

CADTH Health Technology Review

Stepped Care Models for Chronic Pain

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Abbreviations

| | |
|---------------|--|
| CBT | cognitive behaviour therapy |
| CINAHL | Cumulative Index to Nursing and Allied Health Literature |
| ESCAPE | Evaluation of Stepped Care for Chronic Pain |
| MeSH | Medical Subject Headings |
| NCCP | Non-cardiac chronic pain |
| PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analyses |
| RCT | randomized controlled trial |
| SCS | Stepped Care Strategy |
| SCM-PM | Stepped Care Model for Pain Management |

Key Messages

- CADTH included 6 reports describing the potential clinical benefits of 5 stepped care models for chronic pain in this review.
 - The randomized controlled trial of the stepped care model for patients who are overweight or obese with chronic pain due medial tibiofemoral osteoarthritis described the impact on pain remission, pain intensity, and function.
 - The before-after and retrospective cohort study of the Stepped Care Model of Pain Management described the effects on pain, quality of chronic pain care, pharmacotherapy use, and health care utilization in US veterans.
 - The before-after study of the biopsychosocial stepped care model for non-cardiac chest pain described the potential benefits on chest pain, depression, anxiety, quality of life, and health care use.
 - The prospective cohort study of the Stepped Care Strategy compared a cohort of patients who received stepped care strategy-consistent care for hip or knee pain due to osteoarthritis with a cohort who received stepped care strategy-inconsistent care and described the results on pain physical function, self-efficacy, active pain coping, and health care use.
 - The Evaluation of Stepped Care for Chronic Pain randomized controlled trial described the effects on pain, disability, and pharmacotherapy use in US veterans.
- CADTH included 1 cost-effectiveness analysis that described the cost implications of a stepped care pathway for treating sciatica pain.
- While all included models used a stepped care approach to chronic pain management, the models were customized, and the evaluation methods were heterogeneous.

Background

Chronic pain is generally defined as pain lasting for 3 months or longer or persisting beyond the time needed for normal tissue healing.¹ It can affect the sufferer's quality of life and can lead to substantial physical and psychological morbidity.² One in 5 Canadians lives with chronic pain, and it is 1 of the most common reasons that Canadians seek medical attention. The economic burden is substantial.² In 2019, between \$15.1 and \$17.2 billion in estimated direct costs were associated with managing chronic pain in Canada.³

Because chronic pain is difficult to cure, the goal of treatment is to control pain, maintain function, maximize coping, and prevent disability, and often involves a multidisciplinary pain management plan.^{1,4} CADTH conducted an Environmental Scan in 2021 to compile information on the models of care for chronic pain and chronic non-pain-related medical conditions being used in Canada and in other countries.⁵ One of the 3 priority models of care of interest in the Environmental Scan is the focus of the current review.

With stepped care, interventions that are used to manage chronic pain are organized into a series "steps" placed on a continuum from lowest to most intensive based on a variety of characteristics, including the facility's level of care (e.g., primary, secondary, and tertiary care centres), type of care provider (e.g., education modules, workshops, individual therapies), treatment needs, patient effort, level of health care provider contact, and cost.^{6,7} Patients are initially offered the least intensive intervention that takes into account the nature, duration,

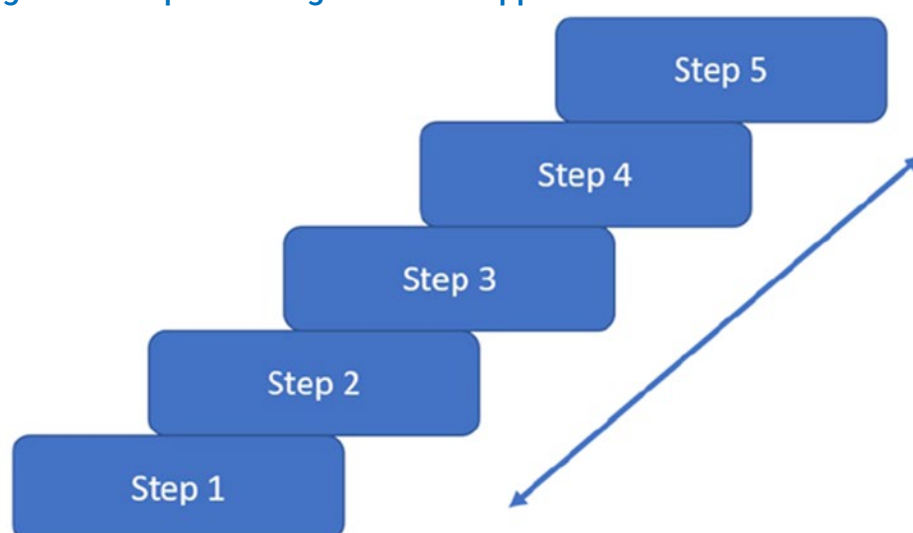
severity and course of symptoms. Immediate access to this first level of care may meet the needs of a considerable portion of the chronic care population and has the potential to alleviate wait lists for patients who need higher levels of specialized care. The progression of symptoms and treatment outcomes are routinely monitored, and subsequent individual treatment efforts are adjusted and stepped up or down, until treatment goals are met.^{7,8} [Figure 1](#) presents a simplified diagram of a stepped care.⁵

The CADTH Environmental Scan⁵ identified 4 stepped care models for chronic pain and 9 stepped models for other medical conditions (mental health and insomnia). The Environmental Scan also summarized the main categories of patient-related outcomes associated with models of care delivery for patients with chronic pain: pain (e.g., intensity and interference), psychosocial (e.g., coping, depression, anxiety, distress, and fear), function (e.g., disability and employment status), and health care use (e.g., prescription of any opioid, long-term opioid therapy, frequency of primary care visits, and number of visits to specialty health care services).

Stepped care programs have demonstrated clinical benefits for other conditions, such as depression and anxiety.^{9,10} In previous reviews of studies on stepped care models for chronic pain the authors reported positive results on pain, disability, general and physical health, depression, and anxiety.^{11,12} Preliminary findings from a 2020 report on the implementation of a stepped care program in Ottawa, Canada suggested that wait times for access to chronic pain programs may be considerably reduced with a stepped care approach.¹³ The current review aims to describe the available literature on the potential clinical benefits and harms of using stepped models for the management of chronic pain.

Stepped care models are designed to maximize the match between health care needs and interventions, while minimizing care costs.⁶ The cost-effectiveness of a stepped care model was shown in people with a depressive disorder in primary care.^{14,15} A 2010 economic evaluation¹⁶ explored the incremental benefit and incremental health services cost of a

Figure 1: Simplified Diagram of a Stepped Care Model



Source: Brett K, MacDougall D. CADTH Health Technology Review Models of Care for Chronic Pain. Ottawa, ON: CADTH: https://www.cadth.ca/sites/default/files/es/ES0350%20_to%20Publishing%20Final.pdf. Accessed 2022 Mar 22.⁵

stepped care intervention in US veterans with chronic pain. The authors reported that the stepped care model resulted in more pain disability-free days compared with usual care. The stepped care group also had significantly higher costs than the usual care group, which the authors claimed were likely attributable to the cost of stepped care as well as changes in treatment due to its implementation.¹⁶ Another aim of the current review is to describe the available literature on potential cost implications of using stepped care models for the management of chronic pain.

Objectives

The key objectives of this CADTH review are as follows

1. Identify and summarize literature on the potential benefits and harms of stepped care models of care for chronic pain.
2. Identify and summarize literature on the potential cost implications of stepped care models of care for chronic pain.

The focus of this review is to summarize what literature exists on the clinical benefits, harms, and cost implications of stepped care models for chronic pain. Since chronic cancer pain and chronic non-cancer pain are distinct entities, as evidenced by unique clinical practice guidelines for each, this review focuses exclusively on chronic non-cancer pain.^{17,18} This review does neither includes a formal critical appraisal of the literature, nor is it a formal program evaluation. Thus, making conclusions or recommendations about the value of stepped care models for chronic pain are outside the scope of this review.

Research Questions

1. What literature describes the potential clinical benefits and harms of providing care using stepped care models for the management of people with chronic non-cancer pain?
2. What literature describes the potential cost implications of providing care using stepped care models for the management of people with chronic non-cancer pain?

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycInfo, the Cochrane Database of Systematic Reviews, the International HTA Database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were stepped care model and chronic pain. No filters were applied to limit the retrieval by study type. The search was limited to English language documents published between January 1, 2012 and April 1, 2022.

Selection Criteria

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text reports was based on the inclusion criteria presented in [Table 1](#).

Chronic non-cancer pain and other disorders or diseases (e.g., mental health conditions, multiple sclerosis, and stroke) frequently occur together.^{19,20} Reports were included if the population included people with chronic non-cancer pain, regardless of the presence of other disorders or diseases. However, reports were excluded if the target population was people with the associated disorders or diseases only and there was no specific mention of addressing chronic pain jointly.

Synthesis Approach

Information from the relevant studies was extracted into tables and organized by objective by 1 reviewer. The information was then used to structure and inform the current review. Narrative summaries of the literature were presented separately for each stepped care model. Data were extracted on the model components and implementation; evaluation methods; and findings that related to potential clinical benefits and harms, and potential costs. The limitations of each study were also described, as reported by the study's authors. No formal critical appraisal (e.g., risk of bias assessment) of the included studies was conducted.

