

Section 1: Responses to Public Comments on PICOTS Framework Organized by Theme

1. Population

1.1. Defining age of individuals

- 1.1.1. *We need health, medical and psychological recommendations to be made with developmental language not ages. The number 18 is a fan-favorite among lawyers, but it does not mean anything special in nature. There may be more differences between adults at age 18 and adults at 48 than there are differences between children at age 17 and adults at 18. [DL Newman (Group: Society of Indian Psychologists)]*

Panel Response: Thank you for your comment. While we philosophically agree that treatment recommendations should be written using a developmental lens, we are currently limited with how the individual studies within the included systematic reviews and meta-analyses characterize the age groups. We will note this important limitation as a footnote in the guideline.

- 1.1.2. *By excluding children from the guideline, it is likely that payers will claim that children will not benefit from behavioral and interventional interventions for pain. [A.J. Rush, MD (Individual)]*

Panel Response: Thank you for your comment. Having our scope limited to adults does not necessarily mean that children and adolescents would not benefit from these treatments. There are a number of systematic reviews that address chronic pain in children and adolescents (Fisher et al., 2018) and we will highlight these in the introduction section of the document.

Reference

Fisher, E., Law, E., Dudeney, J., Palermo, T. M., Stewart, G., & Eccleston, C. (2018). Psychological therapies for the management of chronic and recurrent pain in children and adolescents. *Cochrane Database of Systematic Reviews*.
<https://doi.org/10.1002/14651858.CD003968.pub5>

1.2. Defining “chronic musculoskeletal pain”

- 1.2.1. *I'm sure you will add more detail but I'm wondering if the population will include self-identified individuals or only those with a formal diagnosis. [Kara Ayers (Group: CDIP)]*

Panel Response: Thank you for your comment. The populations included will depend on how the information is aggregated in individual studies within the systematic reviews and meta-analyses. In other words, some studies may define the population of interest as having a formal diagnosis of chronic musculoskeletal pain while other studies may include a broad definition of chronic pain. If the individual studies note this differentiation, we will note this within the guideline. We will also include the issue of how chronic pain populations are defined in the limitations of this review secondary to information provided in the evidence base (i. e., this is not a direct limitation of the review).

- 1.2.2. *We generally agree with the population element but wish to underscore that even "chronic musculoskeletal pain" is an umbrella category that incorporates different etiologies and severities. Although this is a preliminary stage in development of the guideline, we hope that as the process unfolds careful attention will be paid to ensuring that a one-size-fits-all approach is discouraged and, instead, one that expressly makes room for the diversity of conditions, cultural preferences, and values of the patient population to whom the guideline, will be applied. We also hope that input from a diverse group of patients will be solicited throughout the process. [Kate Nicholson (Group: National Pain Advocacy Center)]*

Panel Response: Thank you for your comment. We agree that it is important to pay attention to the diversity of conditions, cultural preferences and values of the patient population to whom the guideline will be applied; however, we are limited to how the studies will define this and whether attention was paid to addressing the issues you outlined in the recommendation statements. We will acknowledge and note, based on observational and other types of studies that may not have met criteria for inclusion in the existing systematic review, these important issues in the body of the guideline document. We will also acknowledge any limitation in this area for the guideline recommendations after examining the available data.

- 1.2.3. *My concern is that the decisions made based on this will be applied to people with all sorts of pain, and limiting it to only this subset of pain patients may result in important factors not being incorporated. However, I understand that broadening this definition may not be feasible within the constraints of this project. I just hope thought is being given to how best to serve pain patients with other types of pain. [J N H (Individual)]*

Panel Response: Thank you for your comment. We will clearly state that the scope of the guideline is adults with chronic musculoskeletal pain. We hope that users will apply the guideline to the population that is intended. We also hope that other types of pain conditions will be addressed by other guidelines in the future.

- 1.2.4. *Chronic pain is a very wide category. The types of chronic pain vary from person to person ie dull, achy, sharp. Plus the intensity of the pain varies [Carol Dhainin (Individual)]*

Panel Response: Thank you for your comment. The panel plans to refer to the International Association for the Study of Pain's definition of pain, which is defined as "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage" (Raja et al., 2020, p. 2). This definition is broad in nature and encompasses a range of different types of pain. Ultimately, however, the panel is limited to how the identified systematic reviews as well as the individual studies that were included in these systematic reviews defined chronic pain. If the individual studies' definitions provide specificity, we will note this differentiation in the guideline.

Reference

Raja, S. N., Carr, D. B., Cohen, M., Finnerup, N. B., Flor, H., Gibson, S., Keefe, F. J., Mogil, J. S., Ringkamp, M., Sluka, K. A., Song, X.-J., Stevens, B., Sullivan, M. D., Tutelman, P. R., Ushida, T., & Vader, K. (2020). The revised International Association for the Study of Pain definition of pain: concepts, challenges, and compromises. *Pain*, 161(9), 1976-1982.
<http://dx.doi.org/10.1097/j.pain.0000000000001939>

- 1.2.5. *The operational definition of "chronic musculoskeletal pain" is challenging. Chronic musculoskeletal pain is difficult to discriminate from and often co-occurs with chronic neuropathic pain, including at the same site of musculoskeletal pain and at other sites.* **[Robert D Kerns (Individual)]**

Panel Response: Thank you for your comment. We will be referring to the International Association for the Study of Pain's definition of pain, which consists of three categories: nociceptive, neuropathic, and nociplastic pain (Raja et al., 2020). We are limited as to whether the identified systematic reviews define pain as nociceptive (i.e., musculoskeletal), neuropathic, nociplastic, or a combination. We understand and agree that there may be variability in how the individual studies define "musculoskeletal pain" and "chronic pain" and we will note this differentiation within the guideline if the individual studies have a specific definition.

Reference

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- 1.2.6. *It may be helpful to include how "chronic" is operationalized and which definition will be followed. For example, leading societies either define pain as chronic by lasting more than (3) or (6) months.* **[Lindsey McKernan, PhD MPH (Individual)]**

Panel Response: Thank you for your comment. We will note the definition of "chronic pain" being pain that is lasting more than 3 months.

- 1.2.7. *I think the panel should be more specific about the pain definition. Examples are provided in parentheses but should include more).* **[A Shah (Individual)]**

Panel Response: Thank you for your comment. We will be referring to the International Association for the Study of Pain's (IASP) definition of pain, which consists of three categories: nociceptive, neuropathic, and nociplastic pain (Raja et al., 2020). We are limited as to whether the identified systematic reviews define pain as nociceptive (i.e., musculoskeletal), neuropathic, nociplastic, or a combination. We understand and agree that there may be variability in how the individual studies define "musculoskeletal pain" and "chronic pain" and we will note this differentiation within the guideline if the individual studies have a specific definition. Meta-analyses that focused exclusively on fibromyalgia were not considered appropriate for the current guideline as it falls under the category of "nociplastic" pain. We will note the limitations of the scope of our review as well as the limitation of the evidence base.

Reference

Raja, S. N., Carr, D. B., Cohen, M., Finnerup, N. B., Flor, H., Gibson, S., Keefe, F. J., Mogil, J. S., Ringkamp, M., Sluka, K. A., Song, X.-J., Stevens, B., Sullivan, M. D., Tutelman, P. R., Ushida, T., & Vader, K. (2020). The revised International Association for the Study of Pain definition of pain: concepts, challenges, and compromises. *Pain*, 161(9), 1976-1982.
<http://dx.doi.org/10.1097/j.pain.0000000000001939>

- 1.2.8. Also, I assume that "musculoskeletal pain" includes LBP, widespread pain, and fibromyalgia, right? Is rheumatoid arthritis included?
[Mark A. Lumley, Ph.D. (Individual)]

Panel Response: Thank you for your comment. We will be referring to the International Association for the Study of Pain's (IASP) definition of pain, which consists of three categories: nociceptive, neuropathic, and nociplastic pain (Raja et al., 2020). We are limited as to whether the identified systematic reviews define pain as nociceptive (i.e., musculoskeletal), neuropathic, nociplastic, or a combination. We understand and agree that there may be variability in how the individual studies define "musculoskeletal pain" and "chronic pain" and we will note this differentiation within the guideline if the individual studies have a specific definition. Meta-analyses that focused exclusively on fibromyalgia were not considered appropriate for the current guideline as it falls under the category of "nociplastic" pain. We will note the limitations of the scope of our review as well as the limitation of the evidence base.

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<http://dx.doi.org/10.1097/j.pain.0000000000001939>

- 1.2.9. From: Barbara Melamed <EMAIL> [Barbara Melamed (EMAIL)]
Sent: Sunday, November 7, 2021 1:29 PM
To: Marzalik, Jacob
Subject: Re: [DIV43ANN] Reminder - Call for Comments: Scoping process for a clinical practice guideline for treatment of chronic musculoskeletal pain in adults

Missed the deadline...IS RLS restless leg syndrome within this category. I hate it...and research shows NO CURE

*Barbara Melamed
Univ of Hawaii Psychol Clinical Affiliates.
/Founder and Director of Behavior Medicine Associates, LLC*

Panel Response: Thank you for your comment. We agree this is a troubling disorder; however, restless leg syndrome was not included in the meta-analyses on which the recommendations in this guideline will be based.

1.3. Including headache, facial pain

- 1.3.1. *I also find it a bit confusing that the examples under "including" are all related to facial/head musculoskeletal pain. [Kara Ayers (Group: CDIP)]*

Panel Response: Thank you for your comment. The panel initially included headache and facial pain as there may be some studies that categorized headache and facial pain within musculoskeletal pain. However, after further consideration, the panel decided to eliminate "headache" and "facial pain" in the PICOTS framework as there may not be enough evidence to develop recommendations for these specific conditions. If the studies included in the systematic reviews categorize headache or facial pain as musculoskeletal pain, we will note this in the guideline document.

- 1.3.2. *What is the basis for including headache as a musculoskeletal condition? And, will migraine and mixed headache be included? Ditto, the inclusion of facial pain that is often presumed to have neuropathic contributors. [Robert D Kerns (Individual)]*

Panel Response: Thank you for your comment. The panel initially included headache and facial pain as there may be some studies that categorized headache and facial pain within musculoskeletal pain. However, after further consideration, the panel decided to eliminate "headache" and "facial pain" in the PICOTS framework as there may not be enough evidence to develop recommendations for these specific conditions. If the studies included in the systematic reviews categorize headache or facial pain as musculoskeletal pain, we will note this in the guideline document.

- 1.3.3. *The inclusion of headache is a bit of a surprise, as many authors, including Williams et al. (2020) Cochrane review, exclude headaches. [Mark A. Lumley, Ph.D. (Individual)]*

Panel Response: Thank you for your comment. The panel initially included headache and facial pain as there may be some studies that categorized headache and facial pain within musculoskeletal pain. However, after further consideration, the panel decided to eliminate "headache" and "facial pain" in the PICOTS framework as there may not be enough evidence to develop recommendations for these specific conditions. If the studies included in the systematic reviews categorize headache or facial pain as musculoskeletal pain, we will note this in the guideline document.

1.4. Including acute, subacute pain

- 1.4.1. *Probably should also focus on identifying individuals with acute pain at risk to become individuals with chronic pain and, potential, implement secondary prevention [Joseph Godges DPT (Individual)]*

Panel Response: Thank you for your comment. Avoidance of acute pain developing into chronic pain is beyond the scope of the guideline; however, the panel shares your concern about individuals with acute pain at risk to develop chronic pain and hope this will be addressed in future guidelines.

