



Non-Pharmacological Management of Pain

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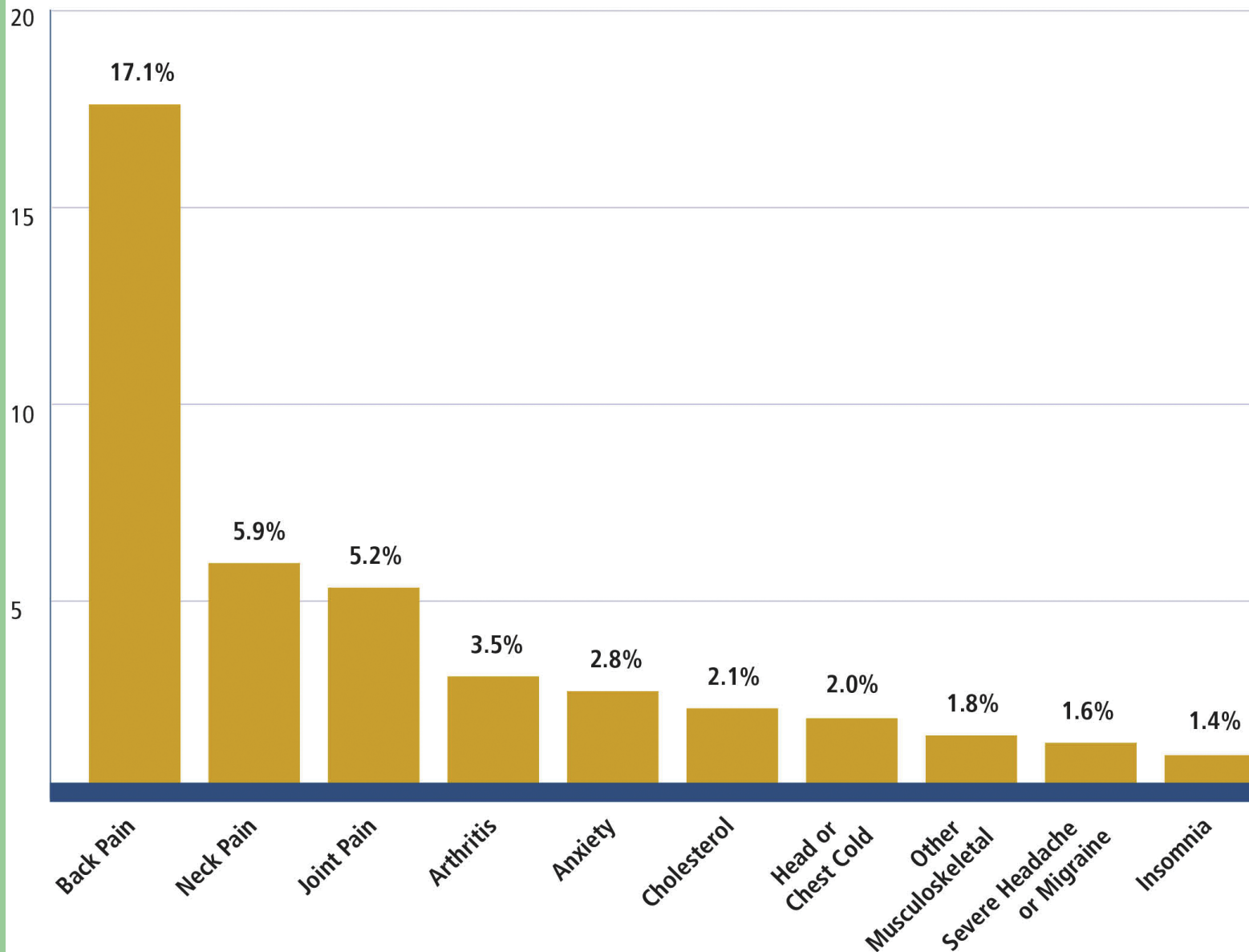
Session Objectives

- Describe the integrative approach to treatment of pain
- Discuss the current evidence and proposed mechanisms for the use of mind-body therapies for pain management
- Discuss the current evidence for the use of acupuncture for pain management

THE ART OF INTEGRATIVE MEDICINE

- The evidence
- Patient preference
- Patient previous experience
- Provider preference/experience
- ACCESS
- Motivation/commitment
- intuition

Diseases/Conditions for Which CAM Is Most Frequently Used Among Adults - 2007



Source: Barnes PM, Bloom B, Nahin R. *CDC National Health Statistics Report #12*. Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007. December 2008.