Summary of Evidence

Quantity of Research Available

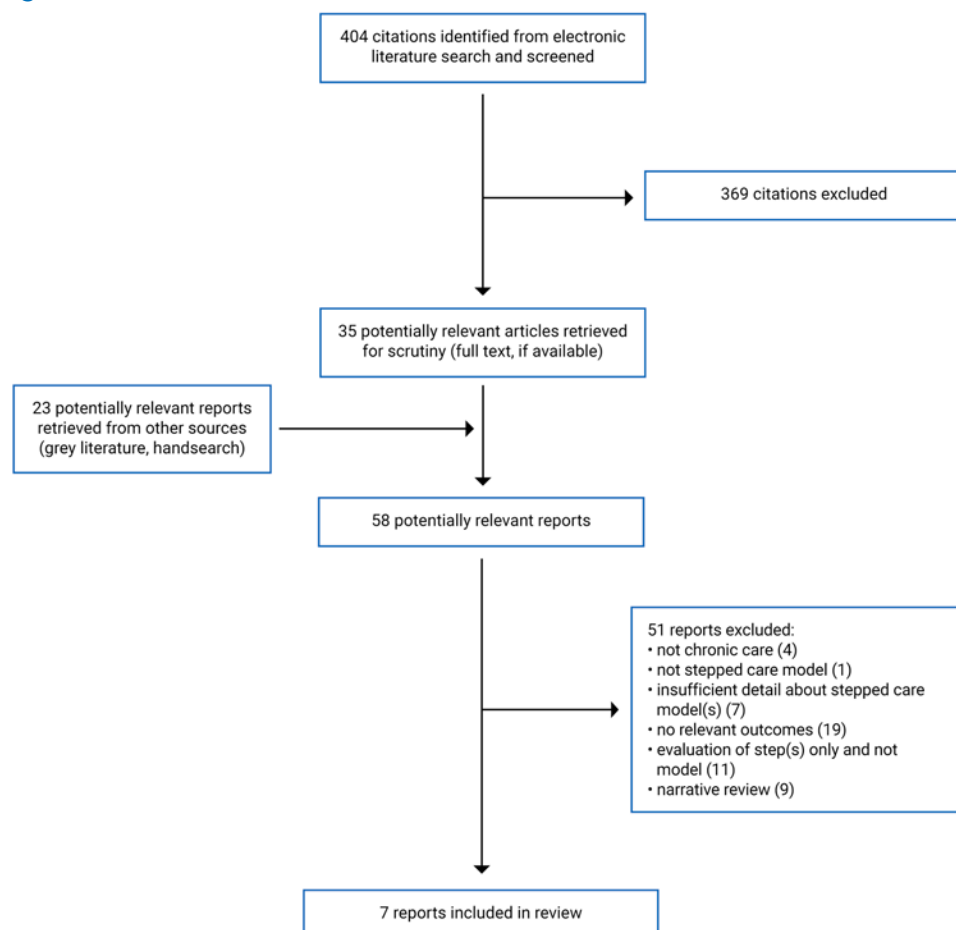
A total of 404 citations were identified in the literature search. Following screening of titles and abstracts, 369 citations were excluded, and 35 potentially relevant reports were retrieved for full-text review. An additional 23 potentially relevant reports were retrieved from the grey literature search for full-text review. Of the 58 potentially relevant reports, 51 were

Table 1: Selection Criteria

| Criteria | Description |
|---------------------|--|
| Population | People (of any age) with chronic non-cancer pain in outpatient settings of publicly funded health care facilities |
| Intervention | Care provided using stepped care models |
| Type of information | Q1: Descriptions of potential clinical benefits (e.g., pain, physical function, sleep, social function, emotional and psychological functioning [e.g., anxiety, depression], health-related quality of life, changes in use of pharmacotherapy [e.g., opioids]) and harms (e.g., hospitalizations, substance use, adverse events) Q2: Descriptions of potential cost implications (e.g., budget impact, cost savings, economic benefits to individuals or health systems) |
| Study designs | No restrictions on study design or type of report |
| Search time frame | 10 years |

excluded. In total, 7 reports of 6 studies (2 randomized controlled trials [RCTs]^{21,22} and 4 non-randomized studies [1 prospective cohort,²³ 1 retrospective cohort,²⁴ and 2 before-after studies],^{25,26} evaluating 5 stepped care models and 1 report of 1 economic evaluation of a stepped treatment pathway²⁷) were included. [Figure 2](#) presents the PRISMA flow chart of the study selection.²⁸

Figure 2: Selection of Included Studies



Reports of studies that evaluated 1 or more steps in the stepped care approach, rather than the implementation and evaluation of the stepped care model itself, were beyond the scope of this review and not included. A list of these reports is presented in [Appendix 1](#).

Guidelines that made recommendations regarding the implementation of stepped care models for chronic pain were outside of the scope of this review but are listed as documents of potential interest in [Appendix 2](#). Other reports of potential interest that were identified in the literature search but did not meet our inclusion criteria are also listed in [Appendix 2](#).

Objective 1: Identify and Summarize Literature on the Potential Benefits and Harms of Stepped Care Models of Care for Chronic Pain

Six studies reporting on 5 stepped care models for chronic non-cancer pain^{21-26,29} were included in this review. Each study described the implementation, evaluation, and potential benefits of a specific stepped care model.

One of the studies²¹ described the potential harms of a stepped care model.

In the following sections, each stepped care model is presented. Details of the model components and implementation, evaluation methods, and relevant findings are presented in individual tables, and briefly summarized narratively. The limitations of each study as reported by the authors are also described. The models are presented in reverse chronological order of their publication dates (i.e., most recent publication is presented first).

Stepped Care Model in People With Excess Body Weight and Knee Osteoarthritis

One RCT evaluated a stepped care strategy for people aged 50 years and older with excess body weight and chronic pain due to medial tibiofemoral osteoarthritis.²¹ Characteristics of the stepped care model and RCT are presented in [Table 2](#) and [Table 3](#). Study participants in the intervention arm received stepped care. The first step in the model involved 18 weeks of a diet and exercise program. In the second step, patients in remission continued with diet and exercise. Disease remission was defined as symptomatic remission of pain plus decrease in disease activity and/or symptomatic remission of functional impairment, as assessed by the Patient Acceptable Symptom State. If remission was not achieved, participants were assigned to cognitive behavioural therapy (CBT), knee brace, or muscle strengthening for 12 weeks, depending on their clinical presentation for symptoms of depression and varus malalignment. The comparison group received education material about the management of knee osteoarthritis. The researchers who enrolled and assessed the study participants were blinded to group allocation. The participants, study coordinator, therapist delivering the strengthening exercises, and statistician were not blinded.²¹

Table 2: Characteristics of Stepped Care Model for People with Excess Body Weight and Knee Osteoarthritis²¹

| Characteristic | Description |
|------------------|---|
| Model, country | Stepped care model for people who are overweight or obese with chronic pain due to medial tibiofemoral osteoarthritis, Australia |
| Model components | |
| Step 1 | Diet and exercise regime (18 weeks) based on Healthy Weight for Life program <ul style="list-style-type: none"> • 3 phases of 6 weeks each: motivational weight loss, consolidation phase, short-term maintenance phase • Evaluation at 20 weeks using PASS to determine Step 2 |

| Characteristic | Description |
|-------------------------------|---|
| Step 2 | 1 of 4 treatments (12 weeks) <ul style="list-style-type: none"> • Diet and exercise maintenance (if disease remission achieved) • Online CBT (if depression sub-score of DASS 21 was ≥ 14 [out of a maximum of 21]) • Knee brace (if varus malalignment was ≥ 6 degrees on the mechanical axis) • Muscle strengthening exercises (no depression or varus malalignment) including 6 supervised sessions and home-based exercises |
| Implementation details | NR |

CBT = cognitive behavioural therapy; DASS 21 = Depression, Anxiety, and Stress Scale – 21 items; NR = not reported; PASS = Patient Acceptable Symptom State.

Table 3: Characteristics of RCT Evaluating the Stepped Care Model for People With Excess Body Weight and Knee Osteoarthritis²¹

| Characteristic | Description |
|-------------------------------|--|
| Study design | RCT |
| Setting | 1 hospital in Sydney, Australia |
| Enrollment period | July 2015 to April 2017 |
| Funding sources | <ul style="list-style-type: none"> • The National Health and Medical Research Council • The University of Sydney |
| Inclusion criteria | Patients ≥ 50 years of age, BMI ≥ 28 kg/m ² , radiographic evidence of predominantly medial tibiofemoral osteoarthritis, pain intensity ≥ 40 of 100 on VAS, scores above PASS cut-off value for patient global assessment of disease activity, functional impairment ≥ 31 of 100 on WOMAC function subscale |
| Sample characteristics | <ul style="list-style-type: none"> • Intervention, N = 87 • Mean age (SD): 62.5 (7.4) years • Female: 66% • Median pain intensity score: 61.0 (range: 50.0 to 70.0) on VAS (0 to 100, higher = more pain) Comparison (educational pamphlets), N = 84 <ul style="list-style-type: none"> • Mean age (SD): 63.8 (7.3) years • Female: 62% • Median pain intensity score: 61.5 (range: 50.0 to 77.5) on VAS (0 to 100, higher = more pain) |
| Relevant outcomes | <ul style="list-style-type: none"> • Disease remission (remission of pain in addition to remission of patient global assessment of disease activity and/or functional impairment, PASS) • Pain intensity (VAS) • Functional impairment (WOMAC function subscale) • Depression (DASS 21) • Adverse events |
| Follow-up | 32 weeks |

BMI = body mass index; DASS-21 = Depression, Anxiety, and Stress Scale – 21 items; PASS = Patient Acceptable Symptom State; RCT = randomized controlled trial; SD = standard deviation; VAS = visual analogue scale; WOMAC = Western Ontario and McMaster Osteoarthritis Index.

The findings of the RCT are presented in [Table 4](#). The study authors²¹ reported that the difference of 13% in disease remission in favour of the stepped care group was below the 25% difference rate that was initially estimated to make the intervention worthwhile for being

implemented in clinical practice. Between-group (stepped care versus the comparison) differences in change from baseline for pain intensity, functional impairment, and depression were 3.3 (95% CI, -3.6 to 10.2), 6.0 (95% CI, 1.0 to 11.0), and -0.5 (95% CI, -3.7 to 2.6), respectively.