2. Interventions

2.1. Addressing pain with psychological interventions

2.1.1. *This language is unclear, muddled and oddly stilted. For one thing, it is unclear why the American Psychological Association does not simply endorse the word "psychological"? Why is there a slash? Why are we still tipping a hat to "behavioral" as if the readers are all foolish and don't understand the meaning of "psychological"? Why do we need two words instead of one to understand a concept? Furthermore, all interventions are 99% psychological, even if they non-verbally involve submission to the behavior of another person injecting something into a patient's joint. If the patient consents to something, they are consenting to the ideas of the treatment as explained, as understood, as entrusted, or in the worst case, as coerced, by another person who also has beliefs, trust, understanding, or a mandate for conducting their practice. These are all psychological activities. The expectation of treatment efficacy is always 72-99.9% psychological, for both the practitioner and the patient.*

Without the recognition that all interventions involve a large psychological component we are not being clear about the domain for this commentary.

For another thing, the entire notion of "pain" is a psychological phenomenon. This is a very weak starting point for "PICOTS" [DL Newman (Group: Society of Indian Psychologists)]

Panel Response: Thank you for your comment. The American Psychological Association (APA) was tasked with developing a clinical practice guideline for the treatment of chronic musculoskeletal pain. We used the International Association for the Study of Pain's (IASP) definition of chronic pain (Raja et al., 2020), which emphasizes both physical and emotional components to the experience. While the IASP definition may not be perfect, it is one of the most widely used and accepted standards for defining chronic pain. Regarding our choice of verbiage, we included a slash between "psychological" and "behavioral" because some studies label the psychological interventions as "behavioral", and we did not want to limit the studies that only mentioned "psychological" interventions.

Reference

Raja, S. N., Carr, D. B., Cohen, M., Finnerup, N. B., Flor, H., Gibson, S., Keefe, F. J., Mogil, J. S., Ringkamp, M., Sluka, K. A., Song, X.-J., Stevens, B., Sullivan, M. D., Tutelman, P. R., Ushida, T., & Vader, K. (2020). The revised International Association for the Study of Pain definition of pain: concepts, challenges, and compromises. *Pain*, 161(9), 1976-1982.
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- 2.1.2. *Pain is not a psychological condition, so it cannot be treated as one. Treating the psychological fallout from chronic pain is absolutely necessary, but this must only be done as an adjunct to direct treatment of the pain itself. Whatever psychological interventions are contemplated by this framework, it is unethical for them to be applied in the absence of adequate pain control through medical, surgical, or PT/OT type interventions. [J N H (Individual)]*

Panel Response: Thank you for your comment. We are looking at multimodal treatments for chronic musculoskeletal pain and we are not opposed to using more than one modality as the primary treatment for chronic pain. Regarding the definition of “adequate pain control” there is currently no standard medical definition of adequately controlling pain. The basis of our guideline is to find what the current evidence says about improving the quality of life in patients with chronic musculoskeletal pain. We also want to emphasize the biopsychosocial nature of chronic musculoskeletal pain and how this guideline can serve as one of the many components of addressing chronic pain as well as improve the quality of life in patients with chronic musculoskeletal pain. There is a need for multimodal approaches to care for chronic pain and that the guideline is not to be used as a singular approach to treating chronic pain.

- 2.1.3. *In order for psychological treatment to work properly I feel that the patients chronic pain with proper pain medications should be prerequisite for other modalities to be successful [Cynthia Boyd (Individual)]*

Panel Response: Thank you for your comment. We are looking at multimodal treatments for chronic musculoskeletal pain and we are not opposed to using more than one modality as the primary treatment for chronic pain. Regarding the definition of “adequate pain control” there is currently no standard medical definition of adequately controlling pain. The basis of our guideline is to find what the current evidence says about improving the quality of life in patients with chronic musculoskeletal pain. We also want to emphasize the biopsychosocial nature of chronic musculoskeletal pain and how this guideline can serve as one of the many components of addressing chronic pain as well as improve the quality of life in patients with chronic musculoskeletal pain. There is a need for multimodal approaches to care for chronic pain and that the guideline is not to be used as a singular approach to treating chronic pain.

- 2.1.4. *Will the amount of time spent or dedicated to the behavioral/ psychological content of a multimodal program be considered? [Sheri P. Silfies (Individual)]*

Panel Response: Thank you for your comment. There is currently not enough research on the specific timing and dosing of treatments; however, we will note this wherever possible in the guideline based on the findings in the studies reviewed.

2.2. Defining interventions / setting parameters

2.2.1. *Very non specific in regards to interventions. Needs parameters.* **[Carol Dhainin (Individual)]**

Panel Response: Thank you for your comment. There is some specificity in our definition; however, we agree that it still casts a wide net. We are ultimately limited to how the existing systematic reviews define “psychological/behavioral components” and wanted to make sure that we did not miss important work due to too narrow a scope.

2.2.2. *Again, the operational definition of "psychological/behavioral components" will be tricky. I encourage some pre-work to establish the inter-rater agreement of application of the definition and to refine the definition accordingly.* **[Robert D Kerns (Individual)]**

Panel Response: Thank you for your comment. We agree that standardization is warranted; however, we are limited to how the existing systematic reviews define “psychological/behavioral components.”

2.2.3. *"Any program" might not be sufficient. What are the elements of the intervention program? For example, acceptance and reprocessing based treatments are way more effective than psychoeducation.* **[Katie Witkiewitz (Individual)]**

Panel Response: Thank you for your comment. We agree that it is important to appropriately define the intervention. Interventions will be described based upon the available information from the systematic reviews and meta-analyses utilized to develop the chronic pain guideline.

2.2.4. *I think that this can be difficult when surgical, pharmaceutical, and other types of interventions are included in a multimodal setting. These should be separated from purely behavioral/psychological interventions.* **[A Shah (Individual)]**

Panel Response: Thank you for your comment. We do intend to separate surgical, pharmaceutical, and other types of interventions within the “Comparators” category of the PICOTS framework.

2.2.5. *I am unsure what "curriculum-based" means. Is this "manualized" or "standardized"? I hope that it does not give priority to "didactic" forms of intervention or "classes", as opposed to the full range of psychological / behavioral therapies or treatments, many of which would not view themselves as "curriculum-based".* **[Mark A. Lumley, Ph.D. (Individual)]**

Panel Response: Thank you for your comment. We appreciate the wide range of psychological/behavioral therapies that are present but have limited our scope to those that are curriculum-based (manualized or standardized) to allow a minimum baseline for comparison.

2.2.6. From: Terri <EMAIL> [Bob Moss (EMAIL)]
Sent: Friday, October 8, 2021 8:01 AM
To: SM EBPP
Subject: information you may find of interest
Attachments: Psychotherapy in Pain Management_hard_man_v1[23170].pdf

I attached my book from last year that discusses views on psychotherapy in chronic pain which incorporates a brain model (based on the cortical column as the binary digit for cognitive processing). I believe you will see how the applied clinical model provides a logical understanding of each of the empirically supported treatments, including that related to emotional awareness and expression therapy. Bob Moss

Sent from [Mail](#) for Windows

Panel Response: Thank you for your message and additional information in your attachment. Your comments and shared insights are appreciated.

3. Comparators

3.1. Overall

- 3.1.1. *Also messy: there is no such thing as TAU - only the fantasy that everyone is doing something that other practitioners might also try. TAU is not operationalized and has no business being in an experimental study. [DL Newman (Group: Society of Indian Psychologists)]*

Panel Response: Thank you for your comment. We agree with your point in that TAU and “usual care” are often poorly defined in studies and are contextual in nature. Upon further discussion, the panel concluded this is not a sufficient reason to exclude these studies from the reviews included in our guidelines. These terms are still commonly used across studies to describe treatment comparators. Having a treatment comparator (even a poorly defined one) will still allow for treatment effects to be generated for the treatment of interest. Admittedly, we are limited to the current literature’s operationalization of TAU/usual care, and this would be a much bigger issue to consider if we were looking to replicate the comparator from a given study. However, our primary charge is to consider in which situations pain treatments of interest might be considered effective, and comparisons with TAU remain a common way to test effectiveness. We will include examples of how TAU/usual care were handled in the systematic reviews and meta-analyses (including descriptive information for what comprised TAU/usual care when available), acknowledge this limitation, and encourage better reporting of TAU / usual care definitions in future research.

- 3.1.2. *“meditation” is listed as a comparator, but mindfulness-based interventions that include mindfulness meditation practices are effective in chronic pain treatment. [Katie Witkiewitz (Individual)]*

Panel Response: Thank you for your comment. We will include “mindfulness meditation” as part of the “meditation” comparator.

- 3.1.3. *This does not indicate that comparators can be other types of behavioral or psychological interventions. [A Shah (Individual)]*

Panel Response: Thank you for your comment. Comparators can be other types of behavioral or psychological interventions and the panel will note this when they are identified in the reviews.

3.2. Efficacy comparators

- 3.2.1. *We believe that it is important to include efficacy comparators. [Kate Nicholson (Group: National Pain Advocacy Center)]*

Panel Response: Thank you for your comment. While there are comparative studies that compared one behavioral intervention to another behavioral intervention the overall charge of the Panel is to look at psychological interventions as a whole and compare with other nonpharmacological interventions for treatment of chronic musculoskeletal pain.

3.2.2. *Include comparative efficacy comparators* [Beth Darnall, PhD (Individual)]

Panel Response: Thank you for your comment. While there are comparative studies that compared one behavioral intervention to another behavioral intervention, the overall charge of the Panel is to look at psychological interventions as a whole and compare with other nonpharmacological interventions for treatment of chronic musculoskeletal pain.

3.3. Patients' voices and wellbeing

3.3.1. *Again, the patient must feel that someone is caring for their chronic pain with medications if need be.* [Cynthia Boyd (Individual)]

Panel Response: Thank you for your comment. The guideline is focusing specifically on the role of psychological/behavioral interventions for the treatment of chronic musculoskeletal pain. The panel fully appreciates that optimal pain care often requires a combination of different interventions to maximize outcomes.

3.3.2. *There could be real physical and psychological damage to the patients if you treat all their pain as psychological vs physical in nature. Plus psychological counseling doesn't decrease pain at all.* [Carol Dhainin (Individual)]

Panel Response: We thank you for your comment and agree that pain has a very physical cause but is also accompanied by psychological effects and both must be treated holistically. We plan to use the International Association for the Study of Pain's (IASP) definition of chronic pain (Raja et al., 2020), which emphasizes both physical and emotional components to the experience. While the IASP definition may not be perfect, it is one of the most widely used and accepted standards for defining chronic pain. We will take care to clarify this in the guideline.

Reference

Raja, S. N., Carr, D. B., Cohen, M., Finnerup, N. B., Flor, H., Gibson, S., Keefe, F. J., Mogil, J. S., Ringkamp, M., Sluka, K. A., Song, X.-J., Stevens, B., Sullivan, M. D., Tutelman, P. R., Ushida, T., & Vader, K. (2020). The revised International Association for the Study of Pain definition of pain: concepts, challenges, and compromises. *Pain*, 161(9), 1976-1982.
<http://dx.doi.org/10.1097/j.pain.0000000000001939>

3.3.3. *Opioids have been an effective pain management tool for me. Now the stigma is making it hard to get proper pain control when opioids are the only option for rare diseases.* [Ann (Individual)]

Panel Response: Thank you for your comment. The guideline is focusing specifically on the role of psychological/behavioral interventions for the treatment of chronic musculoskeletal pain. The panel fully appreciates that optimal pain care often requires a combination of different interventions to maximize outcomes.

