

Neuropathy Hope

Hope through caring, support, research, education, and empowerment

A newsletter for members of Western Neuropathy Association (WNA)



WESTERN NEUROPATHY ASSOCIATION

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VIRTUAL REALITY AND REGULAR MEDITATIVE BREATHING BOTH EASE PAIN

Bailey-Michigan, L. (2021, October). *Virtual Reality and Regular Meditative Breathing Both Ease Pain*. Futurity. <https://www.futurity.org/meditative-breathing-2642062-2/>

Two different kinds of meditative breathing—traditional mindful breathing and virtual reality, 3D-guided mindful breathing—reduce pain but do so differently, research finds. The new findings indicate that the two types of meditative breathing both lessened pain by modulating the somatosensory cortex, a region of the brain responsible for processing pain, but used different mechanisms, says Alexandre DaSilva, associate professor at the University of Michigan School of Dentistry.

With the traditional breathing group, the functional connection with the brain's frontal regions increased, because this region was focused on the body's internal sensory details, called interoception, DaSilva says. This competed with the external pain signals and inhibited the ability of the somatosensory cortex to process pain. This follows the common assumption that mindful breathing exerts its painkilling effect by interoception, which means the conscious refocusing of the mind's attention to the physical sensation of an internal organ function.

In the virtual reality group, subjects wore special glasses and watched a pair of virtual reality 3D lungs, while breathing mindfully. The technology was developed in house and the lungs synchronized with the subjects' breathing cycles in real time, providing an immersive visual and audio external stimulus. Pain decreased when the sensory regions of the brain (visual, auditory) engaged with the immersive virtual reality sound and image stimulations. This is called exteroception, and it weakened the pain processing function of the somatosensory cortex.

"(I was surprised) that both meditative breathing methods decreased pain sensitivity, but oppositely

in the brain, like yin and yang," DaSilva says. "One by engaging the brain in an immersive exterior 3D experience of our own breathing, or exteroception—yang, and the other by focusing on our interior world, interoception—yin. "Though both approaches decreased pain sensitivity, traditional mindful breathing can be challenging because it requires long-time attention and focus on an abstract experience, he says. Virtual reality breathing might be more accessible, especially for beginners, because it lends an immersive "visual and auditory guide" to the meditation experience. And, the virtual reality mindful breathing gives medical professionals another possible option for pain relief, to decrease the tendency to rely solely on pain medications, including opiates, DaSilva says.

The team compared the two methods of breathing by placing a single, unilateral thermode on the left mandibular nerve branch of the trigeminal cranial nerve for each participant—think of a tiny, computer-controlled hotplate on your face. To study the brain mechanisms used during the two types of breathing, researchers analyzed their associated functional connectivity—i.e., what regions of the brain were co-activated and when—during each type of breathing and pain stimulation. They investigated the acute (same session) and long effects (after one week) of breathing techniques, and in the week between the two neuroimaging sessions, both groups did traditional mindful breathing at home.

DaSilva's research group, which focuses heavily on migraine and pain, is working on options to deliver this virtual reality breathing experience via a mobile application and extending its clinical benefit to multiple chronic pain disorders beyond the lab.

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to find out about the
topic/speaker for the
upcoming meeting.

Katherine Stenzel
Editor

Newsletter Design by



NEUROPATHY SUPPORT GROUPS

We urge you to take this opportunity to talk with other people that know about and experience neuropathy. Auburn CA is meeting in-person with Monterey CA and Houston TX meeting virtual. Virtual meeting participation is not limited to the physical location in the name - anyone from any city is welcome to attend, listen and share.

March Schedule

March 7 (Monday)

Auburn CA Support Group 11:00 am PST

Woodside Village Mobile Home Park, 12155 Luther Road

Contact: Sharlene McCord (530) 878-8392 or Kathy Clemens (916) 580-9449 / kaclemens@earthlink.net

March 12 (Saturday)

Houston TX Support Group (*Virtual*) 11:00am-1:00pm PST/1:00pm-3:00pm CST

Contact: Katherine Stenzel at klstenzel@hotmail.com

March 16 (Wednesday)

Monterey CA Support Group (*Virtual*) 10:30am-11:30am PST/12:30pm-1:30pm CST

Sign-in opens at 10:00am PST/12:00pm CDT

Contact: Katherine Stenzel at klstenzel@hotmail.com Note: Dr. Donovan is on medical leave.