The study authors²¹ identified several limitations of the RCT. There was a higher dropout rate in the comparison group (19%) than the stepped care group (6%), which the authors suggested may have influenced the results. Treatment adherence, compliance, and fidelity were not assessed, and the authors were unable to determine if stepped care was not successful due to treatment nonadherence, noncompliance with study procedures, intervention not delivered as it was supposed to be delivered, or lack of effect.²¹

Table 4: Summary of Findings of an RCT Evaluating the Stepped Care Model for People With Excess Body Weight and Knee Osteoarthritis²¹

| Outcome | Findings | |
|---|-------------------------------------|----------------------------|
| | Stepped care intervention n = 87 | Comparison group n = 84 |
| Disease remission, n (%) | 32 (39) | 18 (26) |
| Between-group difference, % (95% CI) | 12.6 (-2.3 to 27.4) | |
| P value ^a | 0.10 | |
| Pain intensity (VAS score) | | |
| Baseline, mean (SD) | 61.0 (14.5) | 64.1 (16.4) |
| 32 weeks, mean (SD) | 40.0 (26.1) | 46.0 (23.6) |
| Between-group difference in change from baseline, mean (95% CI) | 3.3 (-3.6 to 10.2) | |
| P value ^b | 0.35 | |
| Functional impairment (WOMAC score) | | |
| Baseline, mean (SD) | 50.8 (13.3) | 50.5 (12.3) |
| 32 weeks, mean (SD) | 30.4 (20.6) | 35.5 (18.9) |
| Between-group difference in change from baseline, mean (95% CI) | 6.0 (1.0 to 11.0) | |
| P value ^b | 0.02 | |
| Depression (DASS-21 score) | | |
| Baseline, mean (SD) | 6.3 (6.8) | 6.1 (6.2) |
| 32 weeks, mean (SD) | 5.7 (6.4) | 5.9 (7.2) |
| Between-group difference in change from baseline, mean (95% CI) | -0.5 (-3.7 to 2.6) | |
| P value ^b | 0.74 | |

| Outcome | Findings | |
|---------------------------|---|----------------------------|
| | Stepped care intervention n = 87 | Comparison group n = 84 |
| Adverse events, n | 10 patients reported 13 adverse events: <ul style="list-style-type: none"> • 7 pain exacerbation related to strengthening exercises • 2 food intolerances related to diet program • 4 mild gastrointestinal reactions related to diet program | NR |
| Serious adverse events, n | 0 | NR |

CI = confidence interval; DASS-21 = Depression, Anxiety, and Stress Scale – 21 items; NA = not applicable; NR = not reported; PASS = Patient Acceptable Symptom State; RCT = randomized controlled trial; SD = standard deviation; VAS = visual analogue scale; WOMAC = Western Ontario and McMaster Osteoarthritis Index.

^aTested via the 2-proportion Z-test.

^bTested via independent t-test or Wilcoxon rank-sum test, as appropriate.

Additional analyses pre- and post- intervention were conducted in treatment subgroups at Step 2.²¹ The authors acknowledged that the sample size in each sub-treatment group was small and not powered to identify differences in outcomes between subgroups. The authors suggested that the lack of guidance provided to the participants allocated to the maintenance subgroup might have led to the worsening of symptoms observed during step 2 of the stepped care intervention.

The authors also claimed that they overestimated the disease remission rate in both stepped care and comparison groups, which impacted their sample size calculation. Finally, the trial authors stated that they did not conduct a cost-effectiveness analysis that would have assisted them in the decision to potentially implement the stepped care approach.²¹

Stepped Care Model for Pain Management (SCM-PM)

Two studies (1 uncontrolled before-after study²⁵ and 1 retrospective cohort study²⁴) reported on the Veterans Health Administration Stepped Care Model of Pain Management (SCM-PM), established in 2009 to bolster non-opioid, multimodal care for US veterans with chronic pain.^{24,25} The 3 steps in the model are based on levels of care: primary care, consultations with specialty care, and tertiary interdisciplinary care. The goal of the stepped care model was to change primary care providers' behaviours and improve the process of care for people with chronic pain.^{24,25} Further details of the model are presented in [Table 5](#).

The characteristics of both studies are presented in [Table 6](#). The uncontrolled before-after study of 12 primary centres compared electronic health record data at 1 year before the implementation of SCM-PM for chronic pain with data at 1 year following the 3-year intervention.²⁵ Participants included 25 primary care providers and their adult patients with chronic pain of any etiology. The patients were identified by a validated algorithm using available electronic health record data elements (e.g., diagnostic codes, pain scores, and prescribed medication). The retrospective cohort study²⁴ compared a pain cohort treated according to SCM-PM with a non-pain cohort treated in the integrated veteran's health system over the same 5-year period.

The findings of the uncontrolled before-after study²⁵ are presented in [Table 7](#). The authors reported that implementation of SCM-PM was associated with improvements in provider's pain care documentation, pain treatment and pain follow-up. Referrals from primary care providers to behavioural health providers and chiropractic professionals increased and referrals to neurologic and orthopedic surgery decreased following implementation of SCM-PM. The study authors reported no decline in opioid prescribing. However, among patients

Table 5: Characteristics of SCM-PM^{24,25}

| Characteristic | Description |
|------------------------|---|
| Model, country | Stepped Care Model of Pain Management, US |
| Model components | |
| Step 1 | Primary care: <ul style="list-style-type: none"> • Primary care provider identifies and discusses patient's pain concerns and develops a treatment plan based on self-management and primary care interventions • Routine screening for presence and intensity of pain • Comprehensive pain assessment and follow-up • Documentation of function status and goals • Management of common pain conditions • Systematic opioid risk assessment, refill, monitoring • Use of PACTs, comprised of primary care providers, nurses and other providers in a primary care setting |
| Step 2 | Secondary consultation: <ul style="list-style-type: none"> • Additional resources and more active-collaborative treatment such as behavioural health assessment, medication, consultation with specialists • Integrated behavioural health • Mindfulness, stress reduction • Rehabilitation medicine, physical therapy referral • Substance abuse programs, buprenorphine • Chiropractic • Virtual pain specialty referral (e-consults and project ECHO) |
| Step 3 | Tertiary interdisciplinary care: <ul style="list-style-type: none"> • Increased care and involvement from pain management team • Referrals to community partners |
| Implementation details | <ul style="list-style-type: none"> • Pre-implementation qualitative and quantitative assessments • Emphasis was placed on the use of onsite and telehealth resources to account for the limited access to outside specialty care • Promoting Action on Research Implementation in Health Services framework guided implementation • Implementation activities included: provider continuing medical education (including pain care, pain management, opioid prescribing), new protocols for pain assessment and management, EHR templates, chronic pain and opioid prescribing policy, opioid management dashboard, telehealth consultations, enhanced onsite specialty resources |

ECHO = Extension for Community Health Outcomes; EHR = electronic health record; PACT = patient-aligned care team; SCM-PM = Stepped Care Model for Pain Management.

Table 6: Characteristics of Studies Evaluating SCM-PM^{24,25}

| Characteristic | Description | |
|------------------------|--|---|
| Study design | Uncontrolled before-after study ²⁵ | Retrospective cohort study ²⁴ |
| Setting | Community Health Care Centre, Inc, comprising 12 primary health centres at a multi-site community health centre in Connecticut, US | VA Connecticut Health Care System, comprising a tertiary hub with inpatient and outpatient facilities, another large outpatient facility, and 6 community-based outpatient clinics |
| Study period | March 2010 to February 2015 | July 2008 to June 2013 |
| Funding sources | <ul style="list-style-type: none"> • The Mayday Fund • The Wallace Foundation | <ul style="list-style-type: none"> • Program for Research Leadership Award from the Patrick and Catherine Weldon Donaghue Medical Research Foundation: • The Mayday Fund • The Veterans Health Administration Health Services Research and Development Service Center of Innovation |
| Inclusion criteria | <p>All primary care providers who were present during 3-year implementation of SCM-PM</p> <p>Adult patients with chronic pain under the care of the providers with ≥ 1 medical visit in previous year</p> | <p>Veteran patients receiving primary care through an integrated VA health system who had ≥ 1 visit with a documented pain intensity rating of moderate to severe over 5-year period (intervention group)</p> <p>Veteran patients seen in primary care with no indication of pain and veterans reporting only mild pain intensity (comparison group)</p> |
| Intervention | SCM-PM | SCM-PM (pain cohort) |
| Comparison | NA | Non-pain cohort |
| Sample characteristics | <p>N = 25 primary care providers</p> <p>Female: 56%</p> <p>Medical doctor: 68%</p> <p>Advanced practice nurse practitioner: 32%</p> <p>Primary care providers' patients:</p> <p>N = 3,357 patients at pre-intervention</p> <p>Age: 27% were aged 18 to 39 years; 57% were aged 40 to 59 years; and 16% were aged 60 years or older</p> <p>Female: 63%</p> <p>Medicaid insurance: 66%</p> <p>Medicare insurance 19%</p> <p>Private insurance 7%</p> <p>Uninsured 7%</p> | <p>Intervention (pain cohort), N = 31,286</p> <p>Mean age: 62.6 years</p> <p>Female: 6.8%</p> <p>Mean maximum pain score: 6.5, on a scale of 0 (no pain) to 10 (worst pain imaginable)</p> <p>Comparison (non-pain cohort), N = NR</p> <p>Mean age: 68.9 years</p> <p>Female: 3.3%</p> <p>Mean maximum pain score: 0.3, on a scale of 0 (no pain) to 10 (worst pain imaginable)</p> |

| Characteristic | Description | |
|--------------------------|--|--|
| (continued) | N = 4,385 patients at post-intervention Age: 25% were aged 18 to 39 years; 56% were aged 40 to 59 years; and 18% were aged 60 years or older Female: 64% Medicaid insurance: 64% Medicare insurance 19% Private insurance 10% Uninsured 7% | |
| Relevant outcomes | <ul style="list-style-type: none"> • Quality of pain care documentation (Pain Care Quality extraction tool) for 300 randomly selected charts • Documentation of pain scores • Opioid prescribing • Health care use (health care visits, behavioural health, pain referrals, opioid treatment agreements, urine drug screens) | <ul style="list-style-type: none"> • Pharmacotherapy use (pharmacy data) • Health care use (referrals, health care visits) |
| Follow-up | 5 years (1 year before 3-year implementation and 1 year after implementation) | 5 years |

