to the complexity of care management.²⁹ With other competing demands and, in some cases, uncertainty about the evidence base supporting multimodal interventions, PCPs cited “no forum to discuss challenging patients with specialists on a regular basis” as a system-level barrier.²⁹ PCPs also reported that chronic pain patients require more visits and non-visit work to monitor and adjust management strategies.²⁹ At the patient level, variable levels of patient education, activation, and expectations may present challenges to providers’ attempts to promote nonpharmacological treatments and goals of improved function and quality of life. Access to multimodal interventions may also vary by clinical location and provider preference and practice patterns.^{18,28} Further challenges identified by PCPs include controversies surrounding use of opioids, patient-provider relationship difficulties, and provider burn-out.²⁷

A recent Patient-Centered Outcomes Research Institute (PCORI) multi-stakeholder workgroup suggested that systems interventions are needed to support PCPs and provide better tools for managing chronic pain.²⁸ Several strategies exist to address the challenges PCPs face in delivering more effective pain care, informed by experiences in pain management as well as chronic illness management in general. One of the most common approaches used in a variety of clinical areas is to add care coordination mechanisms to reduce the time burden on the primary provider required for organization of care and for frequent and longitudinal proactive monitoring and adjustment. Strong evidence supports short-term benefits of care management for depression, a similarly complex condition often managed in primary care.³⁰ Second, to enhance PCP education and improve difficult decision-making, potential decision-support mechanisms may include supporting collaboration between pain specialists and PCPs, with a pain specialist serving as a resource for PCPs,¹⁸ risk triage, and use of stepped care algorithms. Third, developing and embedding into primary care more evidence-based patient education and activation processes¹⁸ may improve patients’ adherence and perspectives on acceptable outcomes and the patient-provider relationship. Finally, increasing access to multidisciplinary care to underserved areas, such as rural settings, and/or better integrating into primary care, would empower PCPs to refer patients for recommended multimodal care.

Completed and ongoing research is accumulating that evaluates various combinations of these strategies for improving the delivery of multimodal pain care in primary care settings. Our objectives were to determine which multimodal care delivery models relieve chronic musculoskeletal pain and minimize unintended consequences, define key elements of and the resources required for these models, and identify patients who are most likely to benefit from these models.

ELIGIBILITY CRITERIA

The ESP included studies that met the following criteria:

- **Population:** Adults with chronic musculoskeletal pain (persistent for 3 months or longer)
 - Potential effect modifiers of interest include (1) the specific location and/or type of pain; (2) patient demographics (*eg*, age, race, ethnicity, and gender); (3) patient comorbidities (including past or current alcohol or substance use disorders, mental health disorders, medical comorbidities, and those at high risk for substance use disorders)
- **Intervention:** Any model with system-based mechanisms aiming to increase the uptake and organization of multimodal care (*eg*, collaborative care, care management, integrated care, telecare, peer-delivered care, informal caregiving, stepped care models, and algorithms)
- **Comparator:** Any
- **Outcomes:**
 - Effectiveness: Percentages of patients obtaining reductions in pain intensity and pain-related function from baseline of at least 30% or 50%,³¹ quality of life, depression, anxiety, sleep, and opioid doses.
 - Unintended consequences: Adverse effects on patient satisfaction, provider satisfaction, time burden, sustainability
- **Timing:** Any study follow-up durations
- **Setting:** Integrated within primary care; not to include interventions occurring entirely within intensive pain rehabilitation, specialty, or tertiary care
- **Study design:** Systematic reviews, randomized controlled trials, or concurrently-controlled cohort studies

METHODS

To identify relevant articles, we searched MEDLINE® (Ovid) and CINAHL using terms for chronic pain and multimodal care through October 2016. Additional sources searched were Agency for Healthcare Research and Quality (AHRQ), Canadian Agency for Drugs and Technologies in Health (CADTH), Cochrane Database of Systematic Reviews, ECRI Institute, Health Technology Assessments (HTA), National Institute for Health and Care Excellence (NICE) Guidance and Evidence Services, National Library of Medicine, CADTH Grey Matters, Conference Papers Index, The New York Academy of Medicine’s Grey Literature Report, National Institutes of Health (NIH) ClinicalTrials.gov, Clinical Trial Results, World Health Organization (WHO) International Clinical Trials Registry Platform, Research Portfolio Online Reporting Tools (RePORT), National Repository of Grey Literature (NRGL), OpenGrey, Turning Research Into Practice (TRIP), metaRegister of Controlled Trials (mRCT), Scopus, Google Scholar, Google, American Pain Society, University of Southern California Pain Center, Patient-Centered Outcomes Research Institute (PCORI), American Academy of Pain Management, VA HSR&D publications, Australian Government Department of Veterans’ Affairs’ Medicines Advice and Therapeutics Education Services (Veterans’ MATES), American Chronic Pain Association, The Pain Community, University of New Mexico, UK’s National Back Pain Association’s Backcare, Pain Association Scotland, and University of New Mexico Project TeleECHO (ECHO Pain). See Appendix A in the supplemental materials for complete search strategies. Additional citations were identified from hand-searching reference lists and consultation with content experts. We limited the search to articles involving human subjects available in the English language. Study selection was based on the eligibility criteria described above. Titles and abstracts and full-text articles were reviewed by one investigator and checked by a second investigator. All disagreements were resolved by consensus.

We used predefined criteria to rate the internal validity of all studies. For controlled trials, we used the Drug Effectiveness Review Project methods.³² For cohort studies, we used Cochrane’s Risk of Bias Tool.³³⁻³⁵ We abstracted data from all included studies and results for each included outcome. All data abstraction and internal validity ratings were first completed by one reviewer and then checked by another. All disagreements were resolved by consensus.

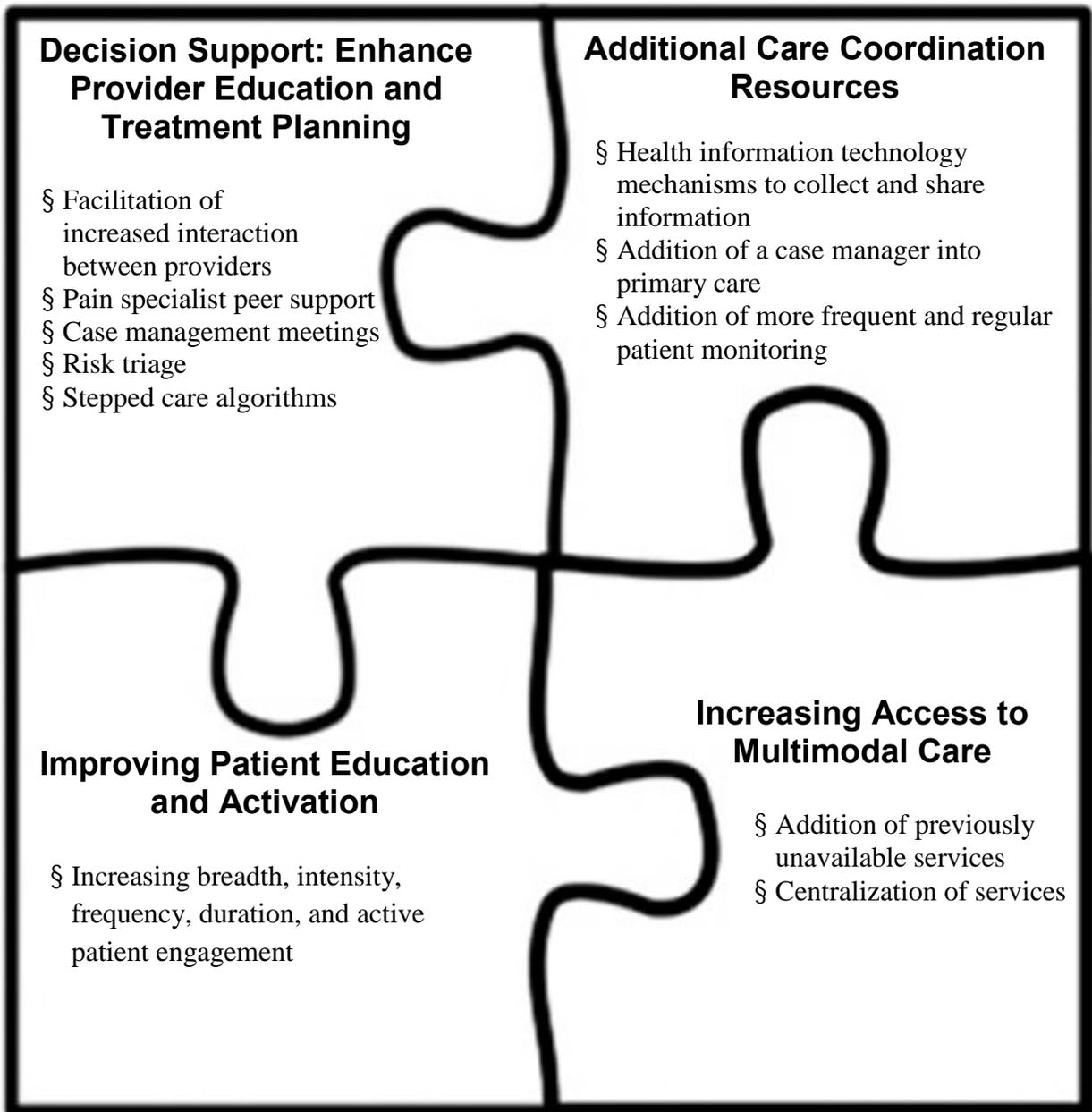
We graded the strength of the evidence based on the AHRQ Methods Guide for Comparative Effectiveness Reviews.³⁶ This approach incorporates 5 key domains: risk of bias (includes study design and aggregate quality), consistency, directness, precision of the evidence, and reporting biases. Ratings range from high to insufficient, reflecting our confidence that the evidence reflects the true effect. Strength of evidence ratings were first completed by one reviewer and then checked by another, and we resolved disagreements using consensus.