March 26 (Saturday)

Houston TX Monthly Open Discussion on Neuropathy (*Virtual*) 11:00am-1:00pm PST/1:00pm-3:00pm CST

Contact: Katherine Stenzel at klstenzel@hotmail.com

For *Virtual Meetings*, contact the group leader for the Zoom link.
Provide your name, mailing address, and telephone number.
(first time attendees only)

FDA APPROVES SPINAL CORD STIMULATION THERAPY FOR TREATING CHRONIC PAIN RESULTING FROM DIABETIC PERIPHERAL NEUROPATHY

Medtronic Press Release, January 24, 2022. (Summarized by NH staff)

Medtronic announced it has received U.S. Food and Drug Administration approval of its Intellis™ rechargeable neurostimulator and Vanta™ recharge-free neurostimulator for the treatment of chronic pain associated with diabetic peripheral neuropathy (DPN). The Intellis and Vanta spinal cord stimulators (SCS) had already been cleared to lessen chronic pain caused by a variety of conditions, and those indications now include the treatment of painful diabetic neuropathy.

Medtronic claims this more comprehensive treatment revolves around their neurostimulation technology, in which small devices are implanted in the epidural space between the vertebral canal and the spinal cord. Once in place, the devices emit electrical pulses to intercept and block pain signals in the nervous system before they can reach the brain.

Independent studies show patients with DPN achieve significant pain relief when treated with SCS compared to conventional treatments alone. Overall, 70% of patients receiving treatment with SCS experienced relief of their pain symptoms compared to 6% of patients receiving only conventional treatments. And those treated with SCS experienced a 53% average reduction in pain.

EDITOR'S NOTE Katherine Stenzel, Editor, WNA Board Director

I love it when a reader finds an error – it means they are reading the newsletter! Member Wojciech Makowski noted that my date of the pandemic starting in March 2019 was a year early – it was only March 2020. Really? Doesn't it seem like forever that we've been living in this new normal lifestyle. Wojciech forwarded an article from the University of Miami titled "*The pandemic has played with our perception of time*" which supports my (unconscious) perception of a longer pandemic period. I'm paraphrasing one of the article's concepts: since we've had fewer new experiences and therefore few new memories, there's an increase in the phenomenon known as "prediction error" which impacts our sense of time. Another concept is that the pandemic has increased stress which in turns creates time illusions. Stressing the body or mind can subjectively extend time while experiencing positive stresses, arousal or excitement can dilute or lessen time. An interesting concept for sure!

Now on to this issue. The front-page story extends the series of articles on breathing and pain. This concept of **virtual reality breathing** resonated with me as I find it difficult to empty my mind in a typical mindful breathing exercise. Having an external device to focus my breathing via both audio and visual feedback would have a better chance of working for me to focus my body to diminish the pain. While this is not in production yet, there are many apps for the smartphone for mindful breathing. One such is "The Mindfulness App" which offers guided meditations and breathing exercises to help you through chronic pain flare-ups to find a calmer state of being. Priced at \$2.99 it's an inexpensive way to try out meditation and mindfulness as a pain management technique. Two other **smartphone apps that may help with pain relief** are described on the back page.

Continuing with President Bev Anderson's tips on **pain control** as addressed in the WNA's November letter to members from Executive Vice President Karen Polastri, the article on page 4 expands on taking medications and includes advice on when to call your doctor or pain specialist. This is followed by a description of the newly designed drug "194" which has shown promise in reducing neuropathic pain in animal models. You can follow the drug's development at www.regulonix.com.

I found the table on Page 5 to be highly interesting. It lists the **drugs approved by the FDA for use in neuropathic pain**. For each drug, the starting dose is detailed followed by how the dose should be increased. Next is the maximum dose plus how long the patient should stay on the dosage to achieve relief. As this table is dated 2018, the recently approved 8% capsaicin patches are not included.