NA = not applicable; SCM-PM = Stepped Care Model for Pain Management; VA = Veterans Affairs.

receiving chronic opioid therapy, the use of opioid treatment agreements and urine drug screens increased by 27.3% and 22.6%, respectively.²⁵

The findings of the retrospective cohort study²⁴ are presented in [Table 8](#). The study authors reported that, within the pain cohort, long-term opioid treatment decreased over 5 years, while non-opioid prescriptions increased. The authors also reported that SCM-PM was associated with increased referrals by primary care providers for any consultations. Overall, the number of referrals to specialty services increased for the pain cohort, but little change was observed for those not in the pain cohort. The authors reported that the largest increases in the pain cohort were in referrals to physiotherapy and occupational therapy. Similarly, patient visits for any reason increased in the pain cohort, with the largest increases being in visits for mental health, clinical health psychology and physiotherapy. The study authors also reported that the proportion of veterans in the pain cohort receiving at least 1 non-opioid pain medication and at least 1 referral to a specialty care service increased from 24.5% in year 1 to 29% in year 5, which the authors considered receipt of multimodal pain care.²⁴

Limitations were reported by the authors of both studies.^{24,25} In the uncontrolled before-after study,²⁵ the authors acknowledged that the evaluation focused on process measures and did not include measures of patient outcomes other than pain scores. The interventions used in the study, such as templates and dashboards, were implemented agency-wide and could not be limited to selected practices. As such, randomization was not possible, limiting the ability to eliminate unmeasured confounders. Provider turnover, which ranged from 11% to 20% over the study period, also limited the number of health care providers included in the analysis.²⁵

In the retrospective cohort study,²⁴ the authors defined the pain cohort as veterans reporting moderate to severe pain during at least 1 outpatient primary care encounter. Neither did this

definition distinguish presentations of acute versus chronic pain or include veterans with mild pain intensity, nor was information on pain-related diagnoses available. Also, some of the

Table 7: Summary of Findings of an Uncontrolled Before-after Study Evaluating SCM-PM²⁵

| Outcome | Findings | | |
|---|------------------|-------------------|----------------------|
| | Pre-intervention | Post-intervention | P value ^a |
| Pain care documentation (Pain Care Quality extraction tool), n (%) | N = 108 | N = 213 | — |
| Documentation of pain | 69 (64) | 174 (81) | < 0.001 |
| Source or cause of pain | 67 (62) | 158 (74) | 0.025 |
| Functional assessment | 5 (5) | 42 (19) | < 0.001 |
| Review of diagnostic tests | 6 (6) | 37 (17) | < 0.003 |
| Treatment plan | 99 (92) | 209 (98) | 0.006 |
| Pain medication ordered | 102 (94) | 182 (85) | 0.017 |
| Pain consult ordered | 7 (7) | 60 (28) | < 0.001 |
| Patient education | 16 (15) | 47 (22) | 0.121 |
| Diagnostic imaging ordered | 25 (23) | 59 (28) | 0.379 |
| Assessment of treatment effectiveness | 18 (17) | 83 (39) | < 0.001 |
| Documented pain score , n (%) | N = 3,330 | N = 4,385 | — |
| Pain score > 8 (scale NR), n (%) | 2,504 (75.2) | 3,245 (74.0) | 0.351 |
| Opioid prescribing , n (%) | | | |
| Any opioid prescribed | 1,615 (48.5) | 1,943 (44.3) | 0.117 |
| Chronic opioid therapy (≥ 90 days in 1 year) | 763 (22.9) | 921 (21.0) | 0.486 |
| Health care visits | | | |
| Mean number of visits (SD) | 7.3 (14.37) | 6.83 (14.37) | 0.094 |
| Patients with behavioural health visit, n (%) | 809 (24.3) | 1,276 (29.1) | 0.009 |
| Pain referrals , n (%) | | | |
| Chiropractic | 3 (0.1) | 48 (1.1) | 0.008 |
| Physical therapy | 480 (14.4) | 750 (17.1) | 0.508 |
| Neurologic or orthopedic surgery | 663 (19.9) | 693 (15.8) | < 0.001 |
| Rheumatology | 120 (3.6) | 136 (3.1) | 0.419 |
| Health care use (for patients receiving chronic opioid therapy), n (%) | N = 1,309 | N = 1,230 | — |
| Opioid treatment agreement | 360 (34) | 778 (61) | < 0.05 |
| Urine drug screen | 680 (64) | 1,103 (87) | < 0.05 |

NR = not reported; SD = standard deviation.

^aTested via multiple-group models that account for the clustering within provider.

Table 8: Summary of Findings of a Retrospective Cohort Study Evaluating SCM-PM²⁴

| Outcome | Findings | | |
|--------------------------------------|---------------------|---------------------|-----------------------|
| | Year 1 ^a | Year 5 ^b | P value ^c |
| Pharmacotherapy use, % | | | |
| Long-term opioid therapy (> 90 days) | — | — | < 0.0001 ^d |
| Pain cohort | 4.2 | 3.3 | — |
| Any non-opioid medication | — | — | < 0.0001 |
| Pain cohort | 36.7 | 39.8 | — |
| Non-pain cohort | 23.3 | 22.6 | — |
| Sedative or hypnotic | — | — | < 0.0001 |
| Pain cohort | 17.4 | 17.2 | — |
| Non-pain cohort | 12.4 | 11.3 | — |
| Topical analgesics | — | — | 0.0058 |
| Pain cohort | 3.5 | 4.8 | — |
| Non-pain cohort | 0.7 | 0.7 | — |
| NSAIDs | — | — | < 0.0001 |
| Pain cohort | 15.7 | 19.3 | — |
| Non-pain cohort | 7.3 | 7.3 | — |
| Antidepressant | — | — | < 0.0001 |
| Pain cohort | 5.7 | 5.9 | — |
| Non-pain cohort | 3.5 | 3.1 | — |
| Anticonvulsant | — | — | < 0.0001 |
| Pain cohort | 10.9 | 12.8 | — |
| Non-pain cohort | 6.4 | 6.7 | — |
| Referrals, % | | | |
| Any referral | — | — | < 0.0001 |
| Pain cohort | 43.4 | 51.8 | — |
| Non-pain cohort | 27.5 | 28.6 | — |
| Mental health | — | — | 0.56 |
| Pain cohort | 6.0 | 5.0 | — |
| Non-pain cohort | 3.1 | 2.6 | — |
| Physical therapy | — | — | < 0.0001 |
| Pain cohort | 14.8 | 27.4 | — |
| Non-pain cohort | 4.0 | 5.6 | — |
| Occupational therapy | — | — | < 0.0001 |

| Outcome | Findings | | |
|--|---------------------|---------------------|----------------------|
| | Year 1 ^a | Year 5 ^b | P value ^c |
| Pain cohort | 5.2 | 11.0 | — |
| Non-pain cohort | 1.9 | 2.2 | — |
| Chiropractic | — | — | < 0.0001 |
| Pain cohort | 1.4 | 3.2 | — |
| Non-pain cohort | 0.3 | 0.5 | — |
| Neurology | — | — | 0.002 |
| Pain cohort | 10.3 | 10.7 | — |
| Non-pain cohort | 3.4 | 3.0 | — |
| Pain medicine | — | — | < 0.0001 |
| Pain cohort | 3.2 | 3.8 | — |
| Non-pain cohort | 0.2 | 0.4 | — |
| Health care visits (≥ 1 visit by patient), % | | | |
| Any health care visit | — | — | < 0.0001 |
| Pain cohort | 27.9 | 37.3 | — |
| Non-pain cohort | 11.4 | 12.6% | — |
| Mental health | — | — | < 0.0001 |
| Pain cohort | 28.0 | 30.5 | — |
| Non-pain cohort | 20.0 | 19.3 | — |
| Clinical health psychology | — | — | < 0.0001 |
| Pain cohort | 4.7 | 7.2 | — |
| Non-pain cohort | 2.0 | 2.5 | — |
| Physical therapy | — | — | < 0.0001 |
| Pain cohort | 16.2 | 22.9 | — |
| Non-pain cohort | 4.1 | 4.8 | — |
| Occupational therapy | — | — | < 0.0001 |
| Pain cohort | 5.6 | 10.0 | — |
| Non-pain cohort | 2.0 | 2.3 | — |
| Chiropractic | — | — | 0.0019 |
| Pain cohort | 1.4 | 3.8 | — |
| Non-pain cohort | 0.3 | 0.8 | — |
| Neurology | — | — | < 0.0001 |
| Pain cohort | 10.0 | 13.3 | — |
| Non-pain cohort | 6.0 | 6.4 | — |
| Pain medicine | — | — | < 0.0001 |

| Outcome | Findings | | |
|-----------------|---------------------|---------------------|----------------------|
| | Year 1 ^a | Year 5 ^b | P value ^c |
| Pain cohort | 2.9 | 3.2 | — |
| Non-pain cohort | 0.5 | 0.3 | — |
| Multimodal care | — | — | < 0.0001 |
| Pain cohort | 24.5 | 29.0 | — |
| Non-pain cohort | 12.8 | 12.6 | — |

NSAID = nonsteroidal anti-inflammatory drug.

^aSample sizes for year 1: Pain cohort, n = 11,601; non-pain cohort, n = 32,347.

^bSample sized for year 5: Pain cohort, n = 15,099; non-pain cohort, n = 29,375.

^cInteraction test via general estimating equations logit-linked, logistic regression models with robust variance estimation and intercept, controlling for patients nested within providers, and patient age and sex.

