



Topic Brief: Wearable Mechanical Oscillation Devices for Pain

Date: 12/12/2023

Nomination Number: 1049/1052

Purpose: This document summarizes the information addressing a nomination submitted on November 18, 2022, through the Effective Health Care Website. This information was used to inform the Evidence-based Practice Center (EPC) Program decisions about whether to produce an evidence report on the topic, and if so, what type of evidence report would be most suitable.

Issue: The United States Food and Drug Administration (FDA) recently granted approval for several 510K devices for the treatment of pain. As wearable mechanical oscillation devices are emerging as a viable option for non-pharmacologic pain relief for several musculoskeletal and systemic conditions, there exists a need to review the literature on the comparative effectiveness of these devices.

Findings: The EPC Program will not develop a new systematic review because we did not find enough primary studies addressing the concerns of this nomination.

Background

Pain is one of the most common reasons that individuals seek care for in outpatient clinics. Chronic pain affects at least 116 million Americans according to the National Academy of Medicine's (formerly the Institute of Medicine) Committee on Advancing Pain Research, Care and Education.¹ It is estimated that treating chronic and acute pain in the U.S. costs between \$560–635 billion annually in direct medical costs and lost productivity.¹ Treatment for chronic pain usually consists of both pharmacological and nonpharmacological options. The opioid crisis has led to increased efforts to find non-pharmacological treatments for pain.²

The FDA, National Institutes of Health (NIH) and other agencies have encouraged the development of new approaches to pain management.^{3,4} A recent report by AHRQ addressing non-invasive and non-pharmacological pain treatments found some evidence to support the adoption of integrated, multimodal management for chronic pain.⁵ Manufacturers of wearable devices designed to alleviate chronic and acute pain have advanced their products as safe and effective alternatives to opioids.⁶⁻⁸ Wearable pain relief devices employ various approaches to pain relief including high-frequency electrical stimulation, cryotherapy, and high-frequency low-amplitude vibration for example. These devices are eligible for Section 510(k) premarket approval by the FDA if they are determined to be substantially equivalent similar devices already on the market under the Medical Device Amendments.⁹

Scope

What is the effectiveness and comparative effectiveness of wearable, mechanical oscillation devices for:

- a) Pain related to musculoskeletal and joint issues?
- b) Pain related to other systemic conditions?

Table 1. Questions and PICO (population, intervention, comparator, and outcome)

Key Question(s) What is the effectiveness and comparative effectiveness of wearable, mechanical oscillation devices for:	a) Pain related to musculoskeletal and joint issues	b) Pain related to other systemic conditions
Populations	Adults with chronic or acute pain related to musculoskeletal or joint issues (e.g., osteoarthritis, low back pain, neck pain, joint and limb pain, soft tissue injuries)	Adults with chronic or acute pain related to systemic conditions (e.g., fibromyalgia or other chronic pain syndromes, migraines or other headaches)
Interventions	Include: External wearable neuromechanical oscillation devices, wearable body vibration therapy Exclude: chest wall vibration therapy (for cystic fibrosis, among other conditions), whole body vibration (e.g., platforms), implantable devices	
Comparators	Other pain management therapies, procedures, or devices; no comparator	
Outcomes	Pain levels, inflammation levels, healing time, quality of life, harms, and adverse events	

Scope context and intentional deviation: While search results included many systematic reviews regarding the use of transcutaneous electrical nerve stimulation (TENS), this technology was excluded post factum, as it did not adhere to the spirit of the nomination. However, if meeting all other inclusion criteria, technology involving other types of radio-waves or ultrasound were included. Additional eligibility context includes:

- Device must be available for use by outpatient population without advanced training;
- Device must be currently commercially available (as of December 2023) to purchase without a prescription;
- Device must be external and removable.

Assessment Methods

See Appendix A.

Summary of Literature Findings

We identified one small systematic review of three studies examining deep oscillation therapy on reducing swelling and pain in athletes with ankle sprains.¹⁰

We identified seven studies, all pertaining to wearable devices for musculoskeletal or joint issues, specifically four addressing lower back pain,¹¹⁻¹⁴ one on neck pain,¹⁵ one examining a device for knee osteoarthritis,¹⁶ and one study involving local vibration therapy during rehabilitation after anterior cruciate ligament (ACL) reconstruction.¹⁷

We identified no systematic reviews or primary research studies examining the effectiveness of wearable mechanical oscillation devices for systemic conditions, such as fibromyalgia.