Skipping to page 7, the article on **FDA types of approval** was prompted by an advertisement for Axon Therapy system. I'm initially skeptical of any new treatments until I research its concept and FDA approval. I found a press release that mentioned 'FDA Clearance' for the parent company, Neuralace Medical, and this started my FDA nomenclature research. The article on page 7 is the result. While I didn't include information about the Axon Therapy system, page 2 does discuss **spinal cord stimulators** which show significant pain relief compared to conventional treatment.

Lastly, check out the study on **exercise for neuropathic pain** on page 6. Note that the study's recommendations are only drawn from the specific clinical trials reviewed. In my opinion, each exercise in the clinical trial brought some type of pain relief leading me to believe that exercise in general has pain-relieving benefits for those of us suffering from neuropathy. Finding the one that fits our physical constraints and is something we like is key to including exercise in our everyday lives.

As always, send your comments, corrections and suggestions to kstenzel@hotmail.com

...Katherine

CHANGES TO THE BOARD OF DIRECTORS

We welcome Glenn Ribotsky to the Western Neuropathy Association leadership as a Board Director. Glenn's knowledge on peripheral neuropathy will greatly benefit the Board as we strive to provide our members with information, support and hope to live a more abled and pain free life.

Many thanks to Sonya Wells, PharmD, MPH, for her service to WNA as a Board Director. Due to work demands, she is resigning from this active role. She will still contribute to WNA through the Emeritus Council.

Help With Health Care Challenges

If the number is not in your area, call the one listed and ask for the right number.

Medicare

www.Medicare.gov

...

The Affordable Health Care Act

For current information go to www.HealthCare.gov

...

HICAP

Health Insurance Counseling

for seniors and people with disabilities.
www.cahealthadvocates.org/HICAP/
Call (800) 434-0222 to ask a question or to make an appointment.

...

Health Rights Hotline

Serving Placer, El Dorado, Yolo, & Sacramento Counties, regardless where you receive your health coverage.
Tollfree (888) 354-4474 or TDD (916) 551-2180.
In Sacramento, (916) 551-2100.
www.hrh.org.

...

HMO Help Center

Assistance
24 hours a day, seven days a week.
(888) HMO-2219
or (877) 688-9891 TDD

...

DRA's Health

Access Project Free publications about the health care, insurance rights and concerns of people with disabilities and serious health conditions. For more information, go to <http://dralegal.org/> and click on "Projects".

DISCOUNTS FOR WNA MEMBERS

The following companies or individuals have agreed to give WNA a discount to WNA members. Give them a call or visit. If you choose to purchase the service or wares of any on this list, pull out your WNA Membership Card and claim the discount.

Anodyne Therapy

Infrared Light Therapy equipment - **12% off all home units.**
Contact: 800-521-6664 or www.anodynetherapy.com

Auburn

The Footpath

825 Lincoln Way
(530) 885-2091
www.footpathshoes.com
WNA Discount: 10% off the regular price shoes.

Elk Grove

Shoes That Fit

8649 Elk Grove Blvd.
(916) 686-1050
WNA Discount: 20% off the regular price shoes.

Fortuna

Strehl's Family Shoes & Repair

Corner of 12th & Main
1155 Main Street
(707) 725-2610
Marilyn Strehl, C.PED
is a Certified Pedorthic
WNA Discount: 10% off the regular price shoes.

West Sacramento

Beverly's Never Just Haircuts and Lilly's Nails
2007 W. Capitol Ave
Hair - (916) 372-5606
Nails - (916) 346-8342
WNA discount: 10% off the regular price.

- Continued on page 6

PRESCRIPTION PAIN MEDICINE SAFETY

Pain Management, <https://www.drugs.com/cg/pain-management.html>, Drugs.com, Jan 5, 2022

- **Do not suddenly stop taking prescription pain medicine.** If you have been taking prescription pain medicine for longer than 2 weeks, a sudden stop may cause dangerous side effects. Ask your healthcare provider for more information before you stop taking your medicine.
- **Take your medicine as directed.** Take only the amount prescribed or recommended by your healthcare provider. Too much medicine may cause breathing problems or other health issues. If you use a pain patch, be sure to remove the old patch before you place a new one.
- **Do not drink alcohol while you use prescription medicines.** Alcohol with prescription medicines can make you sleepy and slow your breathing rate. You may stop breathing completely.
- **Do not drive or operate heavy machinery after you take prescription pain medicine.** Prescription pain medicine can make you drowsy and make it hard to concentrate. You may injure yourself or others if you drive or operate heavy machinery while taking your medicine.
- **Time your medicine correctly.** Take your pain medicine 30 minutes before exercise or physical therapy. This helps decrease pain to help meet your treatment goals. You may need to take medicine before you go to bed. This may help you sleep and not be woken by pain.
- **Watch for side effects.** Some foods, alcohol, and other medicines may cause side effects when

you take pain medicine. Ask your healthcare provider how to prevent these problems.