^dChange over time in the pain cohort only.

specialty pain care services included in the analyses provided services that extend beyond pain. Because the authors did not examine diagnoses associated with care in these settings, they were unable to conclude whether pain-specific care was delivered. Sedatives and/or hypnotics, antidepressants, and anticonvulsants are also commonly used for management of disorders other than pain. The data did not specify the diagnosis for the prescription. Furthermore, although the authors used a broad definition of 1 non-opioid pharmacological treatment and 1 nonpharmacological pain management service to represent multimodal pain care and guideline concordant care, details regarding veterans' presenting problems and the services they received were not available and it was not possible to determine whether veterans were receiving appropriate services. Finally, because several changes were implemented at national, regional, and local levels, and changes were implemented throughout Veterans Health Administration Connecticut Health Care System, it was not possible to isolate what caused any specific change; rather, the authors were only able to examine temporal trends.²⁴

Stepped Care Model for Non-Cardiac Chest Pain (NCCP)

One uncontrolled before-after study evaluated a pilot multidisciplinary biopsychosocial model with a stepped care approach that was set up in a cardiology outpatient clinic in London, UK for people with non-cardiac chest pain (NCCP).²⁶ The model consisted of 3 steps: comprehensive physician and psychological assessment, low intensity CBT in the form of guided self-help delivered by a trained cardiac nurse or clinical psychologist, and high intensity CBT with a clinical psychologist. Details of the model are presented in [Table 9](#).

The uncontrolled before-after study²⁶ included 77 adult patients with NCCP occurring more than once per month. Patients were evaluated for chest pain and chest pain interference, beliefs about chest pain,²⁶ depression, anxiety, quality of life, and health care use at baseline, then at 3- and 6-months after the initiation of treatment (post-treatment and follow-up beyond the end of treatment, respectively). The characteristics of the study are presented in [Table 10](#).

The findings of the uncontrolled before-after study are presented in [Table 11](#). The authors reported that the stepped care approach had large effects on chest pain post-intervention (3 months) and at 6 months compared to baseline (before the intervention), as indicated by reduced frequency of pain, improved chest pain interference and severity scores, and improved negative beliefs and/or convictions that chest pain is attributable to a cardiac

Table 9: Characteristics of Stepped Care Model for NCCP²⁶

| Characteristic | Description |
|-------------------------------|--|
| Model, country | Stepped care approach for NCCP, UK |
| Model components | |
| Step 1 | Biopsychosocial assessment: in-depth assessment of chest pain by cardiologist and psychological factors by psychologist; medical therapy offered when appropriate (medical or referral to another medical services) |
| Step 2 | Low intensity CBT: guided self-help, supported by a standardized booklet and audio CD, delivered in 30-minute sessions (up to 6 sessions available), 4 modules (mindful abdominal breathing, progressive muscle relaxation, increasing activity, cognitive therapy) |
| Step 3 | High intensity CBT: additional information and support, delivered in 50-minute sessions (up to 8 sessions available), tailored treatment and additional aspects (such as psychoeducation about stress and specific psychosocial disorders, exploring beliefs, problem-solving and cognitive work, and behavioural activation for depression) |
| Implementation details | Can be delivered by a cardiac nurse, clinical psychologist (trained in providing and supervising CBT), and a cardiologist, and integrated into any chest pain clinic |

CBT = cognitive behavioural therapy; CD = compact disc; NCCP = non-cardiac chest pain.

Table 10: Characteristics of Prospective Study Evaluating Stepped Care Model for NCCP²⁶

| Characteristic | Description |
|-------------------------------|---|
| Study design | Uncontrolled before-after study |
| Setting | 1 chest pain clinic at a teaching hospital, London, UK |
| Enrollment period | December 2011 to December 2012 |
| Funding source | Guy's and St Thomas' Charity |
| Inclusion criteria | Adult patients with NCCP more than once per month for at least 3 months |
| Sample characteristics | N = 77 patients at pre-intervention; 68 at post-intervention Mean age (SD): 50 (10.9) years, range 25 to 73 years Female: 54% Chest pain present > 6 months: 79% |
| Relevant outcomes | <ul style="list-style-type: none"> • Pain frequency • Pain severity (scale of 1 [not at all] to 10 [extremely]) • Pain interference (scale of 1 [not at all] to 10 [extremely]) • Negative beliefs about chest pain (scale of 1 [do not believe] to 10 [definitely believe]) • Depression (PHQ9; higher score = more depressive symptoms) • Anxiety (GAD7; higher score = more anxiety symptoms) • Quality of life (WSAS; higher score = more impairment) • Health care resource use (CSRI; not further described in study) |
| Follow-up | 6 months |

CSRI = Client Service Receipt Inventory; GAD7 = Generalized Anxiety Disorder 7-item Scale; NCCP = non-cardiac chest pain; PHQ9 = Patient Health Questionnaire 9; SD = standard deviation; WSAS = Work and Social Adjustment Scale.

cause. Depression and anxiety scores decreased at post-intervention and at 6 months compared to baseline, as did impact on daily life scores (i.e., less impairment). In addition, there was less use of numerous health care resources (e.g., general practitioner, emergency department, cardiologist, appointments, consultations) at 6 months following participation in the stepped care model.²⁶

The study authors²⁶ stated their limitations. There was no comparison group. The length of the intervention was not standardized, as treatment was tailored to each patient's needs. Some participants, particularly those in the high intensity CBT group, continued to receive treatment after 3 months. Longer-term follow-up (e.g., 12 months) was not offered, which limited any claims about sustained improvement. There was no formal economic analysis, so the impact of the stepped care model on health care costs is uncertain.²⁶

Table 11: Summary of Findings of an Uncontrolled Before-after Study Evaluating the Stepped Care Model for NCCP²⁶

| Outcome | Findings | | | |
|--|--------------------------|--------------------------------------|------------------------------|----------------------|
| | Pre-intervention, n = 77 | Post-intervention (3 months), n = 75 | Follow-up (6 months), n = 68 | P value ^a |
| Pain frequency, % | — | — | — | < 0.001 |
| Daily or more often | 44 | 13 | 7 | — |
| Weekly | 39 | 28 | 19 | — |
| Monthly | 17 | 20 | 25 | — |
| Less than monthly | 0 | 39 | 49 | — |
| Presence of pain, % | | | | |
| Do you have chest pain that bothers you? (Yes) | 100 | 73 | 65 | < 0.001 |
| Scores on scale, mean (SD) | | | | |
| Severity of chest pain | 5.8 (2.5) | 4.0 (2.7) | 3.4 (2.4) | < 0.001 |
| Interference of chest pain | 5.9 (2.2) | 3.2 (2.6) | 2.6 (2.1) | < 0.001 |
| Negative beliefs | | | | |
| Chest pain is a heart attack | 5.6 (3.3) | 2.0 (2.1) | 1.9 (2.0) | < 0.001 |
| Chest pain indicates a serious condition | 5.4 (3.2) | 2.2 (2.2) | 2.1 (2.2) | < 0.05 |
| Depression (PHQ9 score) | 8.8 (7.2) | 5.4 (5.8) | 4.4 (5.0) | < 0.05 |
| Anxiety (GAD7 score) | 6.9 (6.0) | 4.6 (5.) | 3.6 (4.7) | < 0.05 |
| Quality of life (WSAS score) | 10.4 (10.4) | 3.9 (7.5) | 2.5 (5.7) | < 0.001 |
| Health care use (CSRI), n (%) | | | | |
| GP ≥ 3 visits | 47 (63) | NR | 30(47) | < 0.05 |
| ED ≥ 1 visit | 21 (28) | NR | 5 (8) | < 0.05 |

| Outcome | Findings | | | |
|---|-----------------------------|---|---------------------------------|----------------------|
| | Pre-intervention, n = 77 | Post-intervention (3 months), n = 75 | Follow-up (6 months), n = 68 | P value ^a |
| Cardiologist ≥ 1 visit | 57 (63) | NR | 2 (3) | < 0.05 |
| Other physician ≥ 1 visit | 25 (33) | NR | 19 (30) | < 0.05 |
| Health care appointments, mean (SD) | 2.5 (1.1) | NR | 0.8 (1.2) | < 0.05 |
| Consultations for chest pain, mean (SD) | 2.6 (3.1) | NR | 0.1 (0.5) | < 0.05 |

ED = emergency department; CSRI = Client Service Receipt Inventory; GAD7 = Generalized Anxiety Disorder 7-item Scale; GP = general practitioner; PHQ9 = Patient Health Questionnaire 9; SD = standard deviation; WSAS = Work and Social Adjustment Scale.

^aTested via the Wilcoxon test for chest pain frequency and via paired t-tests for chest pain interference. For other outcomes, t-tests were used for normally-distributed data and Wilcoxon tests were used for proportions.

Stepped Care Strategy for Chronic Hip or Knee Pain (Beating osteoARthritis)

One prospective cohort study evaluated a multidisciplinary stepped care strategy (SCS), named Beating osteoARthritis, that was developed to improve the non-surgical care of people with chronic pain due to hip or knee osteoarthritis.²³ The model and its implementation in general practices in Nijmegen, the Netherlands was also described in another separate publication.²⁹ SCS aimed to support primary care providers and patients to achieve high-quality care by presenting the ideal sequence for care in a 3-step model. The first step includes modalities (e.g., education, lifestyle advice, and paracetamol), which should be offered to all patients or can be provided through self-care. The second and third steps include more advanced modalities (e.g., physical therapy, dietary therapy, and intra-articular injections) that can be provided if the previous options had not succeeded.^{23,29} Details of SCS are presented in [Table 12](#).