3.4. Defining “complementary and alternative medicine”

- 3.4.1. *Likewise, everything else is vague and symbolic in this sentence. For example, the term “complementary and alternative medicines” is not a comparative entity; it is just the whatever the “other guy” is doing that I do not understand well enough to explain. [DL Newman (Group: Society of Indian Psychologists)]*

Panel Response: Thank you for your comment. We plan to revise “complementary and alternative medicines” to “complementary and integrative health” approaches, which is based on the National Center for Complimentary and Integrative Health’s (NCCIH) definition.

- 3.4.2. *I question the addition of “complementary and alternative medicines” here – if this is referring broadly to CAM, this might not be a great comparator. This branch of treatment can be quite different from “usual care.” [Robert J. Trager (Individual)]*

Panel Response: Thank you for your comment. We agree that it is different than “usual care” and is why we included “complementary and integrative health approaches.”

- 3.4.3. *With regard especially to “complementary and alternative medicines”, care must be taken to only include legitimate interventions, and not lend legitimacy to quackery. For pain patients, many examples of this category are nothing more than distractions or gaslighting, and they result in additional and unnecessary psychological and physical harm. [J N H (Individual)]*

Panel Response: Thank you for your comment. We are revising the terminology from “complementary and alternative medicines” to “complementary and integrative health” approaches, which is based on the National Center for Complimentary and Integrative Health’s (NCCIH) definition.

- 3.4.4. *I encourage the more contemporary label of “complementary and integrative health” approaches, rather than CAM [Robert D Kerns (Individual)]*

Panel Response: Thank you for your comment--we have made this change.

- 3.4.5. *Massage and acupuncture are included as “complimentary and alternative medicines,” but these two treatment approaches. At least for chronic low back pain, per the American College of Physicians and separately created VA / Dept. of Defense LBP guidelines, both published in 2017, these two approaches are recommend. They are no longer complimentary and alternative but are part of mainstream guidelines. [Robb Russell (Individual)]*

Panel Response: Thank you for your comment. We will further clarify the definition of “complementary and integrative health” approaches by listing interventions that fall under the National Center for Complimentary and Integrative Health’s (NCCIH) definition.

3.5. Defining “Physical Therapy”

- 3.5.1. *“Physical Therapy” is a vague comparator, as it more readily describes a profession than an intervention. The committee may want to consider being more specific (e.g., “physical therapist-directed interventions”). Interventions provided by a physical therapist for chronic pain may include exercise therapy, manual therapy (e.g., soft tissue manipulation, thrust and non-thrust joint manipulation), or passive modalities (e.g., dry needling, transcutaneous electrical nerve stimulation [TENS], electrical dry needling, taping, or other applications of electromagnetic or other superficial cold or heat). Listing “physical therapy” as a single treatment comparator is incredibly vague and will likely limit the clinical usefulness of the CPG’s recommendations when they are related to that comparator. [Kenneth A. Taylor (Individual)]*

Panel Response: Thank you for your comment. We agree that “physical therapy” alone is a vague term; however, it is still commonly used in the literature for trials. When available in the identified systematic reviews and meta-analyses, we will provide further details of what is encompassed in “physical therapy” interventions.

4. Outcomes

4.1. Overall

- 4.1.1. *I am not sure why the physical is separated from the patient's reported outcome. Mind-body problem in this distinction and it seems arbitrary.* **[DL Newman (Group: Society of Indian Psychologists)]**

Panel Response: Thank you for your comment. It is necessary to separate physical from patient-reported outcomes because of the poor correlations between objective and subjective outcomes measures.

- 4.1.2. *Your outcomes are not realistic in the sense that patients who do not feel their pain is believed will stop telling you about their pain. Therefore, you will think you have succeeded based of your outcomes, but in reality, you have failed to meet the needs of the patients.* **[Carol Dhainin (Individual)]**

Panel Response: Thank you for your comment. The panel will add discussion of the topic of patient-centered care and the importance of patient important outcomes.

- 4.1.3. *How will pre-specified primary versus secondary outcomes be considered?* **[Robert D Kerns (Individual)]**

Panel Response: Thank you for your comment. The panel will be focusing on the pre-specified primary outcomes but will note secondary outcomes whenever they are identified in the studies reviewed.

- 4.1.4. *It may be helpful to frame this as assessing at least (1) of the recommended (6) core domains in chronic pain trials outlined in IMPAACT recommendations (aligns with the areas noted above).* **[Lindsey McKernan, PhD MPH (Individual)]**

Panel Response: Thank you for your comment. The panel considered a range of options and determine to use the set we included due to the lack of consistent use of others in studies and often not reported in meta-analyses. We recognize that others may be important, but sufficient evidence is not available on these to allow us to make firm recommendations at this time.

- 4.1.5. *I think other potential options can also be included.* **[A Shah (Individual)]**

Panel Response: Thank you for your comment. The panel considered a range of options and determine to use the set we included due to the lack of consistent use of others in studies and often not reported in meta-analyses. We recognize that others may be important, but sufficient evidence is not available on these to allow us to make firm recommendations at this time.

- 4.1.6. *The "outcomes" category is very unclear to me. The first bullet appears to give primacy to "functioning" as the leading or primary DV, although it is unclear if this refers to patient-reported functioning, performance/behavioral, or both. If both, then why is the second bullet presented separately, as patient-reported outcomes.* **[Mark A. Lumley, Ph.D. (Individual)]**

Panel Response: Thank you for your comment. It was not our intention to set up both the "physical functioning or performance" and "patient reported outcomes (PROMs)" as separate outcomes; rather, the PROMs section was to provide further clarification within the "physical functioning or performance" category. We will restructure the format of the "outcomes" category and further clarify that the outcomes are based on objective data or patient reported outcomes.

4.2. Assessment

- 4.2.1. *It is important to include measures of trust in a physician and trust in a health care institution; measures of PTSD; measures of psychological and physical harm from initial disease treatments as well as from subsequent treatments.* **[John Kusiak (Group: The TMJ Association)]**

Panel Response: Thank you for your comment. Measures of trust in health care providers and institutions -- and the impact of trauma -- are critical for understanding the contextual factors that may impact a given intervention effect on pain outcomes, especially for historically disenfranchised populations. While our inclusion criteria for literature do allow for eligible studies that also capture data on these important factors, our review is not limited to studies that captured these data elements. However, we intend to acknowledge the salience of these important contextual elements as potential limitations of the review.

- 4.2.2. *In addition to QoL, consider wellness or patient satisfaction. Ensure that QoL measures aren't inherently biased against disability with overly broad assumptions that and/or how disability lowers QoL* **[Kara Ayers (Group: CDIP)]**

Panel Response: Thank you for this suggestion. We agree that the term "quality of life" (QOL) lacks a clear definition, and that some outcome measures conflate QOL with an individual's ability to function, ambulate etc. We will strive to interpret research studies using QOL measures with this in mind.

- 4.2.3. *There is no validity to using pain rating scales in chronic pain. It is important to only use functional outcomes.* **[A.J. Rush, MD (Individual)]**

Panel Response: Thank you for your comment. We agree that pain rating scales can be interpreted in problematic ways, and that the assessment of functioning is important. Pain is an amorphous experience that is difficult to assess, and yet is also a very real sensory experience that is a primary concern for patients. We believe that both functional and pain assessments play a role in pain treatment and note that some functional assessments (pain interference measures) combine pain and functional assessment in a single measure.

- 4.2.4. *Should consider assessing group cohesion for group-based pain mgmt programs; this variable has not yet been explored in the context of pain programs, though the literature suggests it could be a useful variable, worth looking at exploratively.* **[Sean Woodland, PhD (Individual)]**

Panel Response: Thank you for your comment. This is an important variable; however, we are currently limited with how the individual studies within the included systematic reviews and meta-analyses report on group variables.

- 4.2.5. *I do not understand the Patient global impression of change?* **[Ruta (Individual)]**

Panel Response: Thank you for your comment. The patient global impression of change is a specific questionnaire that, according to the National Institute of Mental Health (NIMH; Guy, 1976), “evaluates all aspects of patients’ health and assesses if there has been an improvement or decline in clinical status.” We will note whether this specific instrument was used in the included studies within the systematic reviews.

Reference

Guy, W. (Ed.). (1976). *ECDEU assessment manual for psychopharmacology*. U.S. Department of Health, Education, and Welfare, Public Health Service Alcohol, Drug Abuse, and Mental Health Administration.
<https://archive.org/stream/ecdeuassessmentm1933guyw#page/218/mode/2up>

- 4.2.6. *Relative to chronic spine pain, range of motion, despite the dictates of AMA guidelines for permanent disability, are not predictive of pain, do not identify a pain generator, do not lead to a diagnosis or suggest a particular evidence-based treatment.* **[Robb Russell (Individual)]**

Panel Response: Thank you for your comment. We agree with your assertions about this measure; however, we selected spinal range of motion as an outcome measure because it captures information on physical impairment, a domain of relevance and importance in many clinical settings. The panel nonetheless recognizes the limitations with this outcome measure and will take this into consideration as we make our recommendations.

- 4.2.7. *Probably should be specific about "disability", for example, the ability to work or return to work after an injury where pain is experienced, like neck pain or back pain. I bring this up because PROMs do not always address the relevant question of ability to function in society* **[Joseph Godges DPT (Individual)]**

Panel Response: Thank you for your comment. We agree that more specificity regarding “disability” would be beneficial; however, this is challenging due to the discrepancy between objective measures and patient self-report, with the latter potentially influenced by issues related to secondary gain.

- 4.2.8. *Third, the PROMs list in bullet # 2 includes constructs that should really be thought of as "processes" or mechanisms, NOT as primary outcomes. Thus self-efficacy and coping (catastrophizing, acceptance) are the mechanisms targeted by therapies, but they are not the clinical outcomes patients desires or clinicians strive for. I believe that it would be incorrect to make guidelines based on how a treatment changes mechanisms rather than actual clinical outcomes. [Mark A. Lumley, Ph.D. (Individual)]*

Panel Response: Thank you for your comment. The identification of clinically relevant pain outcomes is the subject of much debate, including among our own panel members. Without question, self-efficacy and coping can be framed as process factors contribute to physical pain, pain interference, and pain severity. However, these process elements have also been conceptualized as important, stand-alone clinical outcomes. Given the scope and breadth of our review, we elected to include intervention studies that concentrate on these types of (debatable) outcomes. Results will be stratified according to these outcomes and, thus, the subsequent guidelines will consider these important distinctions as they inform our understanding of the complex causal pathways of pain-related treatments.

4.3. Pain interference, pain coping, pain intensity

- 4.3.1. *We believe that it is very important to consider pain interference. [Kate Nicholson (Group: National Pain Advocacy Center)]*

Panel Response: Thank you for your comment. We included "pain interference" as an example under the umbrella of "physical functioning."