Models of multimodal chronic pain care differ substantially in the types of systems interventions they used to promote guideline-concordant multimodal chronic pain management in the primary care setting, and components of each intervention had varying breadth, intensity, frequency, and duration. This type of heterogeneity is often characteristic of complex multicomponent interventions and can be a challenge to constructing a framework for organizing the evidence synthesis. This is because interventions can be conceptually lumped or split by various types of characteristics and there is no agreed-upon single best approach for doing so.³⁷ Figure 1 illustrates how we classified the interventions into 4 categories based on the most common ways that the models attempted to change primary care processes regarding chronic pain management.

A draft version of this report was reviewed by peer reviewers as well as clinical leadership. Their comments and our responses are presented in the Supplemental Materials.

The complete description of our full methods can be found on the PROSPERO international prospective register of systematic reviews (<http://www.crd.york.ac.uk/PROSPERO/>; registration number CRD42016050272).

Figure 1. Four Categories of Most Common System Intervention Components



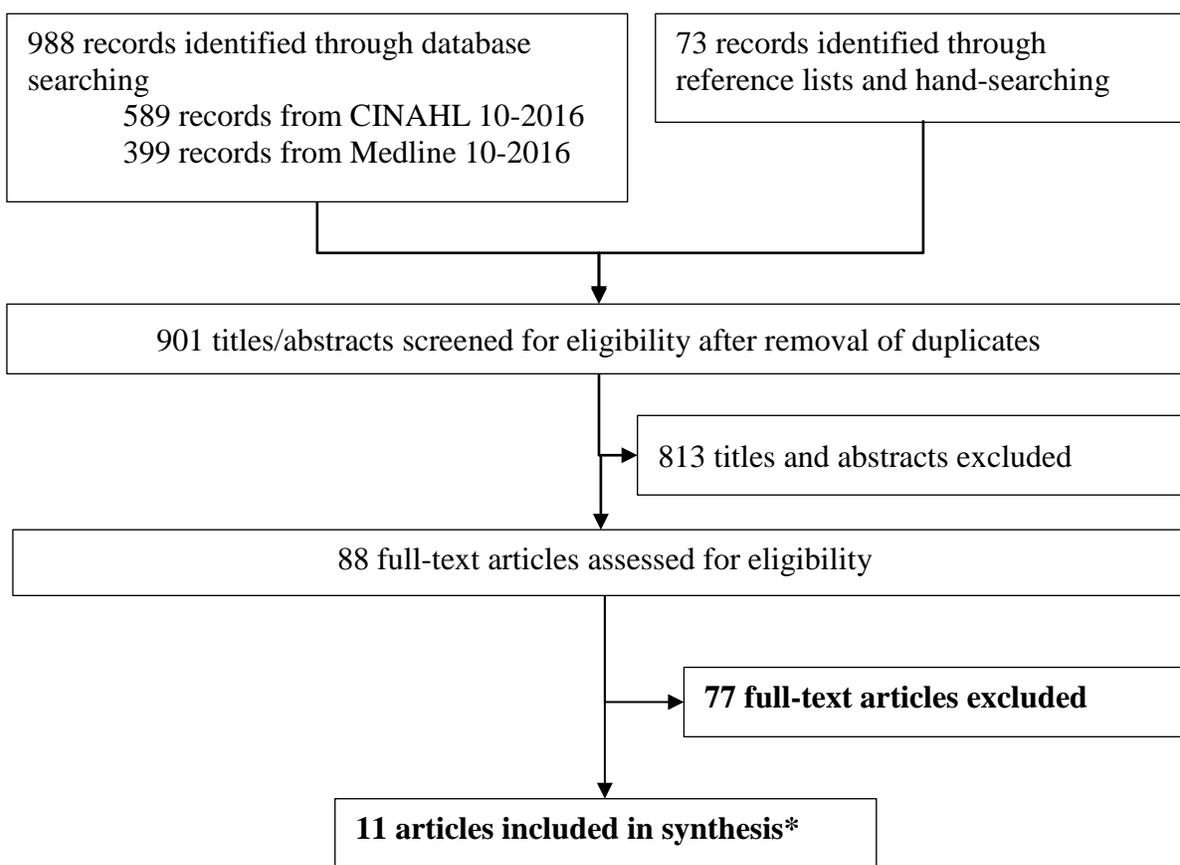
RESULTS

LITERATURE FLOW

Study Design and Quality

The literature flow diagram (Figure 2) summarizes the results of the search and study selection processes. Searches resulted in 901 potentially relevant articles. Of these, we included 8 RCTs (in 10 publications)^{1-3,5-7,38-42} and 1 retrospective cohort.⁴ Detailed reasons for study exclusion are provided in Appendix B in the supplemental materials.