Table 12: Characteristics of SCS^{23,29}

| Characteristic | Description |
|------------------|---|
| Model, country | SCS, the Netherlands |
| Model components | |
| Step 1 | <ul style="list-style-type: none"> • Medical history and physical examination • Assessment function and activity limitations • Setting mutual goals • Education (regarding the disease, treatment modalities, and prognosis) • Lifestyle advice (regarding exercise, weight reduction, and prevention of overload) • Medication: acetaminophen, glucosamine sulphate • Evaluation: 3 months (or earlier if symptoms persist or increase) |

| Characteristic | Description |
|-------------------------------|---|
| Step 2 | <ul style="list-style-type: none"> • Radiological assessment (if discrepancy between medical history and physical examination) • Assessment of pain coping and psychosocial factors • Adjust goals • Exercise therapy • Dietary therapy (i.e., counselling by a dietician) if overweight • Medication: (topical) NSAIDs, Tramadol • Evaluation: 3 to 6 months (or earlier if symptoms persist or increase) |
| Step 3 | <ul style="list-style-type: none"> • Consultation specialist • Adjust goals • Multidisciplinary care • Transcutaneous electrical nerve stimulation • Intra-articular injections • Evaluation: patient-set intervals |
| Implementation details | A regional implementation advisory board, consisting of a patient representative and 9 experts representing the main disciplines involved in osteoarthritis care (2 GPs, 1 practice nurse, 1 physical therapist, 1 dietician, 1 rheumatologist, 1 orthopedic surgeon, 2 researchers) was set up to agree on implementation activities aligned to patients as well as different health care providers. The activities were based on previous implementation studies in related research fields and included: education and reminder material for patients; education outreach visits, education and reminder material, and multidisciplinary seminars for health care professionals. |

GP = general practitioner; NSAID = nonsteroidal anti-inflammatory drug; SCS = stepped care strategy.

The prospective cohort study²³ compared a cohort of patients who received stepped care strategy-consistent (SCS-consistent) care for hip or knee pain due to osteoarthritis with a cohort who received SCS-inconsistent care over 2 years. Participants in the SCS-consistent group received the following: education and lifestyle advice during the study period, all advised step 1 modalities before any step-2 modality (if applicable), and all advised step 1 and step 2 modalities before any step 3 modality (if applicable). Further characteristics of the study are presented in [Table 13](#).

Table 13: Characteristics of a Prospective Cohort Study Evaluating SCS²³

| Characteristic | Description |
|------------------------|--|
| Study design | Prospective cohort study |
| Setting | 38 GP practices, Nijmegen, the Netherlands Rural practices: 61% Solo practices: 17% |
| Study period | August 2010 to March 2013 |
| Funding sources | <ul style="list-style-type: none"> • The Dutch Arthritis Association • The Royal Dutch Society for Physical Therapy • The Sint Maartenskliniek • The Anna foundation |

| Characteristic | Description |
|-------------------------------|---|
| Inclusion criteria | Adult patients who visited their GP for a new episode of hip or knee complaints due to symptomatic hip or knee osteoarthritis |
| Sample characteristics | <p>N = 70 GPs</p> <p>Intervention (SCS-consistent care), N = 117 patients</p> <p>Mean age (SD) = 62 (10) years</p> <p>Female = 63%</p> <p>Pain location: hip = 54%, knee = 74%</p> <p>Duration of symptoms > 1 year: 76%</p> <p>Overweight (BMI > 25kg/m²): 65%</p> <p>Health insurance, with additional coverage: 95%</p> <p>Comparison (SCS-inconsistent care), N = 163 patients</p> <p>Mean age (SD): 65 (10) years</p> <p>Female: 62%</p> <p>Pain location: hip = 49%, knee = 80%</p> <p>Duration of symptoms > 1 year: 80%</p> <p>Overweight: 73%</p> <p>Health insurance, with additional coverage: 88%</p> |
| Relevant outcomes | <ul style="list-style-type: none"> • Pain (WOMAC; scale of 0 to 100 where higher scores reflect better health status) • Physical function (WOMAC) • Self-efficacy (Dutch General Self-Efficacy Scale; scale of 10 to 40, where higher scores reflect higher self-efficacy) • Active pain coping assessed (Pain Coping Inventory; scale of 12 to 48, where higher scores indicate greater use of an active coping style) • Health care use |
| Follow-up | 2 years |

BMI = body mass index; GP = general practitioner; NSAID = nonsteroidal anti-inflammatory drug; SCS = stepped care strategy; SD = standard deviation; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

The authors of the prospective cohort reported²³ that pain and physical function improved after receiving SCS-consistent care; whereas, the levels of self-efficacy and active pain coping did not differ after 2 years. The summary of findings for the SCS-consistent care group of the study is presented in [Table 14](#).

The authors²³ also reported that there were no differences between SCS-consistent and SCS-inconsistent care cohorts on scores for pain physical function, self-efficacy, or active pain coping, after adjusting for potential confounders. Seventeen percent of the patients in the SCS-consistent group and 18% in the SCS-inconsistent group received a surgical procedure within 2 years (P = 0.82). The summary of between-group findings is presented in [Table 15](#).

Table 14: Summary of Findings of Cohort Study Evaluating SCS: Within Group Changes From Baseline in Intervention Group²³

| Outcome | Findings, n = 117 | | | |
|--|---------------------|----------------------|-------------------------------------|----------------------|
| | Baseline, mean (SD) | 24 months, mean (SD) | Change from baseline, mean (95% CI) | P value ^a |
| Pain (WOMAC score) | 62 (22) | 70 (23) | 7.0 (4.2 to 9.8) | 0.00 |
| Physical function (WOMAC score) | 64 (21) | 70 (23) | 5.6 (3.2 to 8.0) | 0.00 |
| Self-efficacy (Dutch Self-Efficacy Scale) | 31 (5) | 31 (5) | 0.0 (–0.6 to 0.6) | 0.99 |
| Active pain coping (Pain Coping Inventory) | 54 (12) | 52 (13) | –1.2 (–2.6 to 0.3) | 0.12 |

CI = confidence interval; SCS = Stepped Care Strategy; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

^aTested via paired t-tests.

Table 15: Summary of Findings of Cohort Study Evaluating SCS: Between-Group Differences^{23,29}

| Outcome | Findings at 24 months | | | |
|--|--|--|--|----------------------|
| | SCS-consistent, Beta coefficient (95% CI) n = 117 | SCS-inconsistent, Beta coefficient (95% CI) n = 163 | Adjusted difference between groups (95% CI) ^a | P value ^a |
| Pain (WOMAC score) | 3.6 (–0.6, 7.7) | 8.8 (4.9, 12.7) | –4.3 (–10.3 to 1.7) | 0.16 |
| Physical function (WOMAC score) | 4.3 (0.42, 8.1) | 7.4 (4.0, 10.8) | –1.9 (–7.0, 3.1) | 0.45 |
| Self-efficacy (Dutch Self-Efficacy Scale) | 0.6 (–0.3, 1.5) | –0.4 (–1.2, 0.4) | 0.6 (–8.3, 2.0) | 0.41 |
| Active pain coping (Pain Coping Inventory) | –0.6 (–2.8, 1.6) | –1.6 (–3.6, 0.4) | 1.7 (–1.5, 4.9) | 0.30 |

CI = confidence interval; EHR = electronic health records; NA = not applicable; SCS = Stepped Care Strategy; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

^aTested via generalized estimating equations analysis. The analyses were adjusted for age, number of comorbidities, additional insurance coverage, number of painful joints, general practitioner's sex, and general practitioner's attitude regarding the effectiveness of non-recommended non-surgical treatment modalities.

The authors²³ noted several limitations of the prospective cohort study. Participants who received SCS-consistent care were younger, had fewer comorbidities and painful joints, and were more likely to have additional health care insurance; therefore SCS-inconsistent care may sometimes have been unavoidable or even preferable. The time frame of the study may have been too short to detect differences in pain, physical function, self-efficacy, and active pain coping. Lastly, the authors noted that an observational study, in contrast to an RCT, may not be the ideal design to evaluate SCS. Although baseline differences were adjusted in the analyses, unknown and not measured differences could not be adjusted for.²³

Evaluation of Stepped Care for Chronic Pain (ESCAPE)

The Evaluation of Stepped Care for Chronic Pain (ESCAPE) RCT²² evaluated the effectiveness of a stepped care model involving 12 weeks of analgesic therapy optimization according to an algorithm coupled with pain self-management strategies (step 1) followed by 12 weeks of CBT (step 2) compared with usual care. US veterans of the Afghanistan and Iraq conflicts with chronic and disabling musculoskeletal pain were block randomized to the stepped care intervention or usual care. All baseline and follow-up assessments were conducted by a researcher who was blinded to the treatment allocation. Characteristics of the stepped care model and RCT are presented in [Table 16](#) and [Table 17](#).

Table 16: Characteristics of Model in ESCAPE²²

| Characteristic | Description |
|-------------------------------|--|
| Model, country | Evaluation of Stepped Care for Chronic Pain, US |
| Model components | |
| Step 1 | <p>12 weeks, with the aim of reducing pain intensity, encouraging activity, and providing education</p> <ul style="list-style-type: none"> Analgesic treatment optimization according to an evidence-based algorithm began with first-line, simple analgesics such as acetaminophen and NSAIDs, followed by topical analgesics, gabapentinoids, tricyclic antidepressants and cyclobenzaprine hydrochloride, tramadol, short-acting opioids, and lastly long-acting opioid analgesics. Pain self-management strategies: education about natural history of chronic pain, common treatments for chronic pain, importance of behavioural activation, including stretching and strengthening exercises, and resumption of normal activities as soon as possible; relaxation techniques, goal setting, problem-solving, behavioural plans, and strategies to improve communication with health care providers. |
| Step 2 | <p>12 weeks</p> <ul style="list-style-type: none"> CBT intervention: 6 biweekly sessions lasting approximately 45 minutes delivered over the telephone by a nurse manager Objectives: identify difficulties, identify negative thoughts, reframe thoughts, enhance coping |
| Implementation details | <ul style="list-style-type: none"> Delivered by 2 nurse managers trained in all treatment components (optimization of analgesic treatment, self-management strategies, CBT) who met weekly with physician investigators and a supervising psychologist to review care of the intervention group, a model of case supervision implemented in previous trials Biweekly telephone contacts between the patients and nurse managers for a total of 12 contacts during the trial period Procedures implemented to ensure treatment fidelity included: extensive training, observation, audiotaping, and feedback after treatment sessions. To enhance reproducibility of stepped care model, a manualized and algorithmic approach in the context of a care management delivery model was used. |

CBT = cognitive behavioural therapy; ESCAPE = Evaluation of Stepped Care for Chronic Pain; NSAID = nonsteroidal anti-inflammatory drug; VA = Veterans Affairs.