- 4.3.2. *I think there is confusion here between outcomes and process variables. Pain coping as defined and self efficacy are not objective outcomes such as return to work, activity levels, etc. [Arnold Holzman, PhD (Individual)]*

Panel Response: Thank you for your comment. The identification of clinically relevant pain outcomes is the subject of much debate, including among our own panel members. Without question, self-efficacy and coping can be framed as process factors contribute to physical pain, pain interference, and pain severity. However, these process elements have also been conceptualized as important, stand-alone clinical outcomes. Given the scope and breadth of our review, we elected to include intervention studies that concentrate on these types of (debatable) outcomes. Results will be stratified according to these outcomes and, thus, the subsequent guidelines will consider these important distinctions as they inform our understanding of the complex causal pathways of pain-related treatments.

- 4.3.3. *Pain intensity be of primary importance as an outcome. [Eric Garland (Individual)]*

Panel Response: Thank you for your comment. Pain intensity is fraught with challenges as an outcome to assess chronic pain due to its high subjectivity. Moreover, improvements in pain intensity do not necessarily yield changes in function, disability, or quality of life, which are other outcomes associated with the economic, societal, or personal burdens of pain. Thus, while we agree that pain intensity has relevance, there are other variables that the panel perceives to be more useful indices of treatment efficacy.

4.3.4. Include pain interference **[Beth Darnall, PhD (Individual)]**

Panel Response: Thank you for your comment. We included “pain interference” as an example within the “physical functioning” critical outcome.

4.3.5. *More importantly, I STRONGLY recommend that the Task Force focus on the three CO-EQUAL outcomes of pain intensity, pain-related functioning/interference, and distress, as was done by Williams et al. (2020) in their Cochrane review. I realize that there is debate in the field out THE primary DV of chronic pain trials. ACT emphasizes functioning but not pain intensity, whereas CBT has fluctuated over time, but most are now focusing on functioning rather than pain intensity. However, many other treatments still seek pain reduction as the primary outcome, and most patients still seek this outcome--and many are achieving it with newer approaches. I think that it would be a serious disservice to the field and the public to prioritize improving functioning over reducing pain. The task force's review of the literature should target both (as well as distress), and make recommendations accordingly.* **[Mark A. Lumley, Ph.D. (Individual)]**

Panel Response: Thank you for your comment. The panel will be focusing on the pre-specified primary outcomes but will note secondary outcomes whenever they are identified in the studies reviewed.

4.3.6. From: Martha Chavez <EMAIL>
Sent: Friday, October 8, 2021 2:20 PM
To: SM EBPP
Cc: Senator Feinstein
Subject: Psychotherapy for Pain Comment

To Whom It May Concern:

I want to comment on my experience with psychotherapy for pain. In March of 2020, I became disabled with debilitating pain from spinal stenosis of the foreman. The pain kept me bed ridden especially because I was not being treated with opioid pain medications. I was prescribed an array of other medications; antidepressants, gabapentin, ibuprofen, Tylenol, lidocaine patches, physical therapy, acupuncture and psychotherapy. The main focus of psychotherapy for pain was pain acceptance. Kaiser offered a two-week, group program guided by a clinician and a physical therapist. Whilst being in debilitating pain, I sat there and listened to ways to accept pain or ‘work’ around it. I found this experience extremely traumatizing and dismissive of my suffering. It was patronizing, because I felt I was being forced to comply with this program in hopes of eventually getting my pain treated, but that never happened. I find that putting patients through psychotherapy for pain without efficaciously treating the pain first is cruel and dehumanizing. I’ve lost faith in all medical systems as it’s all become very authoritarian and patronizing. Pain acceptance talk did NOT help me in any way. Instead it retraumatized me because I felt I was being gaslighted by the medical system. My pain was ignored and I was referred to pain management to learn to accept to live with it. Just imagine treating any other medical condition like that: telling cancer patients that they have to learn to live with it while denying them care. It’s cruel. I believe that psychotherapy as first line treatment to treat pain is not at all efficacious and had a traumatizing effect on me.

Sincerely,
Martha Chavez
Pain patient

Panel Response: Thank you for your message and for sharing your personal journey. We understand that chronic pain is different in each individual and so is the effectiveness of the treatment. The final guideline will note the importance of appreciating individual and contextual differences when developing treatment plans.

4.4. Pain catastrophizing

- 4.4.1. *Extreme caution must be used with the "pain coping" category. "Pain Catastrophizing" and "acceptance of pain" especially are areas where chronic pain patients are often silenced, gaslit, and manipulated. In too many cases attempts to address these are more accurately described as training patients to suffer in silence. [J N H (Individual)]*

Panel Response: Thank you for your comment. We agree that "catastrophizing" can be used in a pejorative way. The same is true of many of the terms that we use, such as "disorder", "dysfunction", "mental illness" etc. As treating professionals our job is to assess where patients are not doing well and help them to do better. While terms like "catastrophizing" have a scientific use for describing a specific clinical phenomenon, in the clinical setting the use of such constructs with patients should be offered in a way that reflects compassion for the patient's pain and suffering.

- 4.4.2. *pain catastrophizing now has a negative connotation in the pain community. Perhaps change wording. [Melissa (Individual)]*

Panel Response: Thank you for your comment. We agree that "catastrophizing" can be used in a pejorative way. The same is true of many of the terms that we use, such as "disorder", "dysfunction", "mental illness" etc. As treating professionals our job is to assess where patients are not doing well and help them to do better. While terms like "catastrophizing" have a scientific use for describing a specific clinical phenomenon, in the clinical setting the use of such constructs with patients should be offered in a way that reflects compassion for the patient's pain and suffering.

5. Timing

5.1. Overall

5.1.1. *There needs to be more defined limits to your timing. Having no limits on duration or frequency casts a too wide of net in regards to the timing, potentially skewing the results.* **[Carol Dhainin (Individual)]**

Panel Response: Thank you for your comment. We are interested in examining initial / short-term response and maintenance of treatment effects; however, we are limited to what is reported in the studies reviewed.

5.1.2. *Given the focus on "chronic" pain conditions, it seems important to consider a minimum follow-up period, such as 6 months.* **[Robert D Kerns (Individual)]**

Panel Response: Thank you for your comment. We are interested in examining initial / short-term response and agree that a follow-up period of 6 months or longer would be ideal. Ultimately, however, we are limited to what is reported in the studies reviewed.

5.1.3. *It would be good to see changes in proposed mechanisms of action as treatment progresses, so session by session data. Post treatment may not be enough period to have consolidation of all concepts included in an intervention so the more important outcomes may be seen at a later point.* **[Maria Karekla, Ph.D. (Individual)]**

Panel Response: Thank you for your comment. Although you pose an interesting and important question regarding time to effect, examining this is not part of the mission of the panel nor the intent of the guideline. Future studies may wish to explore this area.

6. Setting

6.1. Overall

- 6.1.1. *I am not sure how the setting for delivery of services along this distinction is relevant to comment. If we include home care, Telehealth, and community-based settings we improve the review of culturally broad applications. The definition of terms is dulling the point of this commentary even before we've left the pencil case...* **[DL Newman (Group: Society of Indian Psychologists)]**

Panel Response: Thank you for your comment. These are relevant suggestions; however, we are limited to what most studies/systematic reviews report, which is most commonly "outpatient vs inpatient". Whenever possible, we will indicate any higher level of specificity that is provided (e.g., studies conducted in in research or non-medical settings, via telehealth, etc.).

- 6.1.2. *Need a list of outpatient and inpatient settings* **[Carol Dhainin (Individual)]**

Panel Response: Thank you for your comment. These are relevant suggestions; however, we are limited to what most studies/systematic reviews report, which is most commonly "outpatient vs inpatient". Whenever possible, we will indicate any higher level of specificity that is provided (e.g., studies conducted in research or non-medical settings, via telehealth, etc.).

- 6.1.3. *The Settings should not be combined* **[Chris Wolfkiel (Individual)]**

Panel Response: Thank you for your comment. These are relevant suggestions; however, we are limited to what most studies/systematic reviews report, which is most commonly "outpatient vs inpatient". Whenever possible, we will indicate any higher level of specificity that is provided (e.g., studies conducted in in research or non-medical settings, via telehealth, etc.).

6.2. Consider settings other than medical

- 6.2.1. *While the community might be encompassed in outpatient settings, it seems important to consider a non-medical setting as a potential setting.* **[Kara Ayers (Group: CDIP)]**

Panel Response: Thank you for your comment. These are relevant suggestions; however, we are limited to what most studies/systematic reviews report, which is most commonly "outpatient vs inpatient". Whenever possible, we will indicate any higher level of specificity that is provided (e.g., studies conducted in in research or non-medical settings, via telehealth, etc.).

- 6.2.2. *We wish to ensure that settings involved include both treatment and research contexts.* **[Kate Nicholson (Group: National Pain Advocacy Center)]**

Panel Response: Thank you for your comment. These are relevant suggestions; however, we are limited to what most studies/systematic reviews report, which is most commonly "outpatient vs inpatient". Whenever possible, we will indicate any higher level of specificity that is provided (e.g., studies conducted in in research or non-medical settings, via telehealth, etc.).

6.2.3. *How will interventions that are delivered or received outside interactions with the healthcare system be considered? That is, will the growing literature on pain self-management interventions delivered via innovative technologies such as IVR, mobile apps, among others, be excluded?* **[Robert D Kerns (Individual)]**

Panel Response: Thank you for your comment. These are relevant suggestions; however, we are limited to what most studies/systematic reviews report, which is most commonly "outpatient vs inpatient". Whenever possible, we will indicate any higher level of specificity that is provided (e.g., studies conducted in in research or non-medical settings, via telehealth, etc.).

6.2.4. *What about residential or partial hospitalization?* **[Amanda Rhodes (Individual)]**

Panel Response: Thank you for your comment. These are relevant suggestions; however, we are limited to what most studies/systematic reviews report, which is most commonly "outpatient vs inpatient". Whenever possible, we will indicate any higher level of specificity that is provided (e.g., studies conducted in in research or non-medical settings, via telehealth, etc.).

6.2.5. *This definition seems to imply medical settings. Should be framed more broadly to include research settings.* **[Beth Darnall, PhD (Individual)]**

Panel Response: Thank you for your comment. These are relevant suggestions; however, we are limited to what most studies/systematic reviews report, which is most commonly "outpatient vs inpatient". Whenever possible, we will indicate any higher level of specificity that is provided (e.g., studies conducted in in research or non-medical settings, via telehealth, etc.).

Section 2: Responses to Public Comments on Identified Systematic Reviews **Organized by Theme and Specific Review**

1. Overall Selection of Systematic Reviews (*with References to Consider)

- 1.1. *I am concerned that the limit to review of "chronic pain" is omitting studies that look at chronically painful conditions such as Ehlers-Danlos, dislocation, tendonitis, tears, or joint inflammation during due to Lupus or Rheumatoid Arthritis, Osteoporosis, Multiple Sclerosis, post-inflammatory conditions following infection, or other degenerative disk or joint diseases. [DL Newman (Group: Society of Indian Psychologists)]*

Panel Response: Thank you for your comment. Unfortunately, the studies that focus exclusively on these diagnoses are usually small and frequently would not qualify for good evidence under grading standards; thus, they are not included in the systematic reviews which are the basis of our guidelines. Nonetheless, it is possible that participants with these conditions were still included in the studies reviewed given the chronic nature of these disorders.