Figure 2. Literature Flowchart

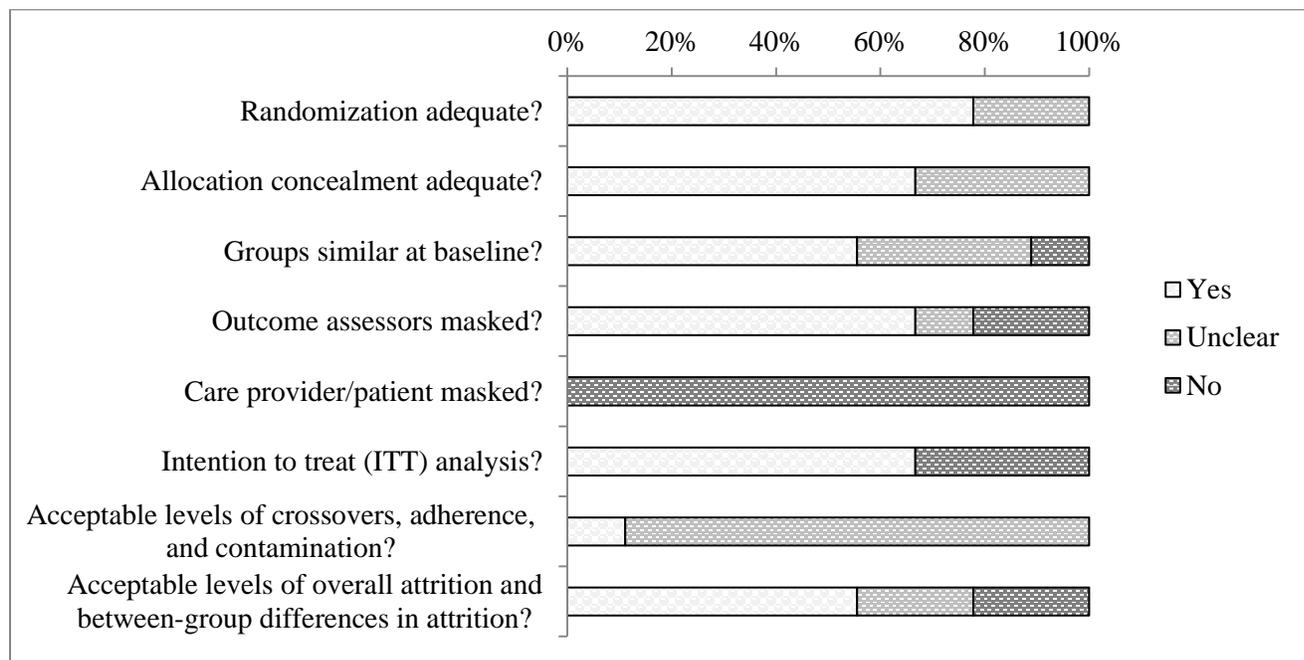


*1 secondary study included but not synthesized

Overall, most studies were fair or good quality. Three studies were rated poor.^{2,4,38} Common limitations among fair-quality studies included greater than 20% attrition and baseline differences in potential prognostic factors. Poor-quality studies also had high levels of exclusions from analyses (34% to 47%). Assessment of intervention fidelity was limited to attendance at group or individual appointments or number of patient contacts. Figure 3 displays the quality indicators of the included RCTs. Despite strong methodology, the strength of the evidence is generally low as each intervention is only supported by a single study with imprecise findings (full details in Appendix C in the supplemental materials). All but one study⁵ were randomized at

the patient level. Most interventions were compared to usual care, which was often minimally described as regular access to primary and specialty care.

Figure 3. Risk of Bias Assessment of Included RCTs



Setting and Subjects

We identified 9 diverse models of multimodal chronic pain care. Most studies involved multiple primary care practices in the USA^{1,3,5,8,38,41} or England.^{6,7} Four interventions were evaluated within either the Indianapolis (Roudebush) VAMC^{3,8,41} or the Portland VAMC.⁵ Two studies took place in single centers in Canada.^{2,4} Table 1 gives the characteristics of the included studies (full details in Appendix C in the supplemental materials). Sample sizes were ≤ 250 patients in the majority of the studies (range, 63 to 1066). Follow-up duration was 12 months in the majority of studies (range, 6 to 18 months). The proportion of male patients ranged from 31% to 92%, with higher proportions in those studies within the VA. The mean patient age ranged from 37 to 62 years old. Most studies reported baseline pain intensity which ranged from 5.1 to 7.7 on a 10-point scale. Most commonly reported mental health comorbidities were major depressive disorder, post-traumatic stress disorder, and substance use disorder, but baseline prevalence of these conditions was low in most studies (range: 1% to 24%). The exception was that one study specifically targeted patients with comorbid musculoskeletal pain and depression.⁸

Table 1. Characteristics of Included Studies*

| Author Year | Sample size | Study Design | Setting | Interventions | Follow-Up (months) | Gender (% male) | Mean Age (years) | Baseline Pain Intensity** | Mental health comorbidities | Study Quality |
|-------------------------------------|-------------|--------------|----------------------------------|---|--------------------|-----------------|------------------|---------------------------|--|---------------|
| Ahles 2001 ³⁸ | 396 | RCT | 4 PC practices (USA) | Computer-based tailored “prescription” algorithm + nurse educator | 6 | 39 | 49 | NR | 27% emotional distress | Poor |
| Ahles 2006 ¹ | 1066 | RCT | 14 PC practices (USA) | Computer-based tailored “prescription” algorithm + nurse educator | 12 | 48 | 48 | NR | 1% SUD | Fair |
| Angeles 2013 ² | 63 | RCT | Single center (Canada) | Group multidisciplinary education co-facilitated by an occupational therapist and a social worker | 6 | 38 | 55 | NR | 19.3% possible or probable SUD | Poor |
| Bair 2015 ³ ESCAPE | 241 | RCT | 5 GM clinics (Indianapolis VAMC) | Stepped care with analgesics, self-management, and CBT delivered by 2 NCM | 9 | 88 | 37 | 6.6 | Mean PTSD Score ^a = 26.4 Mean Depression Score ^b = 11.2 | Good |
| Burnham 2010 ⁴ CAPRI | 82 | OBS | Single rural center (Canada) | Weekly multi-disciplinary group sessions added to analgesic optimization | 18 | 31 | 47 | 7.7 | NR | Poor |
| Dobscha 2009 ⁵ SEACAP | 401 | RCT | 5 PC clinics (Portland VAMC) | Collaborative care delivered by psychologist care manager | 12 | 92 | 62 | 5.2 | 18% MDD, 16% PTSD | Good |
| Hay 2006 ⁶ | 216 | RCT | 15 practices (England) | Pharmacist-led pharmacological treatment optimization | 12 | 36 | 62 | 6.1 | NR | Fair |
| Hill 2011 ⁷ | 851 | RCT | 10 practices (England) | Physiotherapist-led stratified care using STarT Back Screening Tool | 12 | 41 | 50 | 5.3 | NR | Fair |

| | | | | | | | | | | |
|-------------------------------------|-----|-----|----------------------------------|--|----|----|----|-----|--|------|
| Kroekne 2009 ⁸ SCAMP | 250 | RCT | 5 GM clinics (Indianapolis VAMC) | Stepped care with antidepressants and self-management delivered by a NCM | 12 | 47 | 56 | 6.2 | 75% MDD Mean Anxiety score ^c = 8.9 | Good |
| Kroenke 2014 ⁴¹ SCOPE | 250 | RCT | 5 PC clinics (Indianapolis VAMC) | Automated symptom monitoring and optimized analgesic management by NCM and PC pain specialist team | 12 | 83 | 55 | 5.1 | 24% MDD, 17% PTSD | Good |

*Table does not include Thielke 2015, secondary publications of already included studies; **mean score on a 10-pt scale

Abbreviations: RC = retrospective cohort; RTC = randomized controlled trial; PC= primary care; NR= not reported; SUD= substance use disorder; ESCAPE = Evaluation of Stepped Care for Chronic Pain; GM = general medicine; CBT = cognitive behavioral therapy; NCM = nurse case manager; PTSD = post-traumatic stress disorder; CAPRI = Central Alberta Pain and Rehabilitation Institute; OBS= observational; SEACAP = Study of the Effectiveness of a Collaborative Approach to Pain; MDD = major depressive disorder; SCAMP = Stepped Care for Affective Disorders and Musculoskeletal Pain; SCOPE = Stepped Care to Optimize Pain Care Effectiveness; GADS= Generalized Anxiety Disorder scale

^a Determined using the Posttraumatic Stress Disorder Check List-17. Scores range from 0 to 68

^b Determined using Patient Health Questionnaire-9.37 Scores range from 0 to 27,

^c Determined using the Generalized Anxiety Disorder scale. Scores range from 0 to 21.