Table 2. Literature identified for each Question

Question	Systematic reviews (12/2020-12/2023)	Primary studies (12/2018-12/2023)
a. Pain related to musculoskeletal and joint issues	Systematic Review: 1 ¹⁰	Total: 7 <ul style="list-style-type: none"> • Chronic Low Back Pain: 4¹¹⁻¹⁴ • Neck Pain: 1¹⁵ • Knee OA: 1¹⁶ • Rehabilitation after ACL reconstruction: 1¹⁷
b. Pain related to other systemic issues	None identified.	None identified.

Abbreviations: ACL=anterior cruciate ligament; OA=osteoarthritis.

See Appendix B for detailed assessments of all EPC selection criteria.

Summary of Selection Criteria Assessment

This topic is both important and appropriate. There are no gold-standard systematic reviews on the effectiveness of wearable mechanical oscillation devices for chronic or acute pain management across musculoskeletal, joint, or systemic conditions. There is practice variation, especially given a worldwide turn away from opiate pain management, and individual preferences for pain therapies. With the FDA clearance of certain wearable devices for pain management, there is now an evidence gap on the effectiveness of commercially available wearable devices, and particularly, the comparative effectiveness of these devices compared to over-the-counter medications for pain.

Please see Appendix B for detailed assessments of individual EPC Program selection criteria.

References

1. Institute of Medicine (US) Committee on Advancing Pain Research C, and Education; Summary. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Washington (DC): National Academies Press (US); 2011. <https://www.ncbi.nlm.nih.gov/books/NBK92510/>.
2. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain--United States, 2016. JAMA. 2016 Apr 19;315(15):1624-45. doi: 10.1001/jama.2016.1464. PMID: 26977696.
3. National Institutes of Health. Developing Medical Devices to Treat Pain Webinar. Helping to End Addiction Long-term (HEAL) Initiative; 2018. https://www.nibib.nih.gov/sites/default/files/2019-01/HEAL%20devices%20v2.1_508.pdf.
4. United States Food and Drug Administration. FDA Innovation Challenge: Devices to Prevent and Treat Opioid Use Disorder. 2023. <https://www.fda.gov/about-fda/cdrh-innovation/fda-innovation-challenge-devices-prevent-and-treat-opioid-use-disorder>. Accessed on January 3 2024.
5. Skelly AC, Chou R, Dettori JR, et al. Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review Update. Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review Update. Rockville (MD); 2020. <https://www.ncbi.nlm.nih.gov/pubmed/32338846>.
6. Nerivio: How It Works. Theranica Bio-Electronics Ltd. <https://nerivio.com/how-it-works/>. Accessed on January 2 2024.

