

Academic Consortium Appendix 2: Definitions for HHS Docket No. CDC-2020-0029
Management of Acute and Chronic Pain
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Definition of therapies: need to reflect the legal status of regulated professions in the US, modern research as well as the historical roots of a therapeutic intervention. For example, acupuncture therapy is not based in China alone or as Chinese medicine only but as traditional East Asian medicine. Accurate definitions are essential to inform pragmatic clinical trials (PCTs) that are part of the NIH's vision for bridging the gap between research and care.^{1,2} PCTs are performed in real world clinical settings with highly generalizable populations to generate actionable clinical evidence at a fraction of the typical cost/time needed to conduct a traditional clinical trial.^{1,3} PCTs are also supported through initiatives at the Center for Medicare & Medicaid (CMS), the Agency for Healthcare Research and Quality (AHRQ), the Patient Centered Outcomes Research Institute (PCORI), Practice-Based Research Networks (PBRNs) and community-based participatory research initiatives across the Federal government.⁴ Hence if a nonpharmacologic intervention is to be studied in a pragmatic trial, how it is legally defined and practiced not as the single mechanical operation but a clinically contextualized approach will best inform stakeholders relying on this HHS report and recommendations.

Suggested

Acupuncture therapy in the U.S. is a state-regulated practice in which practitioners stimulate specific areas or points on the body by application of heat, pressure, electrical stimulation or insertion and manipulation of thin (pre-sterilized, single-use, filiform) needles for the purpose of achieving a therapeutic or prophylactic effect.⁵ Type, location, dosage and combinations of stimulation are based on physiological interrelationships of body organs and tissue with associated points or combination of points, informed by historical medical texts and modern research. Acupuncture therapy may be used to alleviate pain as a stand-alone therapy or as part of comprehensive pain care, as well as to treat other physical, mental and emotional conditions.

Massage therapy is a state-regulated practice that involves manipulation of soft tissue structures of the body to prevent or alleviate pain, spasm, tension, or stress and to promote health and wellbeing.

Osteopathic and Chiropractic manipulation are state-regulated practices. Spinal manipulative therapy (SMT) involves treatment of the spine and pelvic related joints; manipulative therapy (MT) refers to the treatment of other joints in the body including upper and lower extremities. SMT and MT are often associated with high velocity, low amplitude (HVLA) thrust techniques, as well as low velocity, low amplitude (LVLA) or joint mobilization techniques. SMT, MT, HVLA and LVLA are techniques commonly used to improve pain and function, primarily by osteopathic physicians and chiropractors.⁶

Physical therapy is a state-regulated practice utilizing therapeutic exercise, physical modalities, assistive devices, and patient education and training for the preservation, enhancement, or restoration of movement and physical function impaired or threatened by disease, injury, disability or pain.

Meditative movement therapies: Tai chi and Yoga Tai chi is a low-impact, mind-body exercise originating in China that has become increasingly popular in the West as an effective exercise for rehabilitation related to multiple medical conditions. Tai chi consists of slow prescribed movements with attention to breathing and meditative concentration.

Yoga originated in ancient India and has been adapted in the West. Yoga practice combines attention and meditation (dhyana), breathing (pranayama), and physical postures (asanas) and stretching to promote health and well-being and to help people with health problems manage their health conditions and reduce their symptoms.

Behavioral Health Approaches

Mind Body Behavioral Interventions and Relaxation Therapies

Mindfulness and meditation-based therapies focus training on moment-to-moment awareness of breathing and attention without judgment to transform perception and relationships to pain and the larger environment. Meditative movement therapies like Tai chi and Yoga utilize intentional movement or positioning with present moment awareness and focus on breathing.⁶

Mindfulness-Based Stress Reduction (MBSR) is an organized course of training in mindfulness skills focusing on moment to moment awareness of breathing and attention without judgment to transform perception and relationships to pain and the larger environment. It is the most studied course of mindfulness meditation.⁷

Relaxation therapies: use physiologic techniques (as in slow diaphragmatic breathing or progressive muscle relaxation) to regulate the sympathetic/parasympathetic balance and reduce symptoms of sympathetic arousal often seen in chronic pain including situational stress, muscle tension and shallow breathing. They also include other directed therapies like guided imagery (use of words depicting calming images and music to evoke positive imaginative scenarios), hypnosis and suggestion (induction of a relaxed but focused state of consciousness receptive to positive suggestion), acceptance and commitment therapy (ACT) (strategies of mindful awareness and acceptance) and music therapy.

Reference

1. Weinfurt KP, Hernandez AF, Coronado GD, et al. Pragmatic clinical trials embedded in healthcare systems: generalizable lessons from the NIH Collaboratory. *BMC Med Res Methodol.* 2017;17(1):144.
2. Rethinking Clinical Trials: Living Textbook of Pragmatic Clinical Trials. *NIH Collaboratory Living Textbook of Pragmatic Clinical Trials* <http://rethinkingclinicaltrials.org/>. Accessed September 27, 2018.
3. NIH Introduction to pragmatic clinical trials. *Health Care Systems Research Collaboratory, Rethinking Clinical Trials* 2014; <https://www.nihcollaboratory.org/Products/Introduction%20to%20pragmatic%20clinical%20trials.pdf>. Accessed September 27, 2018.
4. Concannon TW, Guise JM, Dolor RJ, et al. A national strategy to develop pragmatic clinical trials infrastructure. *Clin Transl Sci.* 2014;7(2):164-171.
5. NPG. Acupuncture State Law Summary. 2014; <https://theacupunctureobserver.com/wp-content/uploads/2014/02/State+Law+Summary.pdf>. Accessed January 22, 2019.
6. Tick H, Nielsen A, Pelletier KR, et al. Evidence-based Nonpharmacologic Strategies for Comprehensive Pain Care: The Consortium Pain Task Force White Paper. *Explore (NY).* 2018;14(3):177-211.
7. National Academies of Sciences Engineering and Medicine. *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use (2017)*. Washington, DC: The National Academies Press. doi: <https://doi.org/10.17226/24781>; 2017.