Overview of Multimodal Chronic Pain Care Model Components

Table 2 summarizes the intervention components utilized in the multimodal chronic pain care models. All but one model⁷ involved multiple processes for improving pain care delivery. The majority of interventions included a decision-support component – most commonly algorithm-guided treatment and/or stepped-care – coupled with proactive ongoing treatment monitoring.^{1-3,5,6,8,38,39,41} In 2 studies the decision support was in the form of a stratified approach by way of prognostic screening with matched treatment pathways.^{4,7} One stratified model⁷ focused on adults with back pain from 10 general practices within the Keele General Practice Research Partnership in England and used the validated Keele STarT Back Screening Tool, which is a 9-item inventory that queries patients about referred leg pain, comorbid pain, disability (2 items), bothersomeness, catastrophizing, fear, anxiety, and depression to categorize patients into low-, medium-, and high-risk groups.³⁵ The STarT Back Screening Tool is now also being evaluated in an ongoing study in 6 large primary care clinics in the integrated Group Health system in Washington State.⁴³ Alternatively, the stratified approach used in the Central Alberta Pain and Rehabilitation Institute (CAPRI), a single center in rural Alberta, triaged patients using an unspecified 1.5- to 2-hour assessment process to differentiate one of 4 care pathways based on the extent of their medication management, psychosocial, and/or comorbid medical illness issues (*ie*, minimal, high, complex).⁴ In the majority of studies, designated case managers from various disciplines delivered the treatment monitoring component of the intervention primarily via phone contacts at various frequencies. One notable exception was in the Stepped Care to Optimize Pain Care Effectiveness (SCOPE) study in which patients in the intervention group underwent automated symptom monitoring, either by interactive voice-recorded telephone calls or by internet, which prompted live case manager follow-up on an as-needed basis.⁴¹ Half of the models included active patient education, most of which was in the form of group education sessions. For 2 interventions, the main feature was increasing capacity for² and access to⁴ multimodal care. The McMaster Family Health Team (MFHT) in Hamilton, Ontario sought to use existing resources to increase capacity and access to multimodal care by centralizing services via weekly 2-hour group sessions that incorporated physician, pharmacist, dietician, and physiotherapist resource persons.² The CAPRI represents an example of a Canadian health region administration providing funding for developing a new multidisciplinary program designed specifically to increase access to multimodal chronic pain care in a previously underserved rural setting in Lacombe, Alberta. It featured decision support via risk stratification with matched treatment pathways and weekly symptom monitoring and weekly 5-hour group multidisciplinary education and activation sessions as needed.⁴

Table 2. Overview of Chronic Pain Care Model Components

| | Decision support | Increasing access to and coordination of multimodal care | Additional care coordination resources | Active patient education, activation |
|------------------------------------|---|--|--|---|
| Ahles 2001/2006 ^{1,38} | Algorithm-guided treatment recommendations; nurse educator support for patients with psychosocial problems. | | Weekly telephone contact with nurse educator | |
| Angeles 2013 ² | | Centralization: Multidisciplinary program developed by available providers, tailored to setting, delivered by group visits | | Group sessions |
| Bair 2015 ^{3,39} (ESCAPE) | Algorithm-guided stepped care with analgesics and CBT, delivered by NCM | | Biweekly by NCM | |
| Burnham 2010 ⁴ (CAPRI) | 4 care pathways based on complexity: (1) self-management, (2) spinal block, (3) medication management, (4) multidisciplinary care | Establishment of a multidisciplinary program in a rural setting | Weekly for complex patients | Weekly 5-hr group multidisciplinary sessions for complex patients |
| Dobscha 2009 ⁵ (SEACAP) | Clinician education; stepped care; expert decision support | | Every 2 months by psychologist and internist team | Optional 4-session group workshop |
| Hay 2006 ⁶ | Enhanced pharmacy review: pharmacist-led and algorithm-guided | | Biweekly by pharmacist and nurse | 3 to 6 20-minute sessions with pharmacist |
| Hill 2011 ⁷ | Risk stratification using validated tool; risk-matched treatment pathways | | | |
| Kroenke 2009 ⁸ (SCAMP) | Algorithm-guided stepped care with antidepressants and self-management | | Biweekly to monthly by depression pain clinical specialist | 6 30-minute sessions with NCM |
| Kroenke 2014 ⁴¹ (SCOPE) | Algorithm-guided stepped care with analgesics | | Automated monitoring via IVR or internet that would prompt nurse contacts. | |

Abbreviations: NCM = nurse case manager, CBT = cognitive behavioral therapy, IVR = interactive voice response; ESCAPE = Evaluation of Stepped Care for Chronic Pain; SEACAP = Study of the Effectiveness of a Collaborative Approach to Pain; SCAMP = Stepped Care for Affective Disorders and Musculoskeletal Pain; SCOPE = Stepped Care to Optimize Pain Care Effectiveness; CAPRI = Central Alberta Pain and Rehabilitation Institute

Specific Characteristics of Multimodal Chronic Pain Care Model Components

All interventions were comprised of multiple and heterogeneous components for improving the delivery of multimodal care. Table 3 describes the specific characteristics of the model components, such as the disciplines of the care management team members, frequency and duration of care management, and whether the provider and patient education was active or passive in nature (full detail in Appendix C in supplemental materials). Among the four VA-based models^{3,39, 5, 8, 41} decision support primarily involved weekly case management meetings to facilitate interaction between providers, plus either an analgesic^{3,39, 41} or antidepressant⁸ algorithm. Additionally, the SEACAP study from the Portland VAMC provided the most intense example of active provider education, in which providers participated in two 90-minute education sessions.⁵ In the category of care coordination, VA case management teams represented nursing and mental health and pain specialties. Active symptom monitoring ranged in frequency from biweekly to every 2 months. The VA SCOPE study was notable for including a health information technology component of interactive voice response monitoring.⁴¹ In the category of increasing access to multimodal care, mental health support was the most commonly added modality in the VA models,^{1,3,4,7,8,39,41} which was primarily optional. The majority of VA models included an active patient education component (workshops, individual counseling, *etc*).

Compared to VA-based models, in the remaining models conducted in other non-VA settings,^{1,38, 2,4,6,7} decision support components were less common, case management teams were more diverse – representing occupational therapy, social work, physical therapy, psychiatry, pharmacy, physiotherapy, kinesiology, and dietary needs – mental health treatment was more often a required component, and patient self-management support was more often passive in nature.

Table 3. Specific Characteristics of Multimodal Chronic Pain Care Model Components

| | Decision support | | | Additional care coordination resources | | | Increasing access to multimodal care | Active patient education and activation |
|------------------------------------|---|--|----------------------------------|---|------------------------|---|--|--|
| | <i>Facilitate interaction between providers</i> | <i>Primary care provider education, activation</i> | <i>Pharmacotherapy algorithm</i> | <i>Active symptom monitoring frequency</i> | <i>HIT enhancement</i> | <i>Case management team</i> | <i>Mental health treatment</i> | <i>Patient self-management support</i> |
| Ahles 2001/2006 ^{1,38} | NS | Passive | NS | Study arm 1: NS Study arm 2: Weekly, descending | NS | Study arm 1: PCP Study arm 2: PCP, Nurse | Study arm 1: NS Study arm 2: Required | Study arm 1: Passive Study arm 2: Both |
| Angeles 2013 ² | Weekly CM | NS | NS | Weekly for 8 weeks | NS | Occupational therapist, social worker | NS | Active |
| Bair 2015 ^{3,39} (ESCAPE) | Weekly CM | NS | Analgesic | Biweekly | NS | Nurses | Fixed CBT | Passive |
| Burnham 2010 ⁴ (CAPRI) | Int. 1: NS Int. 2: Weekly CM | NS | Int. 1: Analgesic Int. 2: NS | Study arm 1: NS Study arm 2: Weekly for 12 weeks | NS | Study arm 1: PCP Study arm 2: PCP, Psychiatrist, Psychologist, Physical Therapist, Kinesiologist, Nurse, Dietician | Study arm 1: NS Study arm 2: Required, 1+ hrs psychotherapy | Study arm 1: Passive Study arm 2: Both |
| Dobscha 2009 ⁵ (SEACAP) | NS | Active | NS | Every 2 months | NS | Psychologist, internist | Optional | Both |
| Hay 2006 ⁶ | NS | NS | Analgesic | Biweekly | NS | Pharmacist, nurse | NS | Both |
| Hill 2011 ⁷ | NS | Active | NS | NS | NS | Physiotherapist, nurse | Required, high-risk patients received “psychologically informed physiotherapy” | Passive |



| | | | | | | | | |
|---------------------------------------|-----------|----|----------------|-----------------------|---------------|-------------------------------------|----------|---------|
| Kroenke 2009 ⁸ (SCAMP) | Weekly CM | NS | Antidepressant | Biweekly to monthly | NS | Depression-pain clinical specialist | Optional | Active |
| Kroenke 2014 ⁴¹ (SCOPE) | Weekly CM | NS | Analgesic | Automated, descending | IVR, internet | Nurse, physician pain specialist | Optional | Passive |