- **Prevent constipation.** This is a common side effect of prescription pain medicine. Eat foods high in fiber, such as raw fruit, vegetables, beans, and whole-grain bread and cereal. Ask your healthcare provider how much liquid to drink each day and which liquids are best for you. Exercise and activity may also help decrease the risk for constipation.
- **Follow instructions for what to do with medicine you do not use.** Your healthcare provider will give you instructions for how to dispose of pain medicine safely. This helps make sure no one else takes the medicine.

Call your doctor or pain specialist in the following situations:

- You continue to have breakthrough pain (pain between times of taking your medicine).
- The medicine you are taking makes you sleepier than usual or confused.
- You have pain even after you take your pain medicine.
- You have a new pain or the pain seems different than before.
- You have constipation from prescription pain medicine that is not helped with treatment.
- You have questions or concerns about your condition or care.

NEW DRUG "194" RELIEVED NEUROPATHIC PAIN CAUSED BY CHEMOTHERAPY, HIV AND NERVE INJURY IN ANIMAL MODELS

Angus Liu, Fierce Biotech, November 2021

The NaV1.7 ion channel is expressed in some neurons and plays a critical role in sensing pain, making it a popular target for scientists developing novel pain therapies. But suppressing NaV1.7 head-on has proven tricky. So researchers at the University of Arizona are pursuing an alternate strategy: they're blocking the sodium channel indirectly through two related proteins.

The team has designed a drug, dubbed 194, that disrupts the interaction between a mediator protein called CRMP2 and an enzyme, Ubc9, which is important in the activity of NaV1.7. The researchers tested 194's efficacy in managing pain in several animal models using different administration routes. The drug relieved pain in models of neuropathy induced by HIV, chemotherapy and

nerve injury, they reported.

The University of Arizona has licensed the drug to a startup called Regulonix, which was co-founded by the study's senior author, Rajesh Khanna, Ph.D., to develop ion channel-targeting non-opioid painkillers. Khanna, a professor of pharmacology, and his team have been working with the National Institutes of Health's National Center for Advancing Translational Sciences to optimize the compound, according to the university's health sciences department.

While 194 has shown great promise, Khanna and his colleagues are still working on improving the drug's properties, including extending the length of time the drug remains active before getting washed out of the body.

DRUGS APPROVED BY THE FDA FOR TREATMENT OF NEUROPATHIC PAIN SYNDROMES (TABLE 7)

Vinik, A, M.D. et al. (February 5, 2018). *Diabetic Neuropathies*. <https://www.ncbi.nlm.nih.gov/books/NBK279175/>