- 1.2. *Some of our advisors were involved in this study. Darnall, BD, Roy A, Chen A, Ziadni MS, Tanner R, You DS, Cook, KF, Lorig K, King H, Slater K, Mackey IG, Kao MC, Hong J, Tian L, Mackey SC, Comparison of a Single-Session Pain Management Skills Intervention with A Single Session Health Education Intervention and 8 Sessions of Cognitive Behavioral Therapy in Adults with Chronic Low Back Pain: A Randomized Trial, JAMA New Open. 2021: 4 (8): e2113401. Kate Nicholson (Group: National Pain Advocacy Center)**

Panel Response: Thank you for providing this reference. If there are studies within the systematic reviews that compare one psychological intervention within another psychological intervention, the panel will note this in the guideline document.

- 1.3. Garland 2020. Mind-Body Therapies for Opioid-Treated Pain: A Systematic Review and Meta-analysis. JAMA Internal Medicine. <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2753680> [Eric Garland (Individual)]*

Panel Response: Thank you for providing this reference. The panel will consider whether this review is within the scope of the planned guideline.

- 1.4. *None because this whole study is basically a waste of time and money. It's just another attempt to get on the anti opioid bandwagon, and ignore the relevant understanding that people do have a legitimate and real use for opioids as treatment for chronic pain. The relevant problem is the illicit fentanyl and fentanyl based drug coming in our ports and borders. [Carol Dhainin (Individual)]*

Panel Response: Thank you for your comment. The guideline will not be making recommendations for or against opioids.

- 1.5. *It is very surprising that none of the selected reviews focus on chronic low back pain or osteoarthritis, the two most prevalent chronic musculoskeletal pain condition. I think the selection of the reviews above calls into question the definition of the population to be examined.* [Robert D Kerns (Individual)]

Panel Response: Thank you for your comment. We did not include meta-analyses for specific diagnoses but instead focused more generally on chronic pain. The meta-analyses that were used incorporated studies of back pain, osteoarthritis, and other prevalent chronic musculoskeletal disorders.

- 1.6. *If possible, it may be helpful for the panel to consider including information about specific co-morbidities, such as chronic pain and trauma/PTSD. Chronic pain populations are enriched with trauma survivors and those with higher rates of PTSD symptomology, and symptoms can exacerbate one-another. Often, these disorders are treated in isolation without consideration of this overlap and it could be extremely helpful for clinicians to have guidance taken from existing evidence on how to best address chronic pain in those with PTSD. There is some evidence that emotional processing interventions may be helpful in this subpopulation.* [Lindsey McKernan, PhD MPH (Individual)]*

Fishbain, D. A., Pulikal, A., Lewis, J. E., & Gao, J. (2017). Chronic pain types differ in their reported prevalence of post-traumatic stress disorder (PTSD) and there is consistent evidence that chronic pain is associated with PTSD: an evidence-based structured systematic review. *Pain Medicine*, 18(4), 711-735. <https://doi.org/10.1093/pm/pnw065>

Lumley, M. A., Yamin, J. B., Pester, B. D., Krohner, S., & Urbanik, C. P. (2021). Trauma matters: psychological interventions for comorbid psychosocial trauma and chronic pain. *Pain*. Advance online publication. https://journals.lww.com/pain/Citation/9000/Trauma_matters_psychological_interventions_for.97939.aspx

Otis, J. D., Keane, T. M., & Kerns, R. D. (2003). An examination of the relationship between chronic pain and post-traumatic stress disorder. *Journal of Rehabilitation Research and Development*, 40(5), 397-406. <https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.463.397&rep=rep1&type=pdf>

Otis, J. D., Keane, T. M., & Kerns, R. D. (2009). The development of an integrated treatment for veterans with comorbid chronic pain and posttraumatic stress disorder. *Pain Medicine*, 10(7), 1300-1311. <https://doi.org/10.1111/j.1526-4637.2009.00715.x>

Rometsch-Ogioun El Sount, C., Windthorst, P., Denking, J., Ziser, K., Nikendei, C., Kindermann, D., Ringwald, J., Renner, V., Zipfel, S., & Junne, F. (2019). Chronic pain in refugees with posttraumatic stress disorder (PTSD): a systematic review on patients' characteristics and specific interventions. *Journal of Psychosomatic Research*, 118, 83-97. <https://doi.org/10.1016/j.jpsychores.2018.07.014>

Panel Response: Thank you for your comment. We agree that co-morbidities impact chronic pain; however, we are limited by how the individual studies within the included systematic reviews and meta-analyses reported them. We will nonetheless note the importance of assessing for their presence and appreciating their implications in the final guideline.

- 1.7. *I think it would be good to examine additional reviews or reviews of meta-analysis to ensure that the minimize chances of bias for information coming from a single source. For example evidence on Acceptance and Commitment Therapy is largely missing from this review.*

Look at: Feliu-Soler, A., Montesinos, F., Gutiérrez-Martínez, O., Scott, W., McCracken, L. M., & Luciano, J. V. (2018). Current status of acceptance and commitment therapy for chronic pain: a narrative review. *Journal of pain research*, 11, 2145.

Lin, J., Scott, W., Carpenter, L., Norton, S., Domhardt, M., Baumeister, H., & McCracken, L. M. (2019). Acceptance and commitment therapy for chronic pain: protocol of a systematic review and individual participant data meta-analysis. *Systematic reviews*, 8(1), 1-10. [Maria Karekla, Ph.D. (Individual)]*

Panel Response: Thank you for your comment and for providing these references. The panel agrees that it is important to address Acceptance and Commitment Therapy (ACT) in the clinical practice guideline. If insufficient data that meets inclusion criteria is available to make a recommendation statement, the panel might choose to include ACT in the narrative of the guideline instead.

- 1.8. Cameron M, Chrubasik S. Oral herbal therapies for treating osteoarthritis. *Cochrane Database Syst Rev*. 2014 May 22;2014(5):CD002947. doi: 10.1002/14651858.CD002947.pub2. PMID: 24848732; PMCID: PMC4494689. <https://doi.org/10.1002/14651858.CD002947.pub2> [Robb Russell (Individual)]*

Panel Response: Thank you for providing us with this reference. Unfortunately, the subject area falls outside the scope of the guideline and publication is older than five years.

- 1.9. (1) Darnall BD, Roy A, Chen A, Ziadni MS, Tanner R, You DS, Cook KF, Lorig K, King H, Slater K, Mackey IG, Kao MC, Hong J, Tian L, Mackey SC. Comparison of a Single-Session Pain Management Skills Intervention With a Single-Session Health Education Intervention and 8 Sessions of Cognitive Behavioral Therapy in Adults With Chronic Low Back Pain: A Randomized Trial. *JAMA Netw Open*. 2021;4(8):e2113401. doi:10.1001/jamanetworkopen.2021.13401 <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2783047>

Note: our manuscript reporting data for 6-month posttreatment results is in review.

(2) Ziadni MS, Anderson SR, Gonzalez-Castro L, Darnall BD. Efficacy of a Single-Session "Empowered Relief" Zoom-Delivered Group Intervention for Chronic Pain: Randomized Controlled Trial Conducted During the COVID-19 Pandemic. *J Med Internet Res* 2021;23(9):e29672 DOI: 10.2196/29672 PMID: 34505832 <https://www.jmir.org/2021/9/e29672> [Beth Darnall, PhD (Individual)]*

Panel Response: Thank you for providing these references. If there are studies within the systematic reviews that compare one psychological intervention within another psychological intervention, the panel will note this in the guideline document.

- 1.10. Koesling, D., & Bozzaro, C. (2021). Chronic pain patients' need for recognition and their current struggle. *Medicine, Health Care and Philosophy*, 24, 563-572. <https://link.springer.com/content/pdf/10.1007/s11019-021-10040-5.pdf> [Ann (Individual)]*

Panel Response: Thank you for your comment. We agree that this is a valid issue; unfortunately, it is beyond the scope of the guideline.

- 1.11. Park, J., & Hughes, A. K. (2012). Nonpharmacological approaches to the management of chronic pain in community-dwelling older adults: a review of empirical evidence. *Journal of American Geriatric Society*, 60(3), 555-568. <https://doi.org/10.1111/j.1532-5415.2011.03846.x> [A Shah (Individual)]*

Panel Response: Thank you for this reference. This review lists a number of studies that appear to be good candidates for inclusion in this review; however, the panel is only including reviews that are published within the last five years.

- 1.12. *I will admit to being surprised by some of these five systematic reviews that the Panel plans to use. I fully appreciate Williams et al. (2020), but most of the others tend to be focused on a much wider range of interventions than I think we think of with "psychological/behavioral." It will be interesting to see how the Panel handles its scope.*

But of greater concern to me is what may be left out of this scoping review, and I strongly encourage the Panel to consider a broader range of treatments than these five systematic reviews appear to cover, even though some of these treatments are emerging and have been less commonly studied than CBT, mindfulness-based approaches, BT, and ACT. Some of them, however, have been studied quite a bit, but are simply less popular or well-known than other approaches.

Specifically, I am referring to: 1) Short-term Psychodynamic Psychotherapy (STPP); 2) Emotional Awareness and Expression Therapy (EAET); 3) Eye Movement Desensitization and Reprocessing (EMDR); 4) Pain Reprocessing Therapy (PRT); and 5) Mindfulness-Oriented Recovery Enhancement (MORE).

It is possible that the Panel plans to address these interventions, although given that I do not see them covered in the five systematic reviews that have been selected, I fear that they might be excluded. However, I strongly encourage the Panel to include some of these as having evidence for positive benefits (e.g., STPP, EAET) or at least promising evidence in need of further study (MORE, PRT, EMDR).

If the panel has difficulty accessing any of the below, I would be happy to provide them with any of the following articles, if they contact me (mlumley@wayne.edu).

Panel Response: Thank you for your comment. Some of the interventions listed (i.e., STPP and EMDR) did not meet our criteria of "curriculum-based intervention" and other interventions may be too new to have made it in the systematic reviews and meta-analyses that were identified and met with the PICOTS framework. We anticipate as the CPG goes through revision that new reviews will be uncovered.

The Mindfulness-Oriented Recovery Enhancement (MORE) intervention will be included within the overarching "mindfulness-based interventions" umbrella as long as it meets the "curriculum-based" intervention definition. The panel is aware of the recent publication by Ashar and colleagues (2021) on pain reprocessing therapy (PRT) however it is limited to the evidence within the identified

systematic reviews that met the PICOTS criteria at the time. We anticipate that new reviews will be uncovered as the CPG is updated.

1) I strongly recommend that the task force review and seriously consider the following two systematic reviews and meta-analyses of Short-term Psychodynamic Psychotherapy (STPP): (Disclosure note: I am a co-author on these two reviews.)

Abbass, A., Town, J., Holmes, H., Luyten, P., Cooper, A., Russell, L., . . . Kisely, S. (2020). Short-Term Psychodynamic Psychotherapy for Functional Somatic Disorders: A Meta-Analysis of Randomized Controlled Trials. *Psychotherapy and Psychosomatics*, 89, 363-370. <https://doi.org/10.1159/000507738>

This recent review and meta-analysis demonstrates that STPP has large effect sizes in reducing somatic symptoms generally, and pain specifically, compared to various types of controls. Of the 17 RCTs reviewed, some of them are of GI disorders, but about half are of chronic musculoskeletal pain conditions. The online supplemental tables present the data for each study separately and the forest plots for each study. One can see the effects of STPP on reducing pain severity in the chronic pain samples are medium to large.