Abbreviations: NS = none specified; CM = case management; CBT = cognitive behavioral therapy; HIT = health information technology; PCP = primary care provider; ESCAPE = Evaluation of Stepped Care for Chronic Pain; SEACAP = Study of the Effectiveness of a Collaborative Approach to Pain; SCAMP = Stepped Care for Affective Disorders and Musculoskeletal Pain; SCOPE = Stepped Care to Optimize Pain Care Effectiveness; CAPRI = Central Alberta Pain and Rehabilitation Institute

Patient Outcomes

Decision Support Coupled with Case Management

Among the 6 models that coupled decision support with case management, the proportion of patients with clinically significant improvement in pain intensity or pain-related function based on a 30% or greater reduction in scores on the RMDQ, BPI, or OMERACT-OARSI was significantly increased in ESCAPE,^{3,39} SEACAP,⁵ SCAMP,⁸ and SCOPE⁴¹ (NNT range, 4.1 to 12.7 in 12 months), unchanged in a model that emphasized enhanced pharmacy review and physiotherapy,⁶ and unmeasured in model that emphasized rapid assessment and management via computer-based assessment.¹ In the model that emphasized rapid assessment, pain intensity and function were measured based on the SF-36.¹ Change from baseline on the bodily pain score was greater in the intervention group compared to the control at 6 months (7.6 vs 2.2; P = 0.011), but not at one year (7.8 vs 3.6; P = 0.06). Change in functional interference estimate was reduced both at 6 months (0.96 vs -0.98; P = 0.027) and one year (1.5 vs 0.65; P = 0.02). Quality of life, depression, anxiety, sleep, opioid use, and unintended consequences were variably measured. Three of the models^{5,8,41} also showed improvements on at least one of the additional important outcomes of quality of life,^{8,41} depression,^{5,8,41} anxiety,⁸ and sleep.⁴¹

Risk/Complexity-matched Treatment Pathways

Among the 2 models using risk stratification coupled with risk-matched treatment pathways,^{4,7} only the model using the validated STarT Back screening tool for back pain resulted in greater clinically significant improvement in pain intensity or pain-related function ($\geq 30\%$ decrease in RMDQ scores) at 12 months.⁷ Patients screened with STarT Back and prescribed risk-matched treatment pathways also had greater improvement in depression scores and quality of life at 12 months. However, no differences in anxiety scores, or satisfaction with care were found between intervention and control at 12 months. This evidence is limited by moderate and different levels of attrition among risk groups and has thus far only been assessed in 851 people in England who were mostly female with a mean age of 50 years and with unknown mental health comorbidities. Thus, it is unclear how applicable this evidence is to Veterans. However, as previously mentioned, the STarT Back Screening Tool is now also being evaluated in an ongoing study in 6 large primary care clinics in the integrated Group Health system in Washington State.⁴³

The CAPRI's stratified approach used in a single center in rural Alberta significantly reduced pain intensity scores (rated on a 0-10 scale) compared to medication management.⁴ However, this evidence is insufficient to determine true intervention effects because it was assessed in a single underpowered study (N=82) of poor quality due to lack of outcome assessor blinding, no adjustment for potential confounders, and differential loss to follow-up.

Increasing Access via Group Multidisciplinary Intervention Sessions

The McMaster Family Health Team (MFHT) in Hamilton, Ontario sought to increase access to and coordination of specialty services via their centralization in weekly group sessions.² After 6 months of follow-up, there was a statistically significant improvement in the SF-36 physical domain. But because this finding is supported by only a single underpowered study (N=63) with low adherence (50%), it provides insufficient evidence on which to draw conclusions about this model.

Table 4. Summary of Findings (Intervention versus Control)

| Author Year | Clinically significant* improvement in pain intensity or pain-related function | QOL | Depression | Anxiety | Sleep | Opioid use | Unintended consequences/ treatment satisfaction |
|--|---|--|---|---|-------|---|---|
| <i>Decision Support Coupled with Case Management</i> | | | | | | | |
| Ahles 2001 ³⁸ | NR | SF-36 mean: Pain Component: 59.7 vs 46.9, P<0.005 Role Physical: 54.8 vs 37.5, P<0.03 Role Emotional: 81.9 vs 62.0, P<0.001 Role Social: 79.5 vs 64.5, P<0.001 | NR | NR | NR | NR | NR |
| Ahles 2006 ¹ | NR | SF-36 mean change: Role Emotional: 13.9 vs 3.8, P=0.046 Vitality: 7.4 vs 3.7, P=0.048 | NR | NR | NR | NR | NR |
| Bair 2015 ^{3,39} (ESCAPE) | RMDQ: RR=1.52 (95% CI 1.22 to 1.99) NNT=7.5 | NR | NR | NR | NR | NR | NR |
| Dobscha 2009 ⁵ (SEACAP) | RMDQ: 21.9% vs 14.0%, P=0.04 NNT=12.70 (95% CI 12.48 to 12.74) | Mean change EQ-5D: -0.02 vs -0.04, P=0.17 | Mean change PHQ-9: -3.7 vs -1.2, P=0.003 | NR | NR | Any opioid prescribed: 65% vs 61%, P=0.56 | Mean change global treatment satisfaction: -0.27 vs -0.36, P=0.44 |
| Hay 2006 ⁶ | OMERACT-OARSI (high improvement): 27% vs 28%; P=0.8 | NR | HADS depression: † 0.01 (95% CI -0.7 to 0.7) | HADS anxiety: † -0.23 (95% CI -1.1 to 0.6) | NR | NR | Satisfaction with treatment: † -19% (95% CI -32 to -4) |
| Kroenke 2009 ⁸ (SCAMP) | BPI: 41.5% vs 17.3%; RR=2.4 (95% CI 1.6 to 3.2) NNT=4.1 (95% CI 3.0 to 6.5) | SF-36:** General health: 11.1 (95% CI 4.2 to 18.0) Social functioning: 6.1 (95% CI -1.3 to 13.5) Vitality: 8.8 (95% CI 3.6 to 14.0) | ≥50% decrease in HSCL-20 from baseline: RR=2.3 (95% CI 1.5 to 3.2) | GAD-7:** -2.2 (95% CI -3.5 to -0.9) | NR | Months of opioid use over 12 months: 3.5 vs 3.0, P=0.35 | NR |

| Author Year | Clinically significant* improvement in pain intensity or pain-related function | QOL | Depression | Anxiety | Sleep | Opioid use | Unintended consequences/ treatment satisfaction |
|--|---|---|--|--|---|---|---|
| Kroenke 2014 ⁴¹ (SCOPE) | BPI: 51.7% vs 27.1%; RR=1.9 (95% CI 1.4 to 2.7) NNT=4.1 (95% CI 3.0 to 6.4) | SF-12:** Physical: 2.5 (95% CI 0.0 to 5.0) Mental: 0.2 (95% CI -2.9 to 3.3) SF-36:** Social functioning: 5.3 (95% CI -1.6 to 12.2) Vitality: 2.2 (95% CI -3.9 to 8.2) | PHQ-9:** -1.8 (95% CI -3.4 to -0.2) | GAD-7:** -0.7 (95% CI -1.9 to 0.5) | PROMIS sleep:** -1.0 (95% CI -2.0 to 0.0) | Mean # of months taking opioids: 2.0 vs 1.6, P=0.27 | NR |
| <i>Risk/Complexity-matched Treatment Pathways</i> | | | | | | | |
| Burnham 2010 ⁴ (CAPRI) | NR | NR | NR | NR | NR | NR | NR |
| Hill 2011 ⁷ | RMDQ: 65% vs 57%; OR=1.48 (95% CI 1.02 to 2.15) NNT=10.8 (95% CI 5.8 to 206) | SF-12:** Physical: -2.93 (95% CI -4.31 to -1.56) Mental: -0.69 (95% CI -2.39 to 1.01) | HADS depression:** 0.62 (95% CI 0.07 to 1.17) | HADS anxiety:** 0.45 (95% CI -0.10 to 1.01) | NR | NR | Satisfaction with care (not satisfied): 27% vs 36% |
| <i>Increasing Access via Group Multidisciplinary Intervention Sessions</i> | | | | | | | |
| Angeles 2013 ² | NR | SF-36 mean change: Physical: -15.3 vs 3.4, P=0.01 Emotional: 2.6 vs 3.7, P=.92 Social: 3.2 vs 2.7, P=0.95 Mental: 3.6 vs 3.6, P=1.0 | NR | NR | NR | NR | NR |

Bold indicates statistical significance.