Medication	Indication	Beginning Dosages	Titration (how to increase dosage)	Maximum Dosage	Duration of Adequate Trial
Gabapentin	Postherpetic neuralgia (shingles)	100-300 mg every night or 100-300 mg 3×/d	Increase by 100-300 mg 3×/d every 1-7 d as tolerated	3600 mg/d (1200 mg 3 ×/d); reduce if low creatinine clearance	3-8 wk for titration plus 1-2 wk at maximum tolerated dosage
Pregabalin	DPN	50 mg three times a day	Increase up to 100 mg three times a day	600 mg a day	Start with 50mg TID and increase up to 100mg TID over 1 week
Lamotrigine	Postherpetic neuralgia (shingles)	200-400 mg every night	Start with 25 to 50 mg every other day and increase by 25 mg every week	500 mg a day	3 to 5 wk for titration with 1 -2 wk at maximum tolerated dosage
Carbamazepine	Trigeminal neuralgia (stabbing chronic pain in face)	200 mg/d (100 mg bid)	Add up to 200 mg/d in increments of 100 mg every 12 h	1200 mg/d	
5% lidocaine patch	Postherpetic neuralgia (shingles)	Maximum of 3 patches daily for a maximum of 12 hr	None needed	Maximum of 3 patches daily for a maximum of 12 hr	2 wk
Tramadol hydrochloride	Moderate to moderately severe pain	50 mg 1 or 2×/d	Increased by 50-100 mg/d in divided doses every 3-7 d as tolerated	400 mg/d (100 mg 4×/d); in patients older than 75 yr, 300 mg/d in divided doses	4 wk
Tricyclic antidepressants (nortriptyline hydrochloride or desipramine hydrochloride)	Chronic pain	10-25 mg every night	Increase by 10-25 mg/d every 3-7 d as tolerated	75-150 mg/d; if blood level of active drug and its metabolite is <100 ng/mL, continue titration with caution	6-8 wk with at least 1-2 wk at maximum tolerated dosage
Duloxetine (Serotonin/norepinephrine Reuptake inhibitor)	Diabetic neuropathic pain	30 mg bid	Increase by 60 to 60 bid. No further titration	120 mg/d	4 wk
Fluoxetine (Serotonin/norepinephrine Reuptake inhibitor)	Diabetic neuropathic pain	30 mg bid	Increase by 60 to 60 bid. No further titration	120 mg/d	4 wk
Tapentadol ER	Diabetic neuropathic pain	50 mg bid	Increase by 50 mg/bid every 3 days as tolerated	500 mg/d	(bid: twice a day) (tid: three a day)

DISCOUNTS FOR WNA MEMBERS

Continued from page 4

Neuropathy Support Formula/Nerve Renew

(1-888-840-7142) is a supplement that a number of people are taking and reporting it has helped them. The company gives members of WNA a discount and free shipping. The 30-day supply is \$40 (normally \$49.97). It can be auto-shipped monthly for the same. A 3-month supply via auto-ship is \$95.00. They also have a Nerve Repair Optimizer that is available for \$20 with free shipping. Marsha, the manager, said that if anyone wants more information about the product, they can call and ask for her. If she is not readily available, leave your number and she will call you back. They now have Nerve Renew Fast Acting Cream at \$20 for WNA members. It reportedly takes the edge off numbness.

Building Better Balance DVD, Developing Spine Health

– The DVDs are \$30 each. The price of a full set (4 DVDs) is \$100 (that's a 20% discount). You can order the DVDs by going to the website www.building-better-balance.com. Shipping is free. You can also order the DVDs over the phone using a credit card. Call (707) 318-4476 and leave a message* Vanessa Kettler, Balance and Fall Prevention www.building-better-balance.com (707) 318-4476

Additional Discounts

Do you know a business that might offer our members a discount? Tell them that they will be listed each month in our newsletter and on our website so our members will know of their generosity and patronize their business. Call 888-556-3356 or email admin@WNAinfo.org.

We'll mail an agreement form to the business, and once we have it, we'll add them to this list.

EXERCISE FOR NEUROPATHIC PAIN: A SYSTEMATIC REVIEW AND EXPERT CONSENSUS

Zhang, Y et al. (2021, November 24) Exercise for Neuropathic Pain: A Systematic Review and Expert Consensus. *Frontiers in Medicine*, 8. <https://www.frontiersin.org/article/10.3389/fmed.2021.756940>

This paper is the first expert consensus to report exercise recommendations for different diseases with neuropathic pain (NP), including spinal cord injury, stroke, multiple sclerosis, Parkinson's disease, cervical radiculopathy, sciatica, diabetic neuropathy, chemotherapy-induced peripheral neuropathy, surgery, and HIV/AIDS. Studies published before January 2021 were included in the review.

The study aimed to review the effectiveness and efficacy of exercise on diseases with neuropathic pain through evidence, thereby producing evidence-based exercise recommendations for NP and informing medical staff and policymakers about the formulation of exercise prescription.

(Recommendations for painful polyneuropathies are summarized below. Please refer to the original paper for recommendations for the other diseases reviewed.)

Diabetic Neuropathy

Diabetic peripheral neuropathy marked by pain and sensory and mobility loss is a common and often disabling complication of diabetes mellitus. Diabetic neuropathy has been considered a serious problem because its treatments are likely ineffective.