7. Libassi M. High-frequency electrical stimulation helps reduce inflammation, pain — study. Northwell Health; 2022. <https://www.northwell.edu/news/the-latest/high-frequency-electrical-stimulation-helps-reduce-inflammation-pain>.
8. Amirdelfan K, Hong M, Tay B, et al. High-Frequency Impulse Therapy for Treatment of Chronic Back Pain: A Multicenter Randomized Controlled Pilot Study. *J Pain Res.* 2021;14:2991-9. doi: <https://dx.doi.org/10.2147/JPR.S325230>. PMID: 34588809.
9. United States Food and Drug Administration. 510(k) Clearances. 2023. [https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances#:~:text=Section%20510\(k\)%20of%20the,PMN%20or%20510\(k\)](https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances#:~:text=Section%20510(k)%20of%20the,PMN%20or%20510(k)). Accessed on January 2 2024.
10. Hausmann M, Ober J, Lepley AS. The Effectiveness of Deep Oscillation Therapy on Reducing Swelling and Pain in Athletes With Acute Lateral Ankle Sprains. *J Sport Rehabil.* 2019 Nov 1;28(8):902-5. doi: <https://dx.doi.org/10.1123/jsr.2018-0152>. PMID: 30526277.
11. Sadora J, Vilsmark E, Bashara A, et al. Electromyography-biofeedback for chronic low back pain: A qualitative cohort study. *Complement Ther Med.* 2023 May;73:102922. doi: <https://dx.doi.org/10.1016/j.ctim.2023.102922>. PMID: 36716896.
12. Kim S, Salazar Fajardo JC, Kim M, et al. Immediate effect of sling exercises combined with mechanic vibration and oscillation mobilization in chronic nonspecific low back pain patients: a randomized controlled trial. *Disabil Rehabil.* 2022 Dec 10:1-8. doi: <https://dx.doi.org/10.1080/09638288.2022.2152877>. PMID: 36495107.
13. Muccio P, Schueller J, van Emde Boas M, et al. Therapeutic Effectiveness of AxioBionics Wearable Therapy Pain Management System in Patients with Chronic Lower Back Pain. *Clin Med Insights Arthritis Musculoskelet Disord.* 2021;14:1179544121993778. doi: <https://dx.doi.org/10.1177/1179544121993778>. PMID: 33746519.
14. Lim E, Lim R, Suhaimi A, et al. Treatment of chronic back pain using indirect vibroacoustic therapy: A pilot study. *J Back Musculoskeletal Rehabil.* 2018;31(6):1041-7. doi: <https://dx.doi.org/10.3233/BMR-171042>. PMID: 30149436.
15. Kartaloglu IF, Kus AA. Evaluation of Radial Extracorporeal Shock Wave Therapy on Treatment-Resistant Trigger Points Using Sonographic Shear Wave Elastography. *J Coll Physicians Surg Pak.* 2023 Oct;33(10):1159-64. doi: <https://dx.doi.org/10.29271/jcpsp.2023.10.1159>. PMID: 37804023.
16. Jo NG, Ko MH, Won YH, et al. The efficacy of low-intensity pulsed ultrasound on articular cartilage and clinical evaluations in patients with knee osteoarthritis. *J Back Musculoskeletal Rehabil.* 2022;35(6):1381-9. doi: <https://dx.doi.org/10.3233/BMR-210357>. PMID: 35754261.
17. Coulondre C, Souron R, Rambaud A, et al. Local vibration training improves the recovery of quadriceps strength in early rehabilitation after anterior cruciate ligament reconstruction: A feasibility randomised controlled trial. *Ann Phys Rehabil Med.* 2022 Jun;65(4):101441. doi: <https://dx.doi.org/10.1016/j.rehab.2020.08.005>. PMID: 33059096.

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Appendix A: Methods

We assessed nomination for priority for a systematic review or other AHRQ Effective Health Care report with a hierarchical process using established selection criteria. Assessment of each criteria determined the need to evaluate the next one. See Appendix B for detailed description of the criteria.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

Desirability of New Review/Absence of Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years December 2020- December 2023 on the questions of the nomination from these sources:

- AHRQ: Evidence reports and technology assessments
 - AHRQ Evidence Reports <https://www.ahrq.gov/research/findings/evidence-based-reports/index.html>
 - EHC Program <https://effectivehealthcare.ahrq.gov/>
 - US Preventive Services Task Force <https://www.uspreventiveservicestaskforce.org/>
 - AHRQ Technology Assessment Program <https://www.ahrq.gov/research/findings/ta/index.html>
- US Department of Veterans Affairs Products publications
 - Evidence Synthesis Program <https://www.hsrd.research.va.gov/publications/esp/>
 - VA/Department of Defense Evidence-Based Clinical Practice Guideline Program <https://www.healthquality.va.gov/>
- Cochrane Systematic Reviews <https://www.cochranelibrary.com/>
- University of York Centre for Reviews and Dissemination database <https://www.crd.york.ac.uk/CRDWeb/>
- PROSPERO Database (international prospective register of systematic reviews and protocols) <http://www.crd.york.ac.uk/prospero/>
- PubMed <https://www.ncbi.nlm.nih.gov/pubmed/>
- Joanna Briggs Institute <http://joannabriggs.org/>
- Epistemonikos <https://www.epistemonikos.org/>

Impact of a New Evidence Review

The impact of a new evidence review was qualitatively assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

Feasibility of New Evidence Review

We conducted a limited literature search in PubMed and PsycInfo for the last five years, December 2018 – December 2023. We reviewed all studies and identified titles and abstracts for inclusion. We classified identified studies by question and study design to estimate the size and scope of a potential evidence review.