APS/ACP Systematic Review of Chronic Low Back Pain

- good evidence that cognitive-behavioral therapy, exercise, spinal manipulation, and interdisciplinary rehabilitation are all moderately effective for chronic or subacute (>4 weeks' duration) low back pain.
- fair evidence that acupuncture, massage, yoga (Viniyoga), and functional restoration are also effective for chronic low back pain.
- Chou R, Huffman L. Nonpharmacologic Therapies for Acute and Chronic Low Back Pain: A Review of the Evidence for an American Pain Society/American College of Physicians Clinical Practice Guideline. *Ann Intern Med.* 2007; 147: 492-504.

Mind-Body Medicine

- Hypnosis
- Meditation
- Guided Imagery
- Visualization
- Art therapy
- Music therapy
- Relaxation training
- Qi gong
- Biofeedback
- Prayer/ spiritual healing
- Psychotherapy (?)
- Cognitive-behavioral therapy
- Tai chi
- Yoga

Is There Evidence?

- **NIH Technology Assessment Panel on Chronic Pain and Insomnia**

- **Relaxation Techniques:** strong evidence for chronic pain in a variety of medical conditions
- **Hypnosis:** strong evidence in cancer-related pain; suggestive evidence in IBS, TMJ, tension headache
- **Biofeedback:** moderate evidence in migraine and tension headache, possibly superior to relaxation techniques
- **CBT:** moderate evidence for LBP, RA and OA
- Integration of behavioral and relaxation approaches into the treatment of chronic pain and insomnia. NIH Technology Assessment Panel on Integration of Behavioral and Relaxation Approaches into the Treatment of Chronic Pain and Insomnia. . JAMA. 1996 Jul 24-31;276(4):313-8

MBM for Back Pain

- 2000 systematic review including twenty RCTs; strategies employed in these trials included behavioral counseling, hypnosis, cognitive behavioral therapy, EMG biofeedback, relaxation, and structured group therapy
- strong evidence (generally consistent findings in multiple high quality RCTs) that MBTs when compared with wait list controls or usual medical care have a moderate positive effect on pain (effect size, 0.62) and small effects on functional status (ES, 0.35) and behavioral outcomes (ES, 0.40).
- Little evidence re which approach is superior though CBT appears best
- van Tulder MW, Ostelo R, Vlaeyen JW, et al. Behavioral treatment for chronic low back pain: a systematic review within the framework of the Cochrane back review group. *Spine*. 2000; 25:2688–2699.

Meditation (MBSR) in Older Adults

- 37 community-dwelling patients (65 or older) with moderate intensity CLBP were randomized to a 90 minute 8-week mindfulness-based mediation program or a wait-list control.
- outcome measures (MPQ-SF, SF-36 Pain Scale, CPAQ, SF-36 Health Status Inventory, Roland and Morris Questionnaire, Short Physical Performance Battery, SF-36 Physical Function Scale) at baseline, 8-week, and 3-month follow-ups.
- Morone N, Greco C, Weiner D. Mindfulness Meditation for the Treatment of Chronic Low Back Pain in Older Adults: A Randomized Controlled Pilot Study. *Pain*. 2008; 134(3): 310-9.

Meditation (MBSR) in Older Adults

- Results showed that pain acceptance improved for the meditation group while it worsened for the control group over the 8-week intervention.
- Physical function showed statistically significant improvement in the meditation group.
- The majority of patients also stated that they continued to meditate at the 3-month follow-up marker.
- In addition, half of the patients reported a reduction in pain and sleep medications three months after the study ended.
- Morone N, Greco C, Weiner D. Mindfulness Meditation for the Treatment of Chronic Low Back Pain in Older Adults: A Randomized Controlled Pilot Study. *Pain*. 2008; 134(3): 310-9.

