

**Cognitive and Mind-Body Therapies for
Chronic Low Back and Neck Pain:
Effectiveness and Value**

Final Background and Scope
May 8, 2017

Stakeholder Input:

This scoping document was developed with substantial input from several patient advocacy organizations focusing on pain management. ICER also engaged with and received detailed input from relevant specialty societies, practicing general internists, pain specialists, and payers to inform the research direction outlined in this scope.

The Final Background and Scope reflects feedback gathered during a three-week public comment period. Based on stakeholder input, we have made several updates to the prior document. We have clarified that we intend to conduct our own review of the evidence on chronic neck pain using an approach similar to the Agency for Healthcare Research and Quality (AHRQ) review of treatments for chronic low back pain. We have also added additional detail and context to the Populations and Outcomes sections of the scope. ICER looks forward to continued engagement with stakeholders throughout its review of cognitive and mind-body therapies for chronic low back and neck pain.

Background:

Back and neck pain are two of the most common reasons for patient visits to physicians in the United States. Approximately one in four adults report experiencing low back pain in the prior three months. The estimated costs of back and neck pain in the United States was \$88 billion in 2013, third highest after heart disease and diabetes.¹ Costs for back and neck pain have increased faster than any other group of diagnoses (from \$30.4 billion in 1996 to \$87.6 billion in 2013). These costs do not include the indirect costs related to missed work and disability.

Several organizations have released treatment guidelines for low back and neck pain including the American College of Physicians (ACP), the American Academy of Pain Medicine, the American Pain Society, and the Academy of Integrative Pain Management, among others. There is general agreement that first line therapy for chronic back and neck pain should be non-pharmacologic, but the most effective non-pharmacologic interventions are not known.

Non-invasive therapies that have been evaluated for chronic low back pain and neck pain include pharmacologic therapies (e.g., non-steroidal anti-inflammatory drugs [NSAIDs], opioids, tricyclic antidepressants, anti-epileptic medications), physical therapies (e.g., physical therapy, exercise therapy, high and low velocity manipulation), and mind-body therapies (e.g., yoga, tai chi, cognitive behavioral therapy, mindfulness, acupuncture). These different types of therapies are not mutually exclusive and could potentially be complementary. Patients appear to be referred for mind-body therapies somewhat less commonly than for other non-invasive therapies for low back pain, and it is uncertain whether this reflects appropriate judgments about relative effectiveness, availability of these therapies, and/or coverage by insurance of these therapies.

Advocacy organizations emphasized that chronic low back and neck pain can be life-changing events that force many patients to limit or stop their normal daily activities. Patients with chronic pain report feelings of anger, depression, and guilt related to their pain, which can control all aspects of their life. A diagnosis of chronic pain poses similar challenges to family members who must modify their activities and expend considerable emotional energy to care for a family member in pain. Physicians frequently treat patients suffering from chronic pain with opioids. This is a risk factor for opioid use disorder, which is a national crisis. Appropriate use of effective non-pharmacologic therapy has the potential to reduce the epidemic of opioid therapy use in the United States.

The goal of treatment is to decrease pain and increase function including returning people to work.

Report Aim:

This project will evaluate the health and economic outcomes of cognitive and mind-body therapies for chronic neck and back pain including yoga, tai chi, cognitive behavioral therapy, mindfulness, and acupuncture. The ICER value framework includes both quantitative and qualitative comparisons across treatments to ensure that the full range of benefits and harms - including those not typically captured in the clinical evidence such as innovation, public health effects, reduction in disparities, and unmet medical needs - are considered in the judgments about the clinical and economic value of the interventions.

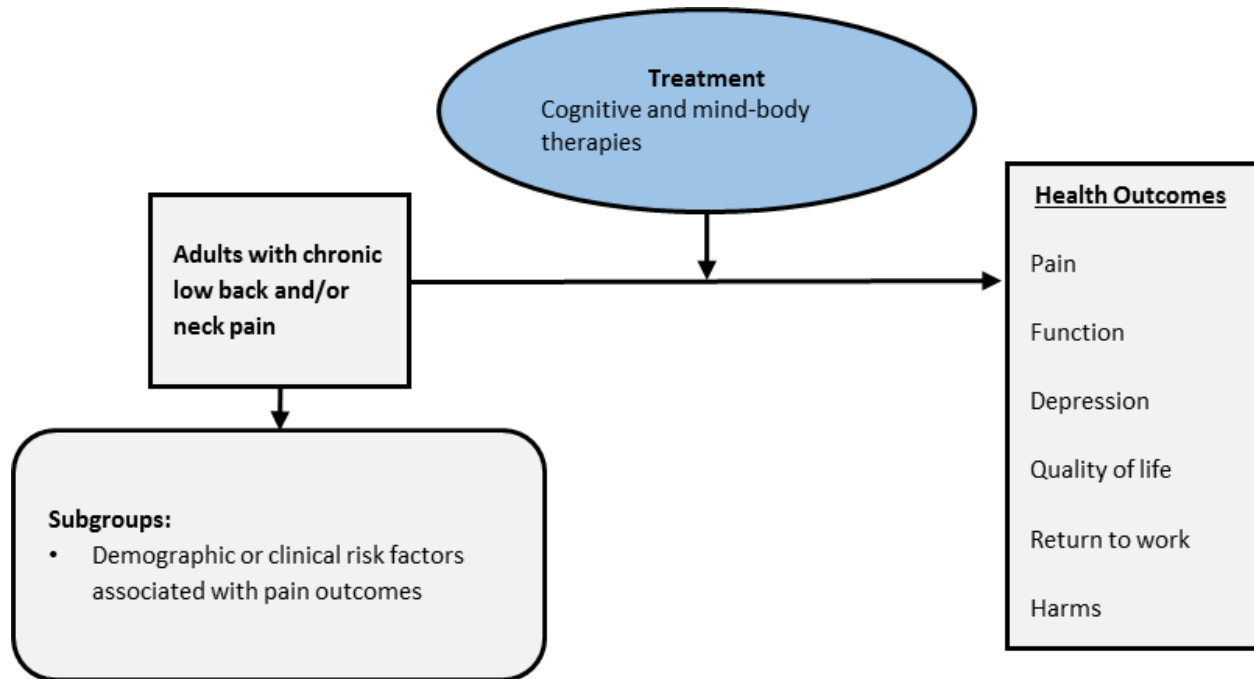
Scope of the Assessment:

The proposed scope for this assessment is described on the following pages using the PICOTS (Population, Intervention, Comparators, Outcomes, Timing, and Settings) framework. Evidence will be abstracted from systematic reviews and randomized controlled trials. For chronic low back pain, our review will be based on the recent AHRQ review performed to support the updated ACP guidelines on low back pain.^{2,3} We will perform our own review, analogous to that performed by AHRQ, for chronic neck pain. Our evidence review will also include input from patients and patient advocacy organizations.

Analytic Framework:

The general analytic framework for assessment of therapies for back and neck pain is depicted in Figure 1.

Figure 1. Analytic Framework: Cognitive and Mind-Body Therapies for Chronic Low Back and Neck Pain



Populations

The population for the review is adults 18 years of age and older suffering from chronic low back or neck pain that is not due to cancer, infection, inflammatory arthropathy, high-velocity trauma, fracture, and pregnancy, and that is not associated with progressive neurologic deficits. Chronic pain is defined by the presence of symptoms for at least 12 weeks. The interventions will be evaluated separately for patients with chronic low back pain and for patients with chronic neck pain. If studies clearly demonstrate effect modification by subgroups of back or neck pain (for example an intervention that has a large increase in function for patients with facet joint arthritis, but not for patients with other causes for their chronic back pain), these subgroups will be highlighted.

Interventions

The list of interventions was developed with input from patient organizations, clinicians, and insurers on which treatments to include. The full list of interventions is as follows:

- Acupuncture
- Cognitive behavioral therapy
- Mindfulness
- Yoga
- Tai Chi

Comparators

Data permitting, we intend to compare all the agents to each other and to usual care as defined in the clinical trials.

Outcomes

The primary goal of treatment is to improve function and reduce pain to allow patients to return to their usual daily activities including work. We will also assess any harms associated with therapy as well as patient reported quality of life.

Primary outcomes

Pain (e.g. visual analog scale)

Function (e.g. Oswestry Disability Index, Roland Morris Disability Questionnaire).

Depression (e.g. Patient Health Questionnaire 9; Center for Epidemiologic Studies Depression Scale)

Return to work / disability

Quality of life (e.g. Short Form 36)

Harms

Timing

Evidence on intervention effectiveness will be derived from studies of at least six months' duration or studies of more limited duration with outcomes assessed at least 4 weeks after the cessation of active therapy.

Settings

All relevant settings will be considered, with a focus on outpatient settings in the United States.

Simulation Models Focusing on Comparative Value:

As a complement to the evidence review, we will develop an economic model to assess the costs and consequences of the treatments of interest relative to relevant comparator treatments. The model structure will be based in part on a literature review of prior published economic models of chronic back and neck pain, and will take a health-care system perspective (i.e., focus on direct medical care costs only). The target population will consist of adults with chronic low back and/or neck pain. The model time horizon will be selected after review of relevant data on the treatments of interest, as data on long-term effectiveness may not be available for all interventions.

Key model inputs will include quality of life values, pain-related outcomes, treatment/health care costs, and the reduction in use of other therapies including opioid medications. Probabilities, costs, and other inputs will differ to reflect varying effectiveness between interventions.

Health outcomes and costs will be dependent on time spent in each health state, rates of adverse events (AEs), and direct medical costs. The health outcomes of each intervention will be evaluated in terms of time spent in different health states defined by pain and functional status. The model will include costs related to the duration and frequency of provider visits for non-pharmacologic therapies, other health care costs associated with back and neck pain, and any costs for serious adverse events. Relevant pairwise comparisons will be made between treatments, and results will be expressed in terms of the cost and consequences over the duration of the model. A separate scenario analysis including costs outside the health care system, such as productivity loss, will be conducted if adequate data are available.

References

1. Dieleman JL, Baral R, Birger M, et al. US Spending on Personal Health Care and Public Health, 1996-2013. *JAMA*. 2016;316(24):2627-2646.
2. Qaseem A, Wilt TJ, McLean RM, Forciea MA. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. *Annals of internal medicine*. 2017.
3. Chou R, Deyo R, Friedly J, et al. Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. *Annals of internal medicine*. 2017.