A recent companion systematic review and meta-analysis examined the "within-treatment" effect of STPP. It included the intervention arm of most of the 17 RCTs from Abbass et al. (2020), but added 22 pre-post studies of STPP, resulting in a review of 37 trials, 18 of which were chronic pain conditions that are addressed by this panel. This review also analyzed the chronic pain studies separately and found a large effect on pain reduction (which was labeled "somatic symptom reduction") of STPP.

Abbass, A., Lumley, M. A., Town, J., Holmes, H., Luyten, P., Cooper, A., . . . Kisely, S. (2021). Short-term psychodynamic psychotherapy for functional somatic disorders: A systematic review and meta-analysis of within-treatment effects. *Journal of Psychosomatic Research*, 145, 110473. <https://doi.org/10.1016/j.jpsychores.2021.110473>

I recognize several issues and potential concerns here. First, people who study "chronic pain" and conduct reviews of those studies typically do not think of "somatic symptom disorders," "functional disorders," "medically unexplained pain" and the like. They search for "chronic pain" in the titles. But as you can see from these reviews, many are of the same populations examined in "chronic pain meta-analyses." Thus, they should be included and considered. Second, although these reviews report on "somatic symptoms," it was the measure of pain intensity / severity extracted from the original studies that was categorized as "somatic symptoms." Third, and perhaps most importantly, we are all aware that psychodynamic therapies have struggled to receive recognition in a cognitive-behavioral (and 3rd wave) dominated culture, especially within American academia. But they have been studied extensively and are especially recognized in Europe as leading, empirically-supported treatments. I strongly urge the Panel to include something about such STPP treatments in the guidelines.

Panel Response: Thank you for your comment. Some of the studies do not meet our criteria (i.e., STPP does not align with the definition of a "curriculum-based" intervention and the "somatic symptoms" category was outside the scope of the PICOTS framework) while others may be new enough the intervention was not addressed in the systematic reviews included. We anticipate as the CPG goes through revision that new reviews will be uncovered. We will be sure to acknowledge in the beginning of the guideline document that chronic pain is a biopsychosocial phenomenon that involves a multidisciplinary approach across specialties for the treatment of chronic pain.

2) *Emotional Awareness and Expression Therapy (EAET): Disclosure: I am a primary developer of this intervention, and I am a co-author on most of the 10 or so publications on it, although several trials were conducted at other centers, without my direct involvement.*

I recommend that the Panel review this article, in which we review the literature (through 2019) on EAET for various chronic pain problems, most of them fitting the purview of these guidelines:

Lumley, M. A., & Schubiner, H. (2019). Emotional awareness and expression therapy for chronic pain: Rationale, principles and techniques, evidence, and critical review. *Current Rheumatology Reports*, 21(7), 8. <https://doi.org/10.1007/s11926-019-0829-6>

This article systematically reviews EAET for chronic pain, concluding that there is a reliable benefit for chronic pain reduction. Here are relevant references included in this review:

1. Lumley, M.A., Schubiner, H., Lockhart, N.A., Kidwell, K.M., Harte, S., Clauw, D.J., & Williams, D.A. (2017). Emotional awareness and expression therapy, cognitive-behavioral therapy, and education for fibromyalgia: A cluster-randomized controlled trial. *PAIN*, 158, 2354-2363. <http://dx.doi.org/10.1097/j.pain.0000000000001036>
2. Ziadni, M.S., Carty, J.N., Doherty, H.K., Porcerelli, J.H., Rapport, L.J., Schubiner, H., & Lumley, M.A. (2018). A life-stress, emotional awareness and expression interview for primary care patients with medically unexplained symptoms: A randomized controlled trial. *Health Psychology*, 37, 282-290.
3. Carty, J.N., Ziadni, M.S., Holmes, H.J., Tomakowsky, J., Peters, K., Schubiner, H., & Lumley, M.A. (2019). The effects of a life-stress emotional awareness and expression interview for women with chronic urogenital pain: A randomized controlled trial. *Pain Medicine*, 20, 1321-1329.
4. Thakur, E.R., Holmes, H.J., Lockhart, N.A., Carty, J.N., Ziadni, M.S., Doherty, H.K., Lackner, J.M., Schubiner, H., & Lumley, M.A. (2017). Emotional awareness and expression training improves irritable bowel syndrome: A randomized controlled trial. *Neurogastroenterology and Motility*, 29:e13143.
5. Burger, A.J., Lumley, M.A., Carty, J.N., Latsch, D.V., Thakur, E.R., Hyde-Nolan, M.E., Hijazi, A.M., & Schubiner, H. (2016). The effects of a novel psychological attribution and emotional awareness and expression therapy for chronic musculoskeletal pain: A preliminary, uncontrolled trial. *Journal of Psychosomatic Research*, 81, 1-8.
6. Slavin-Spenney, O., Lumley, M.A., Thakur, E.R., Nevedal, D.C., & Hijazi, A.M. (2013). Effects of anger awareness and expression training and relaxation training on chronic headaches: a randomized trial. *Annals of Behavioral Medicine*, 46, 181-192.
7. Hsu, M., Schubiner, H., Lumley, M.A., Stracks, J., Clauw, D.J., & Williams, D. (2010). Sustained pain reduction through affective self-awareness in fibromyalgia: A randomized controlled trial. *Journal of General Internal Medicine*, 25, 1064-1070.

8. Lumley, M.A., Cohen, J.L., Stout, R.A., Neely, L.C., Sander, L.M., & Burger, A.J. (2008). An emotional exposure-based treatment of traumatic stress for people with chronic pain: Preliminary results for fibromyalgia syndrome. *Psychotherapy: Theory, Research, Practice, Training*, 45, 165-172.

Note that two other independent groups have published on EAET:

Maroti, D., Ek, J., Widlund, R-M., Schubiner, H., Lumley, M.A., Lilliengren, P., Bileviciute-Ljungar, I., Ljótsson, B., & Johansson, R. (2021). Internet-administered emotional and awareness and expression therapy for somatic symptom disorder with centralized symptoms: A preliminary efficacy trial. *Frontiers in Psychiatry*, 12(104), <https://doi.org/10.3389/fpsyt.2021.620359>

Yarns, B.C., Lumley, M.A., Cassidy, J.T., Steers, W.N., Osato, S., Schubiner, H., & Sultzer, D.L. (2020). Emotional awareness and expression therapy achieves greater pain reduction than cognitive behavioral therapy in older adults with chronic musculoskeletal pain: A preliminary randomized comparison trial. *Pain Medicine*, 21, 2811-2822. <https://doi.org/10.1093/pm/pnaa145>

Of note: two of these trials demonstrated superiority of EAET over bonafide CBT:

Lumley et al. (2017) found that EAET was not only superior to education for fibromyalgia, but superior to expert-provided CBT on several several pain measures (50% pain reduction, widespread pain, overall FM symptoms).

Yarns et al. (2020) found that EAET was superior to CBT for older veterans with chronic musculoskeletal pain with respect to pain reduction (large effect) and pain interference (medium effect).

In summary, EAET may be one of the few interventions that has shown some superiority to other bonafide psychological interventions (CBT). EAET is listed as an evidence-based treatment option in the 2019 U.S. Department of Health and Human Services Pain Management Best Practices Inter-agency Task Force Report. Please consider including it in your report in some fashion.

Panel Response: Thank you for these references. The panel will consider including EAET in its review, depending on what meta-analytic data might be available in the systematic reviews.

3) *Eye Movement Desensitization and Reprocessing (EMDR: I have NOT been involved with developing or studying this treatment).*

EMDR is another of those treatments often thought of as "fringe," but it is not only widely used clinically, but there have been about 8 or 9 RCTs demonstrating its efficacy in chronic pain, ranging from general musculoskeletal to phantom limb to RA. Often the effects on pain reduction are very large. Again, much of this work is coming from Europe.

I recommend that the panel consider this review, even though it is a bit dated:

Tesarz, J., Leisner, S., Gerhardt, A., Janke, S., Seidler, G. H., Eich, W., & Hartmann, M. (2014). Effects of eye movement desensitization and reprocessing (EMDR) treatment in chronic pain patients: A systematic review. *Pain Medicine*, 15(2), <https://doi.org/10.1111/pme.12303>

And here are some updates from that review:

Nia, N. G., Afrasiabifar, A., & Behnammoghadam, M. (2018). Comparing the effect of eye movement desensitization and reprocessing (EMDR) with guided imagery on pain severity in patients with rheumatoid arthritis. *Journal of pain research*, 11, 2107-2113. <https://doi.org/10.2147/JPR.S158981>

Rostaminejad, A., Behnammoghadam, M., Rostaminejad, M., Behnammoghadam, Z., & Bashti, S. (2017). Efficacy of eye movement desensitization and reprocessing on the phantom limb pain of patients with amputations within a 24-month follow-up. *International Journal of Rehabilitation Research*, 40(3), 209-214. <https://doi.org/10.1097/MRR.0000000000000227>

Gerhardt, A., Leisner, S., Hartmann, M., Janke, S., Seidler, G. H., Eich, W., & Tesarz, J. (2016). Eye movement desensitization and reprocessing vs. treatment-as-usual for non-specific chronic back pain patients with psychological trauma: A randomized controlled pilot study. *Frontiers in Psychiatry*, 7, 10. doi:10.3389/fpsy.2016.00201

Tesarz, J., Wicking, M., Bernardy, K., & Seidler, G. H. (2019). EMDR therapy's efficacy in the treatment of pain. *Journal of EMDR Practice and Research*, 13(4), 337-344. doi:10.1891/1933-3196.13.4.337

Panel Response: Thank you for your comment and these references. The panel will consider including EMDR in its review, depending on what meta-analytic data might be available in the systematic reviews.

4) Pain Reprocessing Therapy: (I am connected with the following work)

I want to make sure that the Panel is aware of a recently published highly viewed and discussed article:

Ashar, Y. K., Gordon, A., Schubiner, H., Uipi, C., Knight, K., Anderson, Z., . . . Wager, T. D. (2021). Effect of Pain Reprocessing Therapy vs Placebo and Usual Care for Patients With Chronic Back Pain: A Randomized Clinical Trial. *JAMA Psychiatry*. doi: 10.1001/jamapsychiatry.2021.2669

This therapy is actually related to Pain Exposure Therapy (which I hope is also considered by the Panel), but it has other components (emotional processing, behavioral activation, somatic tracking), coupled with a strong message that pain is brain-based and reversible. It achieved very powerful pain reduction and elimination in people with LBP.

Panel Response: Thank you for your comment. We are aware of the recently published article on PRT however we are limited to the systematic reviews and meta-analyses identified and, as the guideline is updated, we expect new reviews to come out that may include PRT.

5) Mindfulness-oriented Pain Recovery (MORE; I have no associations with this therapy).

Eric Garland has developed this innovative approach to addressing chronic pain and specifically opioid misuse. He has conducted several clinical trials:

Garland EL, Manusov EG, Froeliger B, Kelly A, Williams JM, Howard MO. Mindfulness-oriented recovery enhancement for chronic pain and prescription opioid misuse: results from an early-stage randomized controlled trial. *J Consult Clin Psychol* 2014;82(3):448.