Tai Chi for Fibromyalgia

- single-blind, randomized trial of classic Yang-style tai chi as compared with a wellness education and stretching for the treatment of fibromyalgia
- Sessions lasted 60 minutes each and took place twice a week for 12 weeks for each of the study groups. All assessments were repeated at 24 weeks to test the durability of the response.
- Wang C, Schmid CH, Rones R et al. A Randomized Trial of Tai Chi for Fibromyalgia N Engl J Med 2010;363:74354.

Tai Chi for Fibromyalgia

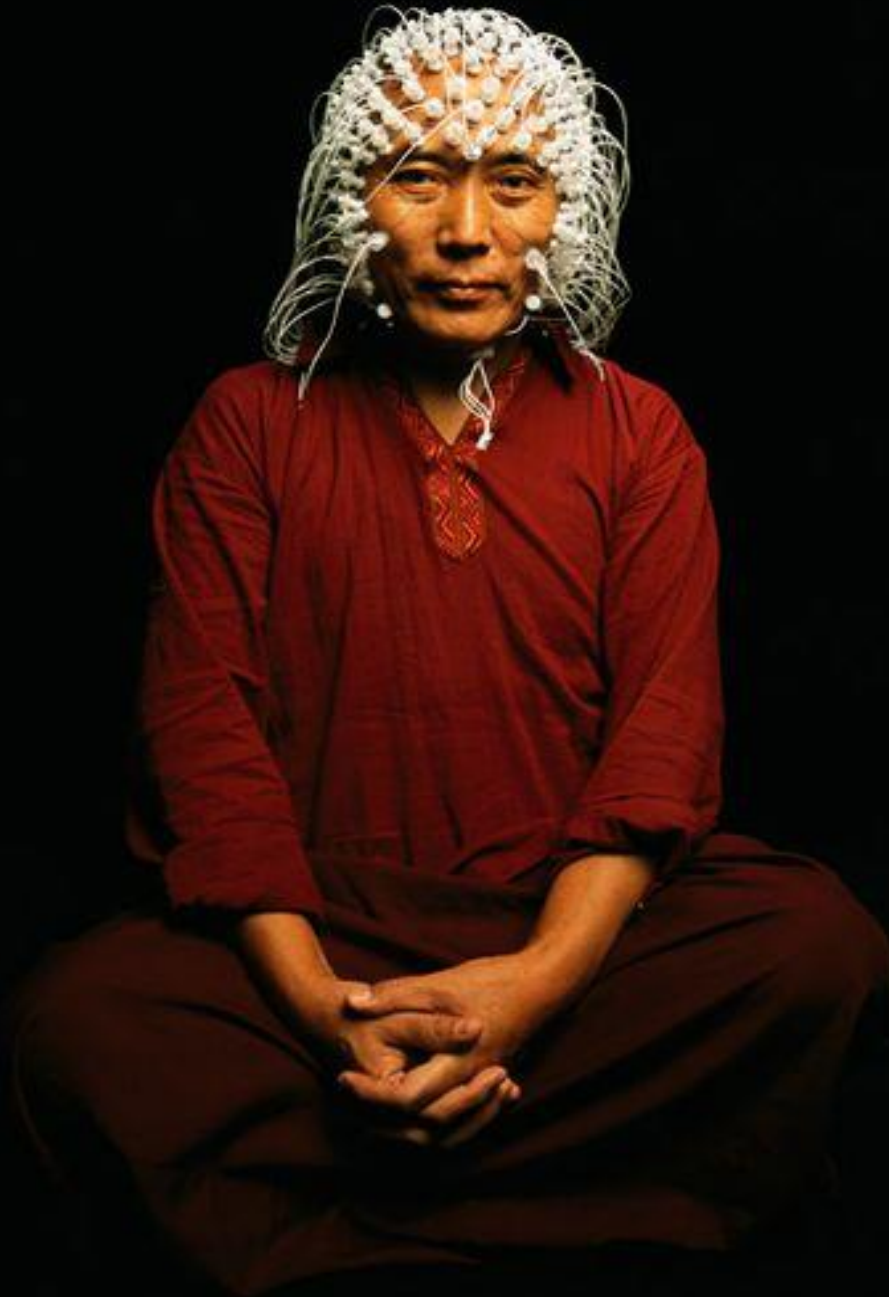
- SF-36 physical-component scores and mental-component scores were also significantly improved in the treatment group vs. controls.
- Of the 66 randomly assigned patients, the 33 in the tai chi group had clinically important improvements in the Fibromyalgia Impact Questionnaire FIQ total score and quality of life. Mean (\pm SD) baseline and 12-week FIQ scores for the tai chi group were 62.9 ± 15.5 and 35.1 ± 18.8 , respectively, versus 68.0 ± 11 and 58.6 ± 17.6 , respectively, for the control group ($P < 0.001$).
- Improvements were maintained at 24 weeks (between-group difference in the FIQ score, -18.3 points; $P < 0.001$). No adverse events were observed.
- Wang C, Schmid CH, Rones R et al. A Randomized Trial of Tai Chi for Fibromyalgia N Engl J Med 2010;363:74354.