Search strategy

Ovid MEDLINE ALL <1946 to November 28, 2023>

Date searched: November 29, 2023

1 (Fibromyalgia/ or Low Back Pain/ or Neck Pain/ or Osteoarthritis/ or Osteoarthritis, Hip/ or Osteoarthritis, Knee/ or Tension-Type Headache/) and (Acute Pain/ or Chronic Pain/ or pain.hw,jw.) (52152)

2 (Fibromyalgia/ or Low Back Pain/ or Neck Pain/ or Osteoarthritis/ or Osteoarthritis, Hip/ or Osteoarthritis, Knee/ or Tension-Type Headache/) and (acute or breakthrough or chronic or intractable or long-term or longer-term or persist* or radicular or refractory).ti,ab,kf. (32097)

3 ((Bouchard* or cervical or fibromyalgi* or finger\$1 or Heberden* or knee\$1 or knuckle\$1 or hand\$1 or hip\$1 or low-back or lower-back or lumbar or neck or osteoarthritis* or osteo-arthritis* or pelvis or radicular or spine or spinal or thumb\$1 or "tension headache*" or "tension-type headache*" or wrist\$1) adj3 (acute or breakthrough or chronic or intractable or longterm or long-term or longer-term or persist* or refractory)).ti,ab,kf. (44813)

4 or/1-3 (94947)

5 Extracorporeal Shockwave Therapy/ or Transcutaneous Electric Nerve Stimulation/ (6678)

6 (bioelectr* or cutaneous* or electro* or eTMS or "e-TMS" or extracorporeal* or extracorporeal* or IFC or IFT or interferential or magnet* or mechanical* or neuromechanical* or neuro-mechanical* or neuromodulat* or neuro-modulat* or neurostimulat* or neuro-stimulat* or nerve or noninvasive or "non-invasive" or nVNS or occipital or oscillat* or PEMS or peripheral or pulsation or pulsed or pulsing or shockwave\$1 or sphenopalatine or stimulat* or TENS or transcutaneous* or trans-cutaneous* or trigeminal or vagus or vestibular or vibrat* or vibro* or wave\$1).ti,kf. (1977462)

7 or/5-6 (1978865)

8 Braces/ or Exoskeleton Device/ or Orthotic Devices/ or Wearable Electronic Device/ (22213)

9 (armband\$1 or band\$1 or brace\$1 or Buzzy or device\$1 or external* or focal or garment\$1 or glove\$1 or headband\$1 or local* or mask\$1 or offload* or orthoses or orthosis or orthotic\$1 or portable or Quell or segmental or textile\$1 or unload* or vest\$1 or wear* or whole or worn or wrap\$1 or wrapping or wristband\$1).ti,ab,kf. (3684591)

10 or/8-9 (3690381)

11 and/4,7,10 (1670)

12 11 or (Axiobionics or BioniCare or "Body Clock" or Cefaly or Enso or Gammacore or Nerivio or "NMES/EMS" or NeuroMetrix or "Omega Professional" or PowerDot or SpringTMS or TensCare or VibraCool).ti,ab,kf. (2981)

13 12 not (animal model* or bitch\$2 or bovine or canine or capra or cat or cats or cattle or cow\$1 or dog\$1 or equine or ewe\$1 or feline or goat\$1 or hamster\$1 or horse\$1 or invertebrate\$1 or macaque\$1 or mare\$1 or mice or monkey\$1 or mouse or murine or nonhuman or non-human or ovine or pig or pigs or porcine or primate\$1 or rabbit\$1 or rat\$1 or rattus or rhesus or rodent* or sheep or simian or sow\$1 or vertebrate\$1 or zebrafish).ti. (2834)

14 13 not ((ablation\$1 or acupuncture or block\$1 or blockade\$1 or "case report" or climate or diagnos* or drug\$1 or EEG or fusion\$1 or implant* or inject* or invasive or molecular or "magnetic resonance" or MRI or needling or nina or nino or occupational or pharmacolog* or radio* or sensor\$1 or surger\$ or surgical\$2 or tanezumab or traction or tumor\$1 or weather or work).ti. or implant*.ab. or ("case report" or comment of editorial or letter).pt.) (1671)

15 limit 14 to english language (1619)

16 remove duplicates from 15 (1614)

17 limit 16 to yr="2020 - 2024" (501)

18 17 and ((meta-analysis or systematic review).pt. or (meta-anal* or metaanal* or ((evidence or review or scoping or systematic or umbrella) adj3 (review or synthesis))).ti.) (16)

19 limit 16 to yr="2018-2024" (735)

20 19 and ((controlled clinical trial or randomized controlled trial).pt. or (random* or sham or trial* or "wait list").ti,ab,kf.) (173)

21 20 not 18 (164)