Garland EL, Hanley AW, Riquino MR, et al. Mindfulness-oriented recovery enhancement reduces opioid misuse risk via analgesic and positive psychological mechanisms: A randomized controlled trial. *J Consult Clin Psychol* 2019;87(10):927–40.

Garland EL, Hanley AW, Kline A, Cooperman NA. Mindfulness-Oriented Recovery Enhancement reduces opioid craving among individuals with opioid use disorder and chronic pain in medication assisted treatment: Ecological momentary assessments from a stage 1 randomized controlled trial. *Drug Alcohol Depend* 2019;203(1):61–5.

Note: that Dr. Garland has also conducted a major RCT comparing MORE to supportive therapy in musculoskeletal pain, showing substantial benefits of MORE for opioid reduction and pain interference reduction. This work has been presented at conferences and is now under review at a major medical journal. I expect that it will be published soon.

Panel Response: Thank you for these references; however, per best practices, our panel is focusing on systematic reviews and meta-analyses for the development of the guideline. The panel is also limited to the studies that meet criteria for inclusion in the identified systematic reviews and some of the studies may have been published after the systematic review's publication.

I have already submitted one extensive comment, providing references for several newer therapies that appear to be missing from the systematic reviews selected by the Panel. Here I recommend two systematic reviews and meta-analyses on popular therapies for chronic pain that I have found to be quite comprehensive and rigorous. Below, I have pasted the reference and link as well as the abstract to each review.

Although these therapies "are effective," their effects on key outcomes (pain intensity, interference, distress) are often quite small and sometimes not significantly different than zero. I encourage the panel to evaluate the effect sizes of these and other treatments in their guidelines.

First, I recommend this excellent review and meta-analysis on mindfulness meditation and related approaches:

Hilton, L., Hempel, S., Ewing, B. A., Apaydin, E., Xenakis, L., Newberry, S., . . . Maglione, M. A. (2017). Mindfulness meditation for chronic pain: Systematic review and meta-analysis. *Annals of Behavioral Medicine*, 51(2), 199-213. <https://doi.org/10.1007/s12160-016-9844-2>

Abstract: Chronic pain patients increasingly seek treatment through mindfulness meditation. This study aims to synthesize evidence on efficacy and safety of mindfulness meditation interventions for the treatment of chronic pain in adults. We conducted a systematic review on randomized controlled trials (RCTs) with meta-analyses using the Hartung-Knapp-Sidik-Jonkman method for random-

effects models. Quality of evidence was assessed using the GRADE approach. Outcomes included pain, depression, quality of life, and analgesic use. Thirty-eight RCTs met inclusion criteria; seven reported on safety. We found low-quality evidence that mindfulness meditation is associated with a small decrease in pain compared with all types of controls in 30 RCTs. Statistically significant effects were also found for depression symptoms and quality of life. While mindfulness meditation improves pain and depression symptoms and quality of life, additional well-designed, rigorous, and large-scale RCTs are needed to decisively provide estimates of the efficacy of mindfulness meditation for chronic pain.

Second, I have found this review of ACT to be quite solid. It appears to cover more ground than Williams et al. (2020), although coming to similar conclusions.

Hughes, L. S., Clark, J., Colclough, J. A., Dale, E., & McMillan, D. (2017). Acceptance and commitment therapy (ACT) for chronic pain: A systematic review and meta-analyses. *Clinical Journal of Pain*, 33(6), 552-568.

<https://doi.org/10.1097/AJP.0000000000000425>

Abstract: **OBJECTIVES:** Chronic pain places a burden on individuals and the economy. Although there is evidence for the effectiveness of cognitive-behavior therapy, it is recognized that the effects are limited. Acceptance and Commitment Therapy (ACT), which aims to increase valued action in the presence of pain, has been suggested as an alternative approach. The objective of this review was to determine the clinical effectiveness of ACT for chronic pain in adults when compared with control conditions and other active treatments. **METHODS:** The searches of this systematic review were conducted in the Cochrane library, MEDLINE, EMBASE, CINAHL Plus (EBSCO), and PsycINFO. Grey literature, reference list, and reverse citation searches were also completed. **RESULTS:** Eleven trials were included. ACT was favored over controls (no alternative intervention or treatment as usual). Significant, medium to large effect sizes were found for measures of pain acceptance and psychological flexibility, which are typically considered processes of ACT. Significant small to medium effect sizes were found for measures of functioning, anxiety, and depression. Measures of pain intensity and quality of life were not significantly different than zero. Generally effect sizes were smaller at follow-up. **DISCUSSION:** ACT was more clinically effective than controls on a number of outcomes. It is possible that methodological limitations, some of which are common to psychological trials, may have led to overestimated effects. Only a few studies compared ACT to active treatments and while the evidence is promising for ACT in the treatment of chronic pain, further methodologically robust trials are required. **[Mark A. Lumley, Ph.D. (Individual)]***

Panel Response: Thank you for providing these references. The panel will consider including ACT in its review, depending on what meta-analytic data might be available in the systematic reviews and whether the reviews meet currency and quality criteria.
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2. Skelly et al (2020) / AHRQ Review

- 2.1. *We have a general concern related to this and other reviews that most studies do not include people with severe or high impact type pain.*
[Kate Nicholson (Group: National Pain Advocacy Center)]

Panel Response: Thank you for your comment. We agree that a limitation of many of the studies we are reviewing is the exclusion of specific populations and plan to specifically address this in the body of the document. We plan to highlight the fact that they are not included as the complexity of these cases frequently includes multiple surgeries, sometimes traumatic brain injury, and other issues that would make our recommendations not easily adoptable. We will note that some of the treatments may nonetheless be effective for these individuals but that is not the population we studied.

- 2.2. *Anything with [specific researcher] attached or involved is immediately suspect as [specific researcher] is known to be very anti opioids, therefore creating a bias before the study has even started.* **[Carol Dhainin (Individual)]**

Panel Response: Thank you for your comment. APA's clinical practice guideline development processes have safeguards in place to protect against bias. For example, APA uses reviews that meet the Institute of Medicine (2011; now National Academy of Medicine) standards for developing systematic reviews or that have been subjected to a quality review using the AMSTAR-2 instrument (Shea et al., 2017).

References

Institute of Medicine. (2011). *Finding what works in health care: Standards for systematic reviews*. National Academies Press.
<https://doi.org/10.17226/13059>

Shea, B. J., Reeves, B. C., Wells, G., Thuku, M., Hamel, C., Moran, J., Moher, D., Tugwell, P., Welch, V., Kristjansson, E., & Henry, D. A. (2017). AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. *BMJ*, 358, Article j4008. <https://doi.org/10.1136/bmj.j4008>

- 2.3. *This review is clear in focusing on "chronic pain" rather than a narrower focus on "chronic musculoskeletal pain." The selection of this review as a core resource seems inconsistent with the narrower target population.* **[Robert D Kerns (Individual)]**

Panel Response: Thank you for your comment. We carefully examined the review's exclusion criteria and found that the pain conditions that were excluded were neuropathic rather than musculoskeletal conditions.

2.4. [specific researcher] is a biased author. Physical therapists perform this duty already. **[Ann (Individual)]**

Panel Response: Thank you for your comment. APA's clinical practice guideline development processes have safeguards in place to protect against bias. For example, APA uses reviews that meet the Institute of Medicine (2011; now National Academy of Medicine) standards for developing systematic reviews or that have been subjected to a quality review using the AMSTAR-2 instrument (Shea et al., 2017).

References

Institute of Medicine. (2011). *Finding what works in health care: Standards for systematic reviews*. National Academies Press.

<https://doi.org/10.17226/13059>

Shea, B. J., Reeves, B. C., Wells, G., Thuku, M., Hamel, C., Moran, J., Moher, D., Tugwell, P., Welch, V., Kristjansson, E., & Henry, D. A. (2017). AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. *BMJ*, 358, Article j4008. <https://doi.org/10.1136/bmj.j4008>

2.5. *Although I believe that these authors are "fair" in their assessment, this review is limited in that many or most of the interventions covered are not "psychological or behavioral"--in the sense that psychologists would use them. This review covers acupuncture, massage, Tai Chi, TENS, physical modalities--just about everything that is not "pharmacological." Three other limitations of this review are that: a) no meta-analysis has been done; b) the control / comparison conditions merge very different conditions (waitlist AND active controls / placebos), which yield quite different effect sizes; and c) the psychological therapies reviewed here tend to get lumped together in undifferentiated ways.* **[Mark A. Lumley, Ph.D. (Individual)]**

Panel Response: Thank you for your comment. We agree that this review includes a wide range of non-psychological / behavioral interventions and that it has limitations; however, we are including it due to the fact that it includes a number of comparators that other reviews were lacking.

3. Geraghty et al (2021)

- 3.1. *We have concerns that some of the self-management programs included were delivered via peers so it seems important to distinguish those delivered via peers and professionals. [Kate Nicholson (Group: National Pain Advocacy Center)]*

Panel Response: Thank you for your comment. After looking at the characteristics of the studies included, one intervention used "discussions with staff and peers", which seems consistent with most group approaches. We did not see evidence of programs exclusively delivered by peers.

- 3.2. *Psychological management of fibromyalgia pain is just a fancy way of saying we don't believe this disease is real and the provider will gaslight the patient in order to obtain the results the provider wants [Carol Dhainin (Individual)]*

Panel Response: Thank you for your comment. The panel will add discussion of the topic of patient-centered care and importance of patient reported outcomes.

- 3.3. *Although pain is a primary feature of fibromyalgia, the focus on this condition raises questions about where the line will be drawn when defining musculoskeletal pain. [Robert D Kerns (Individual)]*

Panel Response: Thank you for your comment. Although there is overlap between musculoskeletal (IASP's category: nociceptive), neuropathic, and nociplastic [IASP's category] (sometimes referred to as chronic widespread pain, chronic overlapping pain syndromes), some studies may define the population of interest as having a formal diagnosis of chronic musculoskeletal pain while other studies may include a broad definition of chronic pain. If the individual studies note this differentiation, we will indicate this within the guideline. We will also note the limitations of the scope of our review as well as the limitation of the evidence base. Note that according to IASP's categories (Raja et al., 2020) fibromyalgia is not included as nociceptive (i.e., musculoskeletal) but rather nociplastic. Thus, although some studies with fibromyalgia patients may have combined fibromyalgia with musculoskeletal patients, meta-analyses that focused exclusively on fibromyalgia were not considered appropriate for the current guideline.

Reference

Raja, S. N., Carr, D. B., Cohen, M., Finnerup, N. B., Flor, H., Gibson, S., Keefe, F. J., Mogil, J. S., Ringkamp, M., Sluka, K. A., Song, X.-J., Stevens, B., Sullivan, M. D., Tutelman, P. R., Ushida, T., & Vader, K. (2020). The revised International Association for the Study of Pain definition of pain: concepts, challenges, and compromises. *Pain*, 161(9), 1976-1982.
<http://dx.doi.org/10.1097/j.pain.0000000000001939>

- 3.4. *Some of these self-management interventions are delivered by trained peers. Would just made very clear the distinction of the interventions and the interventionalists in the final product. [Beth Darnall, PhD (Individual)]*

Panel Response: Thank you for your comment. After looking at the characteristics of the studies included, one intervention used "discussions with staff and peers", which seems consistent with most group approaches. We did not see evidence of programs exclusively delivered by peers.