Table 17: Characteristics of ESCAPE RCT²²

| Characteristic | Description |
|---------------------------|--|
| Study design | RCT |
| Setting | 1 post-deployment clinic and 5 general medicine clinics at 1 VA medical centre, Indiana, US |
| Enrollment period | Enrollment December 2007 to June 2011 |
| Funding source | Merit Review grant from the VA Rehabilitation Research and Development |
| Inclusion criteria | OEF/OIF/OND veteran patients with self-reported chronic pain (> 3 months' duration) of the cervical or lumbar spine or an extremity (hip, knee, or shoulder), and if pain was at least moderately disabling (RMDQ score of ≥ 7) at the initial visit |

| Characteristic | Description |
|-------------------------------|--|
| Sample characteristics | <p>Intervention, N = 121 patients</p> <p>Mean age (SD): 36.4 (10.1) years</p> <p>Female: 9.9%</p> <p>Pain location: back = 52.9%, knee = 23.1%, neck = 8.3%, shoulder = 8.3%, hip = 7.4%</p> <p>Comparison (usual care), N = 120</p> <p>Mean age (SD): 38.2 (10.5) years</p> <p>Female: 13.3%</p> <p>Pain location: back = 61.7%, knee = 20.0%, neck = 6.7%, shoulder = 5.8%, hip = 5.8%</p> |
| Relevant outcomes | <ul style="list-style-type: none"> • Pain interference (BPI; scale of 0 to 10 where higher scores = greater pain interference) • Pain severity (GCPS; scale of 0 to 100 where higher scores = greater pain severity) • Pain-related disability (RMDQ; scale of 0 to 24 where higher scores = greater disability) • Pharmacotherapy use |
| Follow-up | 9 months |

BPI = Brief Pain Inventory; CBT = cognitive behavioural therapy; ESCAPE = Evaluation of Stepped Care for Chronic Pain; GCPS = Graded Chronic Pain Scale; OEF = Operation Enduring Freedom; OIF = Operation Iraqi Freedom OND = Operation New Dawn; RCT = randomized controlled trial; RMDQ = Roland Morris Disability Scale; SD = standard deviation; VA = Veterans Affairs.

The findings of the RCT are presented in [Table 18](#). The authors²² reported that the stepped care model led to improvements in the following pain outcomes compared to usual care: pain interference, pain severity, and pain-related disability. Patients in the stepped care group were more likely to demonstrate at least a 30% improvement in Roland Morris Disability Scale scores by 9 months (relative risk, 1.52 [95% CI, 1.22 to 1.99]; $P < 0.001$), with a number needed to treat of 7.5 for 30% improvement. Participants in the stepped care group received more analgesics at the end of step 1 (3 months) relative to what they were prescribed at baseline. However, at the study end (9 months), the authors reported that participants in stepped care were using more topical analgesics than those in the usual care group, and participants in the usual care group were receiving more tricyclic antidepressants than those in the stepped care group, but the authors stated they did not find a significant difference between groups in opioid use. The authors concluded that the stepped care model was effective in reducing pain-related outcomes in veterans with chronic musculoskeletal pain of the spine and extremities.²²

Table 18: Summary of Findings of ESCAPE RCT²²

| Outcome | Stepped care, n = 121 | Usual care, n = 120 |
|---|--------------------------|------------------------|
| Pain interference (BPI score) | | |
| Baseline, mean (SD) | 5.4 (2.1) | 5.4 (2.4) |
| 9 months, mean (SD) | 3.8 (2.6) | 4.5 (2.7) |
| Change from baseline, mean (95% CI) | -1.7 (-2.1 to -1.3) | -0.9 (-1.2 to -0.05) |
| Between-group difference, mean (95% CI) | -0.8 (-1.3 to -0.3) | |
| P value ^a | 0.003 | |

| Outcome | Stepped care, n = 121 | Usual care, n = 120 |
|---|--------------------------|------------------------|
| Pain severity (GCPS score) | | |
| Baseline, mean (SD) | 67.3 (12.1) | 65.1 (15.2) |
| 9 months, mean (SD) | 56.9 (19.1) | 61.0 (19.3) |
| Change from baseline, mean (95% CI) | -11.1 (-13.9 to -8.3) | -4.5 (-7.3 to -1.8) |
| Between-group difference, mean (95% CI) | -6.6 (-10.5 to -2.7) | |
| P value ^a | 0.001 | |
| Pain-related disability (RMDS score) | | |
| Baseline, mean (SD) | 14.0 (4.3) | 13.7 (4.7) |
| 9 months, mean (SD) | 10.6 (6.3) | 12.1 (6.4) |
| Change from baseline, mean (95% CI) | -3.7 (-4.5 to -2.8) | -1.7 (-2.6 to -0.9) |
| Between-group difference, mean (95% CI) | -1.9 (-3.2 to -0.7) | |
| P value ^a | 0.002 | |
| Pharmacotherapy use (EHR review), % | | |
| Opioids | | |
| Baseline | 34.7 | 44.2 |
| 9 months | 30.6 | 35.8 |
| P value | 0.38 | |
| Simple analgesics | | |
| Baseline | 57.9 | 60 |
| 9 months | 45.5 | 47.5 |
| P value | 0.74 | |
| Topical analgesics | | |
| Baseline | 1.7 | 1.7 |
| 9 months | 16.5 | 0.08 |
| P value | 0.001 | |
| Gabapentin | | |
| Baseline | 5.8 | 19.2 |
| 9 months | 14.9 | 16.7 |
| P value | 0.70 | |
| Muscle relaxants | | |
| Baseline | 17.4 | 15.8 |
| 9 months | 19 | 17.5 |
| P value | 0.76 | |

| Outcome | Stepped care, n = 121 | Usual care, n = 120 |
|----------------------------------|--------------------------|------------------------|
| Tricyclic antidepressants | | |
| Baseline | 0.08 | 4.2 |
| 9 months | 0 | 4.2 |
| P value | 0.023 | |

BPI = Brief Pain Inventory; CI = confidence interval; EHR = electronic health record; GCPS = Graded Chronic Pain Scale; RMDQ = Roland Morris Disability Scale; RCT = randomized controlled trial; SD = standard deviation.

^aEstimates based on mixed-effect model with repeated measurements. Effect sizes are 0.26 for the BPI Pain Interference subscale, 0.21 for GCPS severity, and 0.24 for the RMDQ.

^bP value for between-group differences.

The authors²² identified key limitations of the ESCAPE trial. The participants were all recent US veterans with chronic musculoskeletal pain, and their results may not apply to veterans from other eras or to nonveterans. The RCT was conducted at a single medical centre. Single-centre RCTs have shown larger treatment effects than multicentre RCTs. The trial assessed a multimodal intervention and used a bundled approach to delivery. Finally, while the outcome assessors were blinded to the treatment allocation, the study participants were unblinded.²²

Objective 2: Identify and Summarize Literature on the Potential Cost Implications of Stepped Care Models of Care for Chronic Pain

One economic evaluation²⁷ was identified that described the cost implications of the stepped care approach. The study examined the relative cost-effectiveness of 3 pathways of treatment for sciatica pain. The stepped care pathway included 3 steps of increasing levels of complexity (initial, intermediate, and invasive therapies). The 2 comparison pathways were initial treatments in primary care only and immediate referral for surgery following initial treatments. The patient population was based on a systematic review that included studies of adult patients with sciatica or lumbar nerve root pain diagnosed clinically or confirmed by imaging, with a requirement for leg pain to be worse than back pain (i.e., to distinguish sciatica from nonspecific low back pain).²⁷ To ensure consistency, the same population also formed the basis for the economic model. Further details of the cost-effectiveness study are presented in [Table 19](#).

Table 19: Characteristics of Economic Evaluation²⁷

| Characteristic | Description |
|-----------------------------|---|
| Country | UK |
| Intervention pathway | <p>Stepped care approach</p> <p>Step 1: initial treatments — inactive control, usual care, education or advice, activity restriction, non-opioids, and opioids</p> <p>Step 2: intermediate treatments — manipulation, traction, passive and active physical therapy, alternative or non-traditional treatments (acupuncture), biologic drugs (provided in secondary care by multidisciplinary teams)</p> <p>Step 3 — invasive therapies epidural or nerve block, disk surgery</p> |

| Characteristic | Description |
|-----------------------------------|---|
| Comparison pathways | <p>Primary care only</p> <ul style="list-style-type: none"> Initial treatments: inactive control, usual care, education or advice, activity restriction, non-opioids, and opioids Initial treatments followed by immediate referral for surgery to alleviate symptoms |
| Type of analysis | Cost-effectiveness analysis |
| Funding source | UK National Institute for Health Research Health Technology Assessment program |
| Perspective | UK National Health Service |
| Time horizon | 12 months |
| Population characteristics | Adult patients with sciatica or lumbar nerve root pain diagnosed clinically or confirmed by imaging. A requirement was that leg pain was worse than back pain. |
| Approach | <ul style="list-style-type: none"> Decision analytic model Treatments were categorized and compared in pair-wise meta-analysis followed by mixed treatment comparison analysis Mean cost, probability of success, and 12-month utility gains were calculated for all possible treatment strategies Incremental cost per patient with symptoms successfully resolved for all treatment strategies that were not excluded on the grounds of strict or extended dominance (i.e., where the next regime was both more effective and less costly or whereby a regime had an incremental cost-effectiveness ratio that is higher than the next more effective regime, respectively) was calculated Incremental cost per utility gained over a 12-month period was calculated A series of sensitivity analyses were conducted where baseline estimates were adjusted to reflect best and worst-case scenarios, utility values were adjusted for symptoms and symptom remission, potential for reductions in effectiveness of intermediate therapies and/or surgery in the stepped approach, and utility achieved with symptom resolution only because of successive failures |
| Main outcomes (systematic review) | <ul style="list-style-type: none"> Global effect (including absence of pain) Reduction in pain intensity Improved function (composite condition specific outcome measure as continuous data using weighted mean difference and standardized mean difference) |
| Clinical and cost data | <ul style="list-style-type: none"> Clinical effect estimates derived from a SR of clinical effectiveness and cost-effectiveness Costs of managing patients based on expert opinion and published UK cost sources (2008 to 2009 prices) Drug costs were from British National Formulary list prices Non-traditional or alternative therapies were based on published NHS reference costs |
| Main assumptions | <ul style="list-style-type: none"> Patients presenting with sciatica would be managed through 1 of 3 pathways: primary care, stepped approach, or immediate referral to surgery Base-case assumptions were that there was no reduction in utility for previous unsuccessful treatments and when individual therapies are combined in sequence, effectiveness will be as high as stand-alone treatments |

NHS = National Health Service; SR = systematic review.