22 19 and (Case-Control Studies/ or Cohort Studies/ or Comparative Study/ or Controlled Before-After Studies/ or Cross-Sectional Studies/ or Epidemiologic Studies/ or exp Evaluation Studies as Topic/ or Follow-Up Studies/ or Historically Controlled Study/ or Interrupted Time Series Analysis/ or Longitudinal Studies/ or Prospective Studies/ or Retrospective Studies/ or ("case-control" or cohort\$1 or "before-after" or ((comparative or epidemiologic or evaluation) adj3 study) or cross-sectional or follow-up or (historic* adj4 control*) or "interrupted time" or longitudinal\$2 or prospective\$2 or retrospective\$2).ti,ab,kf.) (162)

23 22 not (18 or 21) (93)

Ovid EBM Reviews - Cochrane Central Register of Controlled Trials <October 2023>

Date searched: November 29, 2023

1 (Fibromyalgia/ or Low Back Pain/ or Neck Pain/ or Osteoarthritis/ or Osteoarthritis, Hip/ or Osteoarthritis, Knee/ or Tension-Type Headache/) and (Acute Pain/ or Chronic Pain/) (1462)

2 (Fibromyalgia/ or Low Back Pain/ or Neck Pain/ or Osteoarthritis/ or Osteoarthritis, Hip/ or Osteoarthritis, Knee/ or Tension-Type Headache/) and (acute or breakthrough or chronic or intractable or long-term or longer-term or persist* or radicular or refractory).ti,ab. (7941)

3 ((Bouchard* or cervical or fibromyalgi* or finger\$1 or Heberden* or knee\$1 or knuckle\$1 or hand\$1 or hip\$1 or low-back or lower-back or lumbar or neck or osteoarthrit* or osteo-arthrit* or pelvis or radicular or spine or spinal or thumb\$1 or "tension headache*" or "tension-type headache*" or wrist\$1) adj3 (acute or breakthrough or chronic or intractable or longterm or long-term or longer-term or persist* or refractory)).ti,ab. (13016)

4 or/1-3 (16238)

5 Extracorporeal Shockwave Therapy/ or Transcutaneous Electric Nerve Stimulation/ (1674)

6 (bioelectr* or cutaneous* or electro* or eTMS or "e-TMS" or extracorporeal* or extracorporeal* or IFC or IFT or interferential or magnet* or mechanical* or neuromechanical* or neuro-mechanical* or neuromodulat* or neuro-modulat* or neurostimulat* or neuro-stimulat* or nerve or noninvasive or "non-invasive" or nVNS or occipital or oscillat* or PEMS or peripheral or pulsation or pulsed or pulsing or shockwave\$1 or sphenopalatine or stimulat* or TENS or transcutaneous* or trans-cutaneous* or trigeminal or vagus or vestibular or vibrat* or vibro* or wave\$1).ti. (97666)

7 or/5-6 (97832)

8 Braces/ or Exoskeleton Device/ or Orthotic Devices/ or Wearable Electronic Device/ (1443)

9 (armband\$1 or band\$1 or brace\$1 or Buzzy or device\$1 or external* or focal or garment\$1 or glove\$1 or headband\$1 or local* or mask\$1 or offload* or orthoses or orthosis or orthotic\$1 or portable or Quell or segmental or textile\$1 or unload* or vest\$1 or wear* or whole or worn or wrap\$1 or wrapping or wristband\$1).ti,ab. (246501)

10 or/8-9 (246788)

11 and/4,7,10 (493)

12 11 or (Axiobionics or BioniCare or "Body Clock" or Cefaly or Enso or Gammacore or Nerivio or "NMES/EMS" or NeuroMetrix or "Omega Professional" or PowerDot or SpringTMS or TensCare or VibraCool).ti,ab. (629)

13 12 not (animal model* or bitch\$2 or bovine or canine or capra or cat or cats or cattle or cow\$1 or dog\$1 or equine or ewe\$1 or feline or goat\$1 or hamster\$1 or horse\$1 or invertebrate\$1 or macaque\$1 or mare\$1 or mice or monkey\$1 or mouse or murine or nonhuman or non-human or ovine or pig or pigs or porcine or primate\$1 or rabbit\$1 or rat\$1 or rattus or rhesus or rodent* or sheep or simian or sow\$1 or vertebrate\$1 or zebrafish).ti. (627)