Two clinical trials investigated the effectiveness of exercise training on pain in diabetic neuropathy:

- One three-arm Random Clinical Trial (RCT) divided 32 inactive patients with type 2 diabetes into three treatment groups: usual care, the combination of aerobic exercise and continuous moderate-intensity resistance training, and the combination of aerobic exercise and high-intensity interval training. The findings suggested that 8-week moderate-intensity and high-intensity exercise interventions are more beneficial in decreasing pain intensity but not neuropathic symptoms compared with single usual care lasting for 8 weeks. Particularly, the combination of aerobic exercise and high-intensity interval training significantly alleviated pain intensity.
- Based on another RCT (n = 104) comparing an 8-week simple hand, finger, and foot exercise with health education and control group with health education, both groups appeared decreased pain and the exercise intervention could relieve more pain than the control group in the short term and at 16-month follow-up.

Expert Recommendation

We recommend using general exercise focusing on distal extremities, or the combination of aerobic and moderate-intensity or high-intensity exercises, as a

treatment for pain in patients with diabetes.

Chemotherapy-Induced Peripheral Neuropathy

Chemotherapy-induced peripheral neuropathy, a common side effect of cancer treatment with a prevalence of 30–80%, is a small-fiber sensory neuropathy in the hands or feet. The typical symptoms are shooting pain, stabbing pain, or burning pain, which progressively becomes worse with chemotherapy.

Three trials were investigated for exercise and chemotherapy-induced neuropathic pain:

- A pre-post clinical trial found a slight reduction in pain intensity and improvement of balance, motor functions, and depression status with higher adherence rates and enjoyment after 8 weeks of progressive exergaming program, which is a combination of exercise and games.
- Similarly, a RCT study (n = 40) found that a 30-min exercise program that includes stretching and aerobic training could reduce pain and improve motor functions in patients after radiotherapy more than self-stretching training after 5 weeks of intervention.
- According to one RCT involving 45 patients with, a 10-week muscle strength and balance training has more positive effects on decreasing the NP intensity and increasing quality of life in patients with cancer who suffer from chemotherapy-induced peripheral neuropathy compared with usual care.

Expert Recommendation

We recommend muscle strengthening and balance training as treatment and exergaming as adjunct therapy for chemotherapy-induced NP (neuropathic pain).

Neuropathy Due to HIV/AIDS

Up to 90% of patients with HIV/AIDS complain about pain due to various reasons, including viral infection of the peripheral or central nervous system and side effects of anti-retroviral therapy.

Two studies were considered for neuropathic pain due to HIV/AIDS:

- A three-arm RCT compared 12-week aerobic exercise (cycling), progressive resistance exercise focused on muscles in the lower extremities, and no exercise control among 136 patients with HIV. The findings suggested that aerobic and progressive resistance exercise are helpful and safe in the treatment of NP compared with no exercise at 6- and 12-week points.

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FDA APPROVED VS. FDA CLEARED: WHY YOU NEED TO KNOW THE DIFFERENCE

Sarah Mitroff , Aug. 5, 2020 9:47 a.m. PT <https://www.cnet.com/health/fda-approved-vs-fda-cleared-whats-the-difference/>

The Food and Drug Administration is responsible for telling us which foods, drugs and medical devices are safe for us to use. Most of us assume that means anything that's been cleared or approved by the FDA has been rigorously tested, but that's not always true.

There's a big distinction between a drug or medical device that's been FDA approved and those that are FDA cleared.

What does the FDA regulate?

For the most part, the Food and Drug Administration evaluates the safety and efficacy of:

- Prescription drugs for humans and animals
- Over-the-counter drugs
- Biologics (e.g. vaccines, blood products, biotechnology products and gene therapy)
- Dietary supplements (not all are subject to FDA regulation)
- Medical devices (everything from wood tongue depressors to pacemakers)
- Surgical implants
- Food additives
- Cosmetics
- Products that give off radiation (e.g. X-rays, microwave ovens)
- Tobacco products
- Infant formula

What does 'FDA approved' mean?

"FDA approved" means that the agency has determined that the "benefits of the product outweigh the known risks for the intended use." Manufacturers must submit a premarket approval (PMA) application and the results of clinical testing in order to get approval.