*≥ 30% decrease from baseline; **between-group mean difference (intervention-control); †between-group mean difference (control-intervention)

Abbreviations: QOL = quality of life; RMDQ = Roland-Morris Disability Questionnaire; SF-36 = Short form-36; SF-12 = Short form-12; EQ-5D = EuroQol health-related quality of life; PHQ-9 = Patient Health Questionnaire-9; OMERACT-OARSI = Outcome measures in rheumatology-Osteoarthritis Research Society International; HADS = Hospital anxiety and depression; BPI = Brief pain inventory; HSCL-20 = Hopkins symptom checklist; GAD-7 = Generalized anxiety disorder; PROMIS = Patient-reported outcomes measurement information system; ESCAPE = Evaluation of Stepped Care for Chronic Pain; SEACAP = Study of the Effectiveness of a Collaborative Approach to Pain; SCAMP = Stepped Care for Affective Disorders and Musculoskeletal Pain; SCOPE = Stepped Care to Optimize Pain Care Effectiveness; CAPRI = Central Alberta Pain and Rehabilitation Institute

Emerging models

We identified several additional multimodal chronic pain care models that have shown promise for improving patient outcomes in single-arm before-after studies⁴⁴⁻⁴⁹ (see Appendix D in supplemental materials for study details). The majority of these studies were small (N<65) and had short follow-up periods of 6 months or less. Most of the care models involved managed care with a multidisciplinary team. One model was unique in that it involved both group visits with a multidisciplinary team along with one-on-one visits with a primary care provider.⁴⁸ One study examined implementation of a stepped care model at a single VA center.⁴⁵ Although these pain care models have shown promise, they still need to be compared to a concurrent control group in larger samples of patients over longer-term durations to determine the true intervention effects.

We also identified several ongoing studies by recognized researchers including Matthew Bair, MD, Dan Cherkin, PhD, Jordan Karp, MD, Lynn Debar, PhD, and Erin Krebs, MD, which may fill gaps in existing research, or provide further support for various models of pain care (see Appendix D in supplemental materials for full listing of identified ongoing studies). Several ongoing studies examine models in new settings, including one national VA study examining telecare for integrated pain management. Previous studies within the VA have been limited to a single center. Another ongoing study is assessing the STarT Back Tool for risk stratification in the US healthcare system,⁴³ which has been previously studied in the UK.⁷ Several other ongoing studies examine care models with common elements such as case management with some form of medication optimization algorithm, or collaborative care programs which increase access to specialty care. Additionally, the Nova Scotia Chronic Pain Care Collaborative Network has been implemented which provides pain and addiction specialist mentors to primary care providers. Through personal correspondence with the principal investigator, we are aware of preliminary findings available in abstract form but have not gained access to them at the time of this draft.

SUMMARY AND DISCUSSION

To our knowledge, this is the first review to focus exclusively on evaluating the effectiveness of models to improve the delivery of multimodal chronic pain care in the primary care setting. We analyzed the models based on the 4 most common ways they promoted guideline-concordant multimodal chronic pain management: decision support, additional care coordination resources, enhanced patient education and activation, and increased access to a broader range of treatments. The 9 models we identified were evaluated in mostly good-quality RCTs comprised of 3,816 individuals primarily from 5 US States. The top 5 models that provided clinically relevant improvement in pain intensity and pain-related function over 9 to 12 months (NNT range, 4.1 to 12.70), as well as variable improvement in quality of life, depression, anxiety, and sleep, coupled a decision-support component – most commonly algorithm-guided treatment and/or stepped care – with proactive ongoing treatment monitoring: ESCAPE,^{3,39} SEACAP,⁵ STarT Back,⁷ SCAMP,⁸ and SCOPE.⁴¹ Findings from ESCAPE,^{3,39} SEACAP,⁵ SCAMP,⁸ and SCOPE⁴¹ have the highest applicability to Veterans because they were studied in VAMC settings. As each of the top 5 models is only supported by a single study with imprecise findings, however, current evidence leaves us with sufficient doubt about their findings to recommend further evidence development.

LIMITATIONS

This evidence base included several key limitations. First, although a larger than usual proportion of studies was conducted with Veterans, the generalizability of their findings may still be limited because they consisted of samples from single centers in Indianapolis and Portland. Second, determination of patients who are most likely to benefit from these models was limited due to under-reporting of key patient characteristics such as pain duration, opioid use at baseline, and prevalence of common medical and mental health comorbidities. Third, factors reducing our confidence that the studies' outcome estimates represent the true effects of the models are that (a) assessment of intervention fidelity was generally limited in most studies and (b) the potential confounding effects of co-interventions is largely unknown due to the limited data available on additional treatments administered outside of the study setting. Although a majority of studies reported adequate fidelity to the case management component, information was scarce about fidelity to other components, including provider training, delivery/receipt of other components, and/or enactment of skills. Only a third of studies described the level and type of co-interventions, which was typically based on patient report alone. Fourth, the comparator group was typically 'usual care,' but was generally very minimally described as regular access to primary and specialty care.⁵⁰ This is problematic because the type of usual care can vary by patient, practice, health care system, and individual providers. The inability to assess the extent to which the type of usual care used in study settings is similar to a particular target setting limits our determination of the potential added benefit of a model of care. Also, a common problem for studies of multimodal interventions is that we cannot distinguish the degree to which benefits can be attributed to the actual treatments versus the nonspecific effects of care management and/or increased monitoring because there was no attention control group.^{3,5,8,39,41} Fifth, the extent to which models for improving the uptake and organization of multimodal chronic pain in primary care provide *clinically relevant* benefits³¹ remains somewhat unclear. Although clinically significant improvement in pain intensity or pain-related function and quality of life outcomes were reported by 60% and 70% of the studies, respectively, only half to a small minority of studies measured other important outcomes: 50% for depression, 40% for anxiety, 10% for sleep, 30% for opioid use, and 20% for unintended consequences. Also, although the Initiative on

Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations on core chronic pain outcome assessment are available to guide chronic pain research, these are a decade old and new assessment instruments have subsequently emerged, including the Patient Reported Outcome Measurement Information System (PROMIS)⁵¹; pain intensity, interference with enjoyment in life, and interference with general activity (PEG); and Defense and Veterans Pain Rating Scale (DVPRS).^{52,53} Additionally, the Pain Assessment Screening Tool and Outcomes Registry (PASTOR) was developed and is being piloted collaboratively by the VA and Department of Defense to use computer-adaptive testing and the internet to implement administration of PROMIS and DVPRS in a military health system's electronic health record system.⁵¹ Finally, as only one study reported outcomes beyond 12 months,⁴ long-term sustainability in improvement is largely unknown.