14 13 not ((ablation\$1 or acupuncture or block\$1 or blockade\$1 or "case report" or climate or diagnos* or drug\$1 or EEG or fusion\$1 or implant* or inject* or invasive or molecular or "magnetic resonance" or MRI or needling or nina or nino or occupational or pharmacolog* or radio* or sensor\$1 or surger\$ or surgical\$2 or tanezumab or traction or tumo?r\$1 or weather or work).ti. or implant*.ab.) (389)
15 limit 14 to yr="2018 - 2024" (207)

PROSPERO November 30, 2020-November 28, 2023

Date searched: November 29, 2023

((fibromyalgi* OR finger* OR knee* OR hand* OR hip* OR low-back OR lower-back OR neck OR osteoarthritis* OR radicular OR spine OR spinal OR headache*) AND (bioelectr* OR cutaneous* OR electro* OR interferential OR magnet* OR mechanical* OR neuromechanical* OR neuromodulat* OR neurostimulat* OR nerve OR noninvasive OR "non-invasive" OR oscillat* OR peripheral OR pulsation OR pulsed OR pulsing OR shockwave* OR stimulat* OR TENS OR transcutaneous* OR vibrat* OR vibro* OR wave*) AND (armband* OR band* OR brace* OR device*1 OR external* OR focal OR garment* OR glove* OR headband* OR local* OR mask* OR offload* OR orthoses OR orthosis OR orthotic* OR portable OR textile* OR unload* OR vest* OR wear* OR whole OR worn OR wrap* OR wristband*)):TI WHERE CD FROM 30/11/2020 TO 29/11/2023 (16)

ClinicalTrials.gov 11/29/2018-11/29/2023

Date searched: November 29, 2023

Recruiting, Not yet recruiting, Active, not recruiting, Enrolling by invitation Studies | (cervical OR fibromyalgi* OR finger* OR knee* OR knuckle* OR hand* OR hip* OR low-back OR lower-back OR lumbar OR neck OR osteoarthritis* OR pelvis OR radicular OR spine OR spinal OR thumb* OR headache* OR wrist*) AND (acute OR breakthrough OR chronic OR intractable OR longterm OR long-term OR longer-term OR persist* OR refractory) | bioelectr* OR cutaneous* OR electro* OR eTMS OR EXPAND[Concept] "e-TMS" OR extracorporeal* OR extra-corporeal* OR IFC OR IFT OR interferential OR magnet* OR mechanical* OR neuromechanical* OR neuro-mechanical* OR neuromodulat* OR neuro-modulat* OR neurostimulat* OR neuro-stimulat* OR nerve OR noninvasive OR EXPAND[Concept] "non-invasive" OR nVNS OR occipital OR oscillat* OR PEMS OR peripheral OR pulsation OR pulsed OR pulsing OR shockwave* OR sphenopalatine OR stimulat* OR TENS OR transcutaneous* OR trans-cutaneous* OR trigeminal OR vagus OR vestibular OR vibrat* OR vibro* OR wave* | First posted from 11/29/2018 to 11/29/2023 (44)

Value

We assessed the nomination for value. We considered whether or not the clinical, consumer, or policymaking context had the potential to respond with evidence-based change, if a partner organization would use this evidence review to influence practice, and if the topic supports a priority area of AHRQ or the Department of Health and Human Services.

Appendix B. Selection Criteria Assessment

Selection Criteria	Assessment
1. Appropriateness	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the United States?	Yes.
1b. Is the nomination a request for an evidence report?	Yes.
1c. Is the focus on effectiveness or comparative effectiveness?	Yes.
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes.
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	Yes. The majority of the human population will experience pain during their life.
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the United States population or for a vulnerable population	Yes. Pain management accounts for roughly \$899 billion dollars per year in the United States.
2c. Incorporates issues around both clinical benefits and potential clinical harms	Yes.
2d. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	Yes.
3. Desirability of a New Evidence Review/Absence of Duplication	
3. A recent high-quality systematic review or other evidence review is not available on this topic	This topic would not be duplicative of another systematic review. We identified only one small systematic reviewing of three studies examining deep oscillation therapy on ankle sprains. ¹⁰
4. Impact of a New Evidence Review	
4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	There is practice variability in pain management recommendations.
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	Due to the recent FDA clearance of wearable mechanical oscillation devices, practice variation exists, likely due to lack of guidelines on the topic.
5. Primary Research	
5. Effectively utilizes existing research and knowledge by considering: - Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies)	Size/scope of review: We identified 7 studies across four musculoskeletal conditions, and 0 examining systemic conditions.

Abbreviations: FDA=United States Food and Drug Administration; AHRQ=Agency for Healthcare Research and Quality.