When deciding to approve a product or drug, the FDA has to decide if the benefits outweigh the risks. The FDA is usually inclined to approve a product that has a higher risk if the potential benefit is significant -- like an artificial heart valve that can save someone's life.

What products need to be FDA approved?

FDA approval is usually mandatory to market or sell products in the US that might have a significant risk of injury or illness, but can also benefit your health -- such as prescription medications, over-the-counter medications, vaccines and Class III medical devices.

The FDA categorizes medical devices into Class III, Class II and Class I. Complex medical devices that are implanted in your body, life-

sustaining, or have the potential to cause significant injury or illness in the body are in Class III. Those include implanted pacemakers, replacement heart valves and even breast implants.

Lower-risk devices and products used outside of the body, like condoms, motorized wheelchairs and catheters, fall into Class II and Class I.

What does 'FDA cleared' mean?

Class II and Class I medical devices are usually "cleared" by the FDA, which means the manufacturer can demonstrate that their product is "substantially equivalent to another (similar) legally marketed device" that already has FDA clearance or approval. Those already-cleared products are called a predicate.

For instance, let's say hypothetically Apple wanted to create a blood pressure monitor, using the same design and features of one that already exists. The company could get FDA clearance if it can compare its product to another that's already on the market and demonstrate that it is just as safe and effective, and works in the same way.

Companies must submit a "premarket notification submission" or 510(k) to the FDA so that it can review the product and clear it. Once the FDA declares that a new medical device is substantially equivalent to a predicate, it is "cleared," and can be marketed and sold in the US.

The system isn't perfect.

The problem with the FDA's approval system is that often companies get their product cleared by using older predicates that were later recalled for safety reasons.

Just because a device was FDA approved or cleared does not always mean it is safe. That's why you see ads for class-action lawsuits asking if you or a loved one used a FDA-approved product, and suffered permanent bodily harm or died as a result. Those defective products ended up causing significant health problems, even though they were cleared or approved.

It's important to understand that the FDA does not develop any of the products it evaluates for approval. Nor does it conduct its own testing -- instead, it reviews the results of independent lab and clinical testing to determine if the product, drug or food additive is safe and as effective as it claims to be.

Exercise For Neuropathic Pain: A Systematic Review And Expert Consensus-- Continued on page 6

- Moreover, one high-quality RCT, which involved 120 patients with HIV who underwent anti-retroviral treatment, supported that supervised aerobic exercise, including isometric, balance, and breath training, could alleviate NP more than non-exercise control after 12 weeks of intervention and at the 12 weeks of follow-up.

Expert Recommendation

We recommend aerobic and progressive resistance training as an adjunct treatment for NP in people with HIV/AIDS.

Conclusion

Various exercise programs may have some benefits in improving pain and functions and proper exercise can be used as an effective alternative treatment or complementary therapy for different disorders with neuropathic pain.



WESTERN NEUROPATHY ASSOCIATION

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Call WNA using our toll free phone number:

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ADDITIONAL APPS THAT MAY RELIEVE PAIN

Acupressure: Heal Yourself

Acupressure is a non-invasive healing technique that can relieve stress and tension. This app can help guide the user to specific points on the body depending on the symptoms being experienced. When done correctly, this may help relieve nerve pain. Acupressure: Heal Yourself is available for iPhones only and costs \$1.99.

Simply Yoga – Home Instructor

For chronic pain patients, exercise can be intimidating but this free app for iOS and Android phones makes incorporating low-impact movement into your life easy. Six beginning yoga routines step you through each pose, which is demonstrated by a certified instructor. Simply follow along in the comfort of your own home.

Reference

Paindoctor.com, *7 Apps To Help Your Chronic Pain*, retrieved January 25, 2022 from <https://paindoctor.com/7-apps-to-help-your-chronic-pain/>



Western Neuropathy Association (WNA)

A California public benefit, nonprofit,
tax-exempt corporation.

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Our mission is to provide support, information and referral to people with neuropathy and to those who care about them, to inform and connect with the health care community, and to support research.

Dues - \$30 a year

All contributions and dues are tax-deductible.

We are supported by dues-paying members, contributions by members and friends, and occasionally, small grants and fundraisers.

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