The primary limitations of our findings that related to our review methods include (1) our literature search, (2) our use of second-reviewer checking in lieu of dual independent assessment of reviewer judgements, and (3) our scope. First, although our search included multiple databases, our shortened timeframe precluded searching a more exhaustive range of sources. Also, searching for literature is a common challenge in review of complex multicomponent health care interventions because of the many dimensions and inconsistent terminology used in the studies.³⁷ We addressed this challenge by including a wider than usual variety of terminology in our search strategy, as well as using a wider than usual range of grey literature searching. However, there is a risk that we may have missed additional relevant studies. Second, regarding our use of second-reviewer checking, surveys of rapid evidence review end-users found that they are willing to accept certain methodological short-cuts to increase reviewer efficiencies⁵⁴ and that availability of rapid reviews increased their uptake of evidence to inform time-sensitive system-level decision-making.⁵⁵ However, there is not yet consensus on what represents best practice for rapid reviews. A scoping review of rapid reviews found that short-cut approaches vary widely across all steps of the review process and are applied inconsistently.⁵⁶ Concerns have been expressed that streamlining standard systematic review methodology may potentially increase the risk of bias of rapid reviews, leading to suggestions for future research comparing findings of standard and rapid reviews.^{54,56-58} However, in contrast to the more common rapid review approach of data abstraction and quality appraisal being performed by only one reviewer – 84% to 86% based on an international survey of 40 rapid review producers – our method of using second reviewer verification was perceived to have lower risk of bias.⁵⁶ But comparison of single reviewer only, second-reviewer verification, and dual independent review methods for data abstraction and quality assessment have not yet been empirically studied. Third, regarding our scope, at the advice of our operational partners, we focused on primary care because it is responsible for the majority of pain management. However, we acknowledge this limits the applicability of the findings of our review to a broader range of specialty settings, including multidisciplinary pain clinics, rehabilitation centers, etcetera.

CLINICAL AND RESEARCH IMPLICATIONS

As a variety of care models have already proven effective in VA settings (SEACAP, SCOPE, SCAMP, ESCAPE),^{3,5,8,41} it seems reasonable to consider wider implementation of one or more of these models across multiple VAMCs with a clear plan for further evidence development that addresses shortcomings of previous research through: (1) better characterization of patients' pain duration, opioid use at baseline, and prevalence of common medical and mental health comorbidities, co-interventions, and usual care; (2) more rigorous evaluation of model fidelity

across a broader range of components; (3) assessment of a broader range of clinically-relevant core outcomes per IMMPACT recommendations; (4) longer-term follow-up; and (5) inclusion of potentially underserved areas, such as rural settings and that have more racial/ethnic diversity. The STarT Back risk stratification approach that matches treatments to physical and psychosocial obstacles in back pain provided a similar extent of clinically-relevant benefit⁷ to the VAMC-tested models. But as it was implemented in England, the applicability of findings from this study to a VAMC setting is unclear. However, the implementation of this strategy in the US Group Health setting is underway, with results anticipated in the near future.⁴³ Upon consideration of those US healthcare system findings, the VHA may also consider implementation with evidence development of the STarT Back approach as another alternative.

As a main focus of these models is to reduce the numerous known challenges to primary care providers in managing the complexities of patients with chronic pain, it is also important to understand how these models are affecting providers' experiences. As provider perspectives were largely unexplored in previous studies, we suggest future research consider assessing the 3 domains identified as important in interviews of providers at the Indianapolis VAMC: (1) patient-centered communication skills; (2) extent of shared decision-making; and (3) provider burnout.⁵⁹

For additional related evidence review work, an updated review of the state of the science of chronic pain outcome assessment could be useful in informing the direction of future research. Also, as this is anticipated to continue to be an important clinical area in the future, with rapid evidence development expected, we suggest conducting an updated evidence review in a few years. For example, several additional multimodal chronic pain care models have already shown promise for improving patient outcomes in single-arm studies, and we also identified several ongoing studies which may fill gaps in existing research or provide further support for various models of pain care.

CONCLUSIONS

Five models coupling a decision-support component – most commonly algorithm-guided treatment and/or stepped-care – with proactive ongoing treatment monitoring have the best evidence from good-quality RCTs of providing clinically relevant improvement in pain intensity and pain-related function over 9 to 12 months, as well as variable improvement in other important core outcomes. It is reasonable to consider wider implementation of any of those models across multiple VAMCs with a clear plan for further evidence development to address shortcomings of previous research.

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REFERENCES

1. Ahles TA, Wasson JH, Seville JL, et al. A controlled trial of methods for managing pain in primary care patients with or without co-occurring psychosocial problems. *Annals of family medicine*. Jul-Aug 2006;4(4):341-350.
2. Angeles RN, Guenter D, McCarthy L, et al. Group interprofessional chronic pain management in the primary care setting: a pilot study of feasibility and effectiveness in a family health team in Ontario. *Pain Research & Management*. Sep-Oct 2013;18(5):237-242.
3. Bair MJ, Ang D, Wu J, et al. Evaluation of Stepped Care for Chronic Pain (ESCAPE) in Veterans of the Iraq and Afghanistan Conflicts: A Randomized Clinical Trial. *JAMA internal medicine*. May 2015;175(5):682-689.
4. Burnham R, Day J, Dudley W. Multidisciplinary chronic pain management in a rural Canadian setting. *Canadian Journal of Rural Medicine*. Winter2010 2010;15(1):7-13.
5. Dobscha SK, Corson K, Perrin NA, et al. Collaborative care for chronic pain in primary care: a cluster randomized trial. *Jama*. Mar 25 2009;301(12):1242-1252.
6. Hay EM, Foster NE, Thomas E, et al. Effectiveness of community physiotherapy and enhanced pharmacy review for knee pain in people aged over 55 presenting to primary care: pragmatic randomised trial. *BMJ*. Nov 11 2006;333(7576):995.
7. Hill JC, Whitehurst DGT, Lewis M, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. *Lancet (London, England)*. Oct 29 2011;378(9802):1560-1571.
8. Kroenke K, Bair MJ, Damush TM, et al. Optimized antidepressant therapy and pain self-management in primary care patients with depression and musculoskeletal pain: a randomized controlled trial. *Jama*. May 27 2009;301(20):2099-2110.
9. Kroenke K, Krebs E, Wu J, et al. Stepped Care to Optimize Pain care Effectiveness (SCOPE) trial study design and sample characteristics. *Contemporary clinical trials*. Mar 2013;34(2):270-281.
10. International Association for the Study of Pain SoT. Classification of chronic pain. Descriptions of chronic pain syndromes and definitions of pain terms. *Pain. Supplement*. 1986;3:S1-226.
11. Haskell SG, Ning Y, Krebs E, et al. Prevalence of painful musculoskeletal conditions in female and male veterans in 7 years after return from deployment in Operation Enduring Freedom/Operation Iraqi Freedom. *The Clinical journal of pain*. Feb 2012;28(2):163-167.
12. Kerns RD, Otis J, Rosenberg R, Reid MC. Veterans' reports of pain and associations with ratings of health, health-risk behaviors, affective distress, and use of the healthcare system. *Journal of rehabilitation research and development*. Sep-Oct 2003;40(5):371-379.
13. Matthias MS, Miech EJ, Myers LJ, Sargent C, Bair MJ. A qualitative study of chronic pain in Operation Enduring Freedom/Operation Iraqi Freedom veterans: "A burden on my soul". *Military medicine*. Jan 2014;179(1):26-30.

14. Heapy AA. VA Pain Coach: Enhancing Use with OEF/OIF/OND Veterans in Clinical Settings. 2014;
http://www.hsrd.research.va.gov/research/abstracts.cfm?Project_ID=2141703397. Accessed 11/16/2016, 2016.
15. Taylor SL. The Cost Effectiveness of Complementary and Alternative Treatments to Reduce Pain. 2014;
http://www.hsrd.research.va.gov/research/abstracts.cfm?Project_ID=2141703951. Accessed 11/16/2016, 2016.
16. Nahin RL. Severe Pain in Veterans: The Impact of Age and Sex, and Comparisons to the General Population. *The journal of pain : official journal of the American Pain Society*. Nov 21 2016.
17. Johannes CB, Le TK, Zhou X, Johnston JA, Dworkin RH. The prevalence of chronic pain in United States adults: results of an Internet-based survey. *The journal of pain : official journal of the American Pain Society*. Nov 2010;11(11):1230-1239.
18. Institute of Medicine (US) Committee on Advancing Pain Research C, and Education. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. Washington DC: National Academy of Sciences.; 2011.
19. Narouze S, Souzdalnitski D. Obesity and chronic pain: systematic review of prevalence and implications for pain practice. *Regional anesthesia and pain medicine*. Mar-Apr 2015;40(2):91-111.
20. Stubbs B, Koyanagi A, Thompson T, et al. The epidemiology of back pain and its relationship with depression, psychosis, anxiety, sleep disturbances, and stress sensitivity: Data from 43 low- and middle-income countries. *General hospital psychiatry*. Nov - Dec 2016;43:63-70.
21. Otis JD, Keane TM, Kerns RD. An examination of the relationship between chronic pain and post-traumatic stress disorder. *Journal of rehabilitation research and development*. Sep-Oct 2003;40(5):397-405.
22. Hooten WM. Chronic Pain and Mental Health Disorders: Shared Neural Mechanisms, Epidemiology, and Treatment. *Mayo Clinic proceedings*. Jul 2016;91(7):955-970.
23. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. *Jama*. Nov 20 2002;288(19):2469-2475.
24. Rosenquist RW, Benzon HT, Connis RT, et al. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. *Anesthesiology*. Apr 2010;112(4):810-833.
25. Kerns RD, Philip EJ, Lee AW, Rosenberger PH. Implementation of the veterans health administration national pain management strategy. *Translational behavioral medicine*. Dec 2011;1(4):635-643.
26. Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Annals of internal medicine*. Oct 2 2007;147(7):478-491.
27. Matthias MS, Parpart AL, Nyland KA, et al. The patient-provider relationship in chronic pain care: providers' perspectives. *Pain medicine (Malden, Mass.)*. Nov 2010;11(11):1688-1697.