The results of the cost-effectiveness analysis²⁷ are presented in [Table 20](#). The incremental cost per patient with symptoms successfully resolved and the incremental cost per utility

gained for a patient with sciatica pain managed through 1 of the 3 treatment pathways over a 12-month period were calculated. The study authors²⁷ reported that the systematic review showed that no therapies can deliver 100% success. Their economic model similarly demonstrated that none of the strategies were 100% successful; however, the most successful regime in the stepped approach pathway was non-opioids, followed by biologic drugs, epidural and/or nerve block, and disk surgery. In the primary care pathway, the most successful regime was non-opioids. The pathway of immediate surgery was not cost-effective. The authors stated that the sensitivity analyses using the highest cost estimates resulted in comparable results. In terms of positive net benefit, the authors claimed that the stepped care approach would be regarded as cost-effective if the ceiling ratio for an additional unit of utility gain over 12 months was less than £5,100 and if the ceiling ratio for each additional success was less than £2,500.²⁷

Table 20: Summary of Findings of the Economic Evaluation²⁷

| Main findings | Authors' conclusion |
|--|---|
| <ul style="list-style-type: none"> • Base-case analysis: costs were inactive control (£0), usual care for 6 weeks (£73.74), education/advice (£81), activity restriction (£70), alternative/non-traditional therapies (£70), non-opioids for 6 weeks (£122.23), opioids for 2- to 4-week prescriptions (£130.26), biologic drugs for 12-week course (£1646.74), manipulation, traction, passive physiotherapy, active physiotherapy (all £349), epidural (£602.76) and disk surgery with average length of hospital stay of 1.9 days (£1433.66). • Results were expressed as incremental cost per patient with symptoms successfully resolved and incremental cost per utility gained over a 12-month period. One-way sensitivity analyses were used to address uncertainty. • The economic model demonstrated that none of the strategies resulted in 100% success (defined as overall improvement or resolution of symptoms). • The most successful strategy in the stepped care pathway was non-opioids, followed by biologic drugs, followed by epidural/nerve block and disk surgery, with a probability of success (overall symptom improvement or resolution) of 0.996 (i.e., 3 patients would be unsuccessful for every 1,000 treated). • The treatment pathway of initial treatment followed by immediate surgery was not cost-effective. • Compared to inactive control, the following ICERs were associated with the following stepped approaches: treatment with non-opioids and alternative/non-traditional treatments (£999); non-opioids, alternative/non-traditional treatments, and epidural (£1992); non-opioids, alternative/non-traditional treatments, epidural, and disk surgery (£5023); and non-opioids, biologic therapies, epidural, and disk surgery (£388,478). • In terms of net benefit, the stepped care approach would be regarded as cost-effective if the ceiling ratio for an additional unit of utility gain over 12 months was < £5100 and if the ceiling ratio for each additional success was < £2500. • Sensitivity analyses identified that use of the highest cost estimates resulted in similar findings. • Sensitivity analysis showed that removal of biologic drugs from the stepped approach made little difference to the cost-effectiveness results. | <p>"The stepped approaches to managing sciatica based on an initial treatment with non-opioids represent the most cost-effective regimens relative to direct referral to disk surgery, with positive net benefits emerging if the acceptable ceiling ratio for an additional unit of success was <£2500 with base-case costs and < £6000 if higher costs were applied to the model. The strategy of referring patients who fail initial treatments directly to disk surgery is unlikely to be cost-effective, with highly improbable reductions in cost and/or rates of success being required to elevate these regimens to the efficiency frontier. However, these findings remain tentative, and more research is required to develop the evidence base to inform more structurally appropriate economic models to inform decision-making and to determine patient preferences regarding treatment durations and extent of invasive treatments that would be acceptable." (p. 1327)</p> |

The authors described a number of limitations associated with the cost-effectiveness analysis.²⁷ The time perspective was limited to a 12-month horizon, with no evidence available to inform the inclusion of relapse and recurrence within the model. The following were not considered in the analysis: issues relating to work and productivity, preferences of patients for symptom resolution and treatment duration, exploration from a personal social services perspective, and possible additional costs associated with disk surgery. The authors reported that the base-case assumption regarding ultimate failure having an additional 0 cost to the National Health Service was contentious, but lack of data and consensus limited the evaluation of alternatives. Because of the small number of relevant studies for some comparisons of treatment strategies, the authors warned that results should be interpreted with caution due to statistical heterogeneity (within pair-wise comparisons) and potential inconsistency (between pair-wise comparisons) with the network. The authors also claimed that inclusion of anti-inflammatory biologic drugs within their economic model could be seen as contentious. Finally, it was acknowledged that the nature of the economic model was simplistic and did not fully account for structural and parameter uncertainty and distributions.²⁷

Limitations

The purpose of this CADTH custom report was to identify and describe the literature on the potential benefits and harms, and cost implications of stepped care models for chronic pain. This report was not a formal program evaluation, and no conclusions were formed. The literature was not critically appraised and the quality of the evidence from included publications is unknown.

The 5 stepped care models describing potential benefits²¹⁻²⁶ were implemented in Australia, the Netherlands, US, and UK, where health care systems differ from those in Canada. The economic evaluation describing the cost implications of stepped care was conducted in the UK.²⁷ Therefore, the applicability of their findings to the Canadian setting is unclear.

Conclusions

Six relevant studies describing the potential clinical benefits of 5 different stepped care models²¹⁻²⁶ and 1 economic evaluation describing the cost implications of stepped care were included in this review. An RCT assessed a stepped care model for patients who are overweight or obese with chronic pain due medial tibiofemoral osteoarthritis (compared to a control group given educational booklets) and described the impact on pain remission, pain intensity and function, and adverse events.²¹ For the SCMP, a before-after study²⁵ and a retrospective cohort study of a pain group versus and non-pain group²⁴ described the effects of the stepped care model on pain, quality of chronic pain care, pharmacotherapy use, and health care utilization in US veterans.^{24,25} A before-after study of a biopsychosocial stepped care model for NCCP described the potential benefits on chest pain, depression, anxiety, quality of life, and health care use.²⁶ A prospective cohort of SCS compared patients who received stepped care strategy-consistent care for hip or knee pain due to osteoarthritis with a cohort who received stepped care strategy-inconsistent care and described the results on pain physical function, self-efficacy, active pain coping and health care use.²³ The ESCAPE RCT described the effects on pain, disability, and pharmacotherapy use in US veterans.²² All studies^{21,22,24-26} described at least some positive results for the clinical outcomes of interest.

The authors of the economic evaluation²⁷ reported that a stepped care pathway based on initial treatment with non-opioids may be cost-effective compared to direct referral to surgery.

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Appendix 1: Evaluations of Step(s) in Stepped Care Model

Note that this appendix has not been copy-edited.

Documents of studies that evaluated one or more steps in the stepped care approach, rather than the implementation and evaluation of the stepped care model itself, are outside the scope of this review and were not summarized in the review. Studies which evaluated components or steps that were part of the included stepped care models are briefly described in the following paragraphs.

Several studies evaluated individual interventions included in the stepped care model in NCCP and described potential clinical benefits. In brief, a retrospective cohort study assessed the impact of 10-week CBT intervention (compared to Acceptance and Commitment Therapy) as part of a stepped care model on pain severity and global distress in US veterans with chronic pain.³⁰ An uncontrolled before-after study in US veterans with chronic pain and posttraumatic stress disorder assessed participation in a biopsychosocial evaluation plus up to 8 behavioural activation sessions on pain, mental health and quality of life.³¹ An RCT evaluated problem-solving compared to behavioural activation (both in addition to treatment with venlafaxine) as the second step in a stepped model for people 60 years of age and older with comorbid depression and low back pain.³²

Several studies evaluated interventions included in ESCAPE and described potential clinical benefits. A qualitative study with 26 participants in the ESCAPE intervention group assessed the self-management education of step 2 in the model.³³ An RCT examined the effectiveness^{34,35} and acceptability³⁶ of a telecare intervention, which included nurse telephone contacts and was coupled with automated symptom monitoring, as part of the Stepped Care to Optimize pain Care Effectiveness (compared to usual care) for US veterans with chronic pain.

Two studies^{37,38} evaluated the delivery of education and exercise therapy interventions. An RCT³⁷ assessed 12 weeks of physiotherapist-led (up to 8 sessions) education and exercise therapy delivered face-to-face versus telerehabilitation delivery in participants with chronic patellofemoral pain.³⁷ An uncontrolled before-after study³⁸ assessed education (2 to 3 sessions) and supervised exercises (twice weekly for 6 weeks) as the first step in a stepped care model for pain due to knee or hip osteoarthritis.

A retrospective cohort study compared 1-year downstream health care use and medical costs for patients with spine or shoulder pain who received manual therapy only compared to manual therapy and opioid prescriptions as the first step in a stepped care model.³⁹

Appendix 2: Documents of Potential Interest

Note that this appendix has not been copy-edited.

Related CADTH Reports

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