- 3.5. *This review is limited to "self-management" which is defined as interventions that must include BOTH exercise and a psychological component. That is a strange requirement for "psychological" treatment guidelines. It appears that psychological interventions that did not include exercise were excluded. This resulted in the exclusion of some unknown number of studies of CBT, mindfulness, and other treatments, including a large, well-powered and well-controlled RCT that I did (Lumley et al., 2017; PAIN), where we studied EAET, CBT, and Education. Thus, this review might be limited in that "pure" psychological interventions, which many psychologists use, are excluded.*
[Mark A. Lumley, Ph.D. (Individual)]

Panel Response: Thank you for your comment. The review defined self-management intervention somewhat broader than just exercise and a psychological component. More specifically, it defined this construct as having at least two of the five components, according to Miles et al (2011):

“psychological (including behavioural or cognitive therapy, or an alternative approach that taught skills), mind-body therapies (MBT) (including components such as relaxation, meditation or guided imagery), physical activity (any form of exercise), lifestyle (such as dietary advice and sleep management) and medical education (such as information to support patients’ understanding of their condition and effective use of medication)” (as cited in Geraghty et al., 2021, p. 4).

References

- Geraghty, A. W. A., Maund, E., Newell, D., Santer, M., Everitt, H., Price, C., Pincus, T., Moore, M., Little, P., West, R., & Stuart, B. (2021). Self-management for chronic widespread pain including fibromyalgia: a systematic review and meta-analysis. *PLoS ONE*, 16(7), Article e0254642. <https://doi.org/10.1371/journal.pone.0254642>
- Miles, C. L., Pincus, T., Carnes, D., Homer, K. E., Taylor, S. J. C., Bremner, S. A., Rahman, A., & Underwood, M. (2011). Review: Can we identify how programmes aimed at promoting self-management in musculoskeletal pain work and who benefits? A systematic review of sub-group analysis within RCTs. *European Journal of Pain*, 15(8), 775.e1-775.e11. <https://doi.org/10.1016/j.ejpain.2011.01.016>

4. Hassan et al (2020)

Note: After further review, the Panel decided it will no longer include the Hassan et al (2020) systematic review as the review authors noted that a meta-analysis could not be completed due to the heterogeneity of the data. The panel will reference this review within the narrative of the guideline.

- 4.1. *We agree with expansion of CAM and Integrative techniques for treating many pain conditions but wish to underscore, given the limits of evidence and the breadth of conditions included in this anticipated guideline, that individualized treatment which respects the patient choice and does not lead to patients having to fail such modalities to receive access to medication, where warranted, is preferred. [Kate Nicholson (Group: National Pain Advocacy Center)]*

Panel Response: Thank you for your comment. We agree that treatment decisions should be made after considering both the perspective of the clinician and the individual with pain. After further review, the panel decided it will no longer include the Hassan et al (2020) systematic review.

- 4.2. *reduction of opioid prescription is not an appropriate factor to analyze. The overall number of opioid prescriptions doesn't give any information about the efficacy of pain interventions, it only counts how many people have been removed from one treatment modality. It cannot analyze whether those patients are getting better results from other modalities, or whether they've been given alternative treatment at all. In too many cases the patients who represent the reductions in opioid prescribing in this analysis will represent patients who are undertreated or even dying of the consequences of denial of opioid therapy. Placing value on this metric is a mistake and not scientifically sound. It is not clinical data; it is political "war on drugs" posturing and has no place in the practice of medicine. [J N H (Individual)]*

Panel Response: Thank you for your comment. After further review, the panel decided it will no longer include the Hassan et al (2020) systematic review.

- 4.3. *Use of marijuana in as alternative treatment for chronic pain has been shown to be unsubstantiated. Same as accupunter, massage, CBT etc. They may be helpful for a small sunset of patients, but to say this approach will be beneficial to a large number of patients is unrealistic and is medically gaslighting chronic pain patients, specifically those who use opioids and are currently stable in their treatment regime. [Carol Dhainin (Individual)]*

Panel Response: Thank you for your comment. The panel believes treatment decisions should be made after considering both the perspective of the clinician and the individual with pain. This guideline endeavors to inform those conversations by providing suggestions of effective therapies, as proven by rigorous studies. After further review, the panel decided it will no longer include the Hassan et al (2020) systematic review.

- 4.4. *This seems inconsistent with the focus on pain outcomes, rather than opioid related outcomes [Robert D Kerns (Individual)]*

Panel Response: Thank you for your comment. After further review, the panel decided it will no longer include the Hassan et al (2020) systematic review.

- 4.5. *There are studies demonstrating reduced opioid use following spinal manipulation which was not noted in the study. This may be due to this treatment not be considered as a CAM approach. [Robb Russell (Individual)]*

Panel Response: Thank you for your comment. After further review, the panel decided it will no longer include the Hassan et al (2020) systematic review.

- 4.6. *I'm glad to see attention to chronic pain in the context of opioid use. Unlike other reviews, this one also includes a wide range of study designs, not just RCTs, although the confidence in the results is limited when not using RCTs. This review includes a number of approaches that psychologists would not directly use (cannabinoids, acupuncture, PT), but the inclusion and consideration of CBT and MORE are valuable. [Mark A. Lumley, Ph.D. (Individual)]*

Panel Response: Thank you for your comment. After further review, the panel decided it will no longer include the Hassan et al (2020) systematic review.

5. Wainwright et al (2019)

5.1. *This systemic review include studies with low quality evidence.* **[Kate Nicholson (Group: National Pain Advocacy Center)]**

Panel Response: Thank you for your comment. Upon further review, the Panel decided it will no longer include the Wainwright et al (2019) systematic review.

5.2. *This places inappropriate emphasis on participation in capitalism. The fact that a person cannot or does not work does not mean their pain is not adequately treated, and also the fact that a person does work does not necessarily mean their pain is under control. Other analyses should be used to interrogate the patient's actual condition and function in their life, regardless of what they do with that life.* **[J N H (Individual)]**

Panel Response: Thank you for your comment. Upon further review, the Panel decided it will no longer include the Wainwright et al (2019) systematic review.

5.3. *This study implies that if a pain patient just thinks positively enough that they will be able to power through their pain and be able to return to work. This approach can and probly does cause lasting damage to chronic pain patients both physically and psychologically.* **[Carol Dhainin (Individual)]**

Panel Response: Thank you for your comment. Upon further review, the Panel decided it will no longer include the Wainwright et al (2019) systematic review.

5.4. *Again, this review is not limited to consideration of "chronic musculoskeletal pain."* **[Robert D Kerns (Individual)]**

Panel Response: Thank you for your comment. Upon further review, the Panel decided it will no longer include the Wainwright et al (2019) systematic review.

5.5. *there are few studies and low quality evidence* **[Beth Darnall, PhD (Individual)]**

Panel Response: Thank you for your comment. Upon further review, the Panel decided it will no longer include the Wainwright et al (2019) systematic review.

5.6. *Pain patients are already resilient. Unnecessary.* **[Ann (Individual)]**

Panel Response: Thank you for your comment. Upon further review, the Panel decided it will no longer include the Wainwright et al (2019) systematic review.

5.7. *I'm on the fence whether this applies to the population directly outlined or really more of a subset of the population outlined (those out of work due to chronic pain / high-impact chronic pain).* **[Kenneth A. Taylor (Individual)]**

Panel Response: Thank you for your comment. Upon further review, the Panel decided it will no longer include the Wainwright et al (2019) systematic review.

5.8. *Return to work is an important outcome, although it limits the pool of patients substantially from the population of people with chronic pain. In addition, almost all of these interventions are "multidisciplinary, combining behavioural, physical and psychological pain management and vocational rehabilitation." For me, this raises the question of the SCOPE of this guideline: Is it going to be "psychological / behavioral" or more focused on multidisciplinary work, including PT, OT, CAM techniques, and other physical interventions? Finally, this review might be limited in that they included only studies that emphasized "resilience"--with a specific definition. I do not know how much this might have excluded other important studies.* **[Mark A. Lumley, Ph.D. (Individual)]**

Panel Response: Thank you for your comment. The panel has decided to not include this systematic review. We do intend to briefly discuss the importance of return to work in the guideline itself.

6. Williams et al (2020)

- 6.1. *There is significant variability in defining CBT as well as in its methods of delivery. Effect sizes for NIH-funded studies that use standardized protocols are larger than those seen in the Cochrane reviews.* **[Kate Nicholson (Group: National Pain Advocacy Center)]**

Panel Response: Thank you for your comment. The panel agrees with this comment and will take it into consideration as we prepare the guideline document.

- 6.2. *Again this is just a fancy way of telling chronic pain patients that their pain is not a physical construct, but psychological. So therefore, the patient can "think good thoughts "and get better. And not need pharmacological interventions beyond over the counter pain meds. Basically, medically gaslighting patients* **[Carol Dhainin (Individual)]**

Panel Response: Thank you for your comment. The panel believes treatment decisions should be made after considering both the perspective of the clinician and the individual with pain. This guideline endeavors to inform those conversations by providing suggestions of effective therapies, as proven by rigorous studies.

- 6.3. *Ditto.* **[Robert D Kerns (Individual)]**

Panel Response: Thank you for your comment. We appreciate your insights and will carefully review the information you provided as we continue with our work.

- 6.4. *It should be noted that there is wide variability in what constitutes CBT, how it is delivered, and how many sessions are received. This variability should be noted. It is one reason why CBT effect sizes are much poorer in the Cochrane reviews relative to other highly rigorous studies (see Cherkin et al 2016, JAMA; Darnall et al JAMA Network Open 2021). Effect sizes for large NIH-funded trials that use standardized protocols are much larger than the 2012 or 2020 Cochrane reviews suggest.* **[Beth Darnall, PhD (Individual)]**

Panel Response: Thank you for your comment. The panel appreciates the variability in how CBT is defined and will take this into consideration as the guideline is being prepared.

- 6.5. *I know this review very well, and I think that--with one exception--if of the highest quality and has substantial implications for the guidelines. The fact that the authors have distinguished CBT, BT, and ACT is valuable, as is their distinction between post-tx and follow-up effects, and their distinction between "neutral" controls (WL, TAU) and "active controls". Importantly, the provision of effect sizes, particularly for CBT is highly relevant--the fact that they are small / very small should also strongly inform the treatment guidelines.*

Note, however, that there is one substantial error in this review that I have detected and informed the authors about--they are in the process of writing an erratum: There are about 5 RCTs comparing ACT to active control. One trial, Thorsell (2011) appears to have extremely large effects of ACT. However, Thorsell (2011) incorrectly presented standard errors rather than standard deviations in their paper, and they did not publish an erratum until a few years later. Williams et al. (2020) accidentally used the SE in Thorsell (2011) for their calculations of effect sizes (rather than the much larger SD), and the results for ACT vs. active control they publish in Tables (Analyses) 5.1 to 5.6) are

greatly inflated by erroneous outlier of Thorsell, In fact, the overall effect sizes for ACT vs. active control are much smaller when they correctly use the SD from Thorsell, as they will be doing in an erratum. [Mark A. Lumley, Ph.D. (Individual)]

Panel Response: Thank you for your comment. The systematic review authors have filed an erratum noting this error and we will refer to this erratum when examining results from this review.