28. Patient-Centered Outcomes Research Institute. Systems Interventions to Improve the Management of Chronic Musculoskeletal Pain: Topic Brief. 2015.
29. Lincoln LE, Pellico L, Kerns R, Anderson D. Barriers and Facilitators to Chronic Non-cancer Pain Management in Primary Care: A Qualitative Analysis of Primary Care Providers? Experiences and Attitudes. *Journal of Palliative Care & Medicine*. 2013;2013.
30. Williams JW, Jr., Gerrity M, Holsinger T, Dobscha S, Gaynes B, Dietrich A. Systematic review of multifaceted interventions to improve depression care. *General hospital psychiatry*. Mar-Apr 2007;29(2):91-116.
31. Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain*. 2005;113(1-2):9-19.
32. McDonagh MS, Jonas DE, Gartlehner G, et al. Methods for the drug effectiveness review project. *BMC Med. Res. Methodol*. 2012;12:140.
33. Higgins JP, Altman DG, Gotzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ*. 2011;343:d5928.
34. Sterne J, Higgins J, Reeves B. A Cochrane risk of bias assessment tool: For non-randomized studies of interventions (ACROBAT-NRSI), version 1.0. 0. 2014.
35. Hill JC, Dunn KM, Lewis M, et al. A primary care back pain screening tool: identifying patient subgroups for initial treatment. *Arthritis Care & Research*. 2008;59(5):632-641.
36. Berkman ND, Lohr KN, Ansari M, et al. Grading the Strength of a Body of Evidence When Assessing Health Care Interventions for the Effective Health Care Program of the Agency for Healthcare Research and Quality: An Update Methods Guide for Effectiveness and Comparative Effectiveness Reviews. 2013.
37. Guise J-M, Chang C, Viswanathan M, et al. Agency for Healthcare Research and Quality Evidence-based Practice Center methods for systematically reviewing complex multicomponent health care interventions. *Journal of clinical epidemiology*. 2014;67(11):1181-1191.
38. Ahles TA, Seville J, Wasson J, Johnson D, Callahan E, Stukel TA. Panel-based pain management in primary care. a pilot study. *J Pain Symptom Manage*. Jul 2001;22(1):584-590.
39. Bair MJ, Ang D, Wu J, et al. Evaluation of Stepped Care for Chronic Pain (ESCAPE) in Veterans of the Iraq and Afghanistan Conflicts: A Randomized Clinical Trial. *JAMA internal medicine*. May 2015;175(5):682-689.
40. Kroenke K, Krebs EE, Bair MJ. Pharmacotherapy of chronic pain: a synthesis of recommendations from systematic reviews. *General hospital psychiatry*. May-Jun 2009;31(3):206-219.
41. Kroenke K, Krebs EE, Wu J, Yu Z, Chumbler NR, Bair MJ. Telecare collaborative management of chronic pain in primary care: a randomized clinical trial. *Jama*. Jul 16 2014;312(3):240-248.
42. Thielke S, Corson K, Dobscha SK. Collaborative care for pain results in both symptom improvement and sustained reduction of pain and depression. *General hospital psychiatry*. 2015;37(2):139-143.

43. Cherkin D, Balderson B, Brewer G, et al. Evaluation of a risk-stratification strategy to improve primary care for low back pain: the MATCH cluster randomized trial protocol. *BMC Musculoskeletal Disorders*. 2016;17(1):361.
44. Unützer J, Hantke M, Powers D, et al. Care management for depression and osteoarthritis pain in older primary care patients: a pilot study. *International Journal of Geriatric Psychiatry*. 2008;23(11):1166-1171.
45. Dorflinger L, Moore B, Goulet J, et al. A partnered approach to opioid management, guideline concordant care and the stepped care model of pain management. *JGIM: Journal of General Internal Medicine*. 2014;29:870-876.
46. Briggs M, Closs SJ, Marczewski K, Barratt J. A feasibility study of a combined nurse/pharmacist-led chronic pain clinic in primary care. *Quality in primary care*. 2008;16(2):91-94.
47. Chelminski PR, Ives TJ, Felix KM, et al. A primary care, multi-disciplinary disease management program for opioid-treated patients with chronic non-cancer pain and a high burden of psychiatric comorbidity. *BMC Health Services Research*. 2005;5(1):1.
48. Gardiner P, Dresner D, Barnett KG, Sadikova E, Saper R. Medical group visits: a feasibility study to manage patients with chronic pain in an underserved urban clinic. *Global Advances in Health and Medicine*. 2014;3(4):20-26.
49. Wiedemer NL, Harden PS, Arndt IO, Gallagher RM. The opioid renewal clinic: a primary care, managed approach to opioid therapy in chronic pain patients at risk for substance abuse. *Pain Medicine*. 2007;8(7):573-584.
50. Möhler R, Bartoszek G, Köpke S, Meyer G. Proposed criteria for reporting the development and evaluation of complex interventions in healthcare (CReDECI): guideline development. *International journal of nursing studies*. 2012;49(1):40-46.
51. Cook KK, Michael; Buckenmaier, Chester (Trip); Gershon, Richard. 22nd Annual Conference of the International Society for Quality of Life Research. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation*. Oct 2015;24 Suppl 1:1-191.
52. Buckenmaier CC, 3rd, Galloway KT, Polomano RC, McDuffie M, Kwon N, Gallagher RM. Preliminary validation of the Defense and Veterans Pain Rating Scale (DVPRS) in a military population. *Pain medicine (Malden, Mass.)*. Jan 2013;14(1):110-123.
53. Polomano RC, Galloway KT, Kent ML, et al. Psychometric Testing of the Defense and Veterans Pain Rating Scale (DVPRS): A New Pain Scale for Military Population. *Pain medicine (Malden, Mass.)*. Aug 2016;17(8):1505-1519.
54. Hartling L, Guise J, Hempel S, et al. EPC Methods: AHRQ End-User Perspectives of Rapid Reviews. 2016.
55. Peterson K, Floyd N, Ferguson L, Christensen V, Helfand M. User survey finds rapid evidence reviews increased uptake of evidence by Veterans Health Administration leadership to inform fast-paced health-system decision-making. *Systematic Reviews*. 2016;5(1):132.
56. Tricco AC, Antony J, Zarin W, et al. A scoping review of rapid review methods. *BMC medicine*. 2015;13(1):1.

57. Hartling L, Guise J-M, Kato E, et al. EPC methods: an exploration of methods and context for the production of rapid reviews. 2015.
58. Polisena J, Garritty C, Umscheid CA, et al. Rapid Review Summit: an overview and initiation of a research agenda. *Systematic reviews*. 2015;4(1):1.
59. Matthias MS, Bair MJ, Nyland KA, et al. Self-management support and communication from nurse care managers compared with primary care physicians: a focus group study of patients with chronic musculoskeletal pain. *Pain Management Nursing*. Mar 2010;11(1):26-34.