MBM FOR PROCEDURAL PAIN

- randomly assigned 200 patients who were scheduled to undergo excisional breast biopsy or lumpectomy to a 15-minute presurgery hypnosis session conducted by a psychologist or nondirective empathic listening (attention control).
- Patients in the hypnosis group required less intraoperative propofol and lidocaine than patients in the control group.
- Patients in the hypnosis group also reported less pain intensity, nausea, fatigue, discomfort, and emotional upset
- Institutional costs for surgical breast cancer procedures were \$8561 per patient at Mount Sinai School of Medicine. Patients in the hypnosis group cost the institution \$772.71 less per patient than those in the control group (95% CI = 75.10 to 1469.89), mainly due to reduced surgical time.
- Montgomery GH et al A Randomized Clinical Trial of a Brief Hypnosis Intervention to Control Side Effects in Breast Surgery Patients. JNCI Journal of the National Cancer Institute 2007 99(17):1304-1312

Mind/Body: What is the Mechanism?

- Decreased sympathetic tone=decreased catecholamine levels
- No evidence re increased endorphin release
- Possible activation of frontal-limbic attention system to inhibit pain transmission to cortical structures from the thalamus
- Increased sense of self-control
- Decreased anxiety/depression



Physiologic Mechanism?

- recorded brain electrical activity before and immediately after, and then 4 months after an 8-week training program in mindfulness meditation.
- Twenty-five subjects were tested in the meditation group. A wait-list control group ($N = 16$) was tested at the same points in time as the meditators.
- Results: significant increases in left-sided anterior activation, a pattern previously associated with positive affect, in the meditators compared with the nonmeditators.
- Davidson RJ. **Kabat-Zinn** J. Schumacher J. Rosenkranz M. Muller D. Santorelli SF. Urbanowski F. Harrington A. Bonus K. Sheridan JF. **Alterations in brain and immune function produced by mindfulness meditation** *Psychosomatic Medicine*. 65(4):564-70, 2003 .

Physiologic Mechanism: fMRI

- using real-time functional MRI (rtfMRI) to guide training, subjects were able to learn to control activation in the rostral anterior cingulate cortex (rACC), a region putatively involved in pain perception and regulation.
- When subjects deliberately induced increases or decreases in rACC fMRI activation, there was a corresponding change in the perception of pain caused by an applied noxious thermal stimulus.
- Chronic pain patients were also trained to control activation in rACC and reported decreases in the ongoing level of chronic pain after training.
- These findings show that individuals can gain voluntary control over activation in a specific brain region given appropriate training, that voluntary control over activation in rACC leads to control over pain perception, and that these effects were powerful enough to impact severe, chronic clinical pain.
- deCharms RC, Maeda F, et al Control over brain activation and pain learned by using real-time functional MRI. Proc Natl Acad Sci U S A. 2005 Dec 20;102(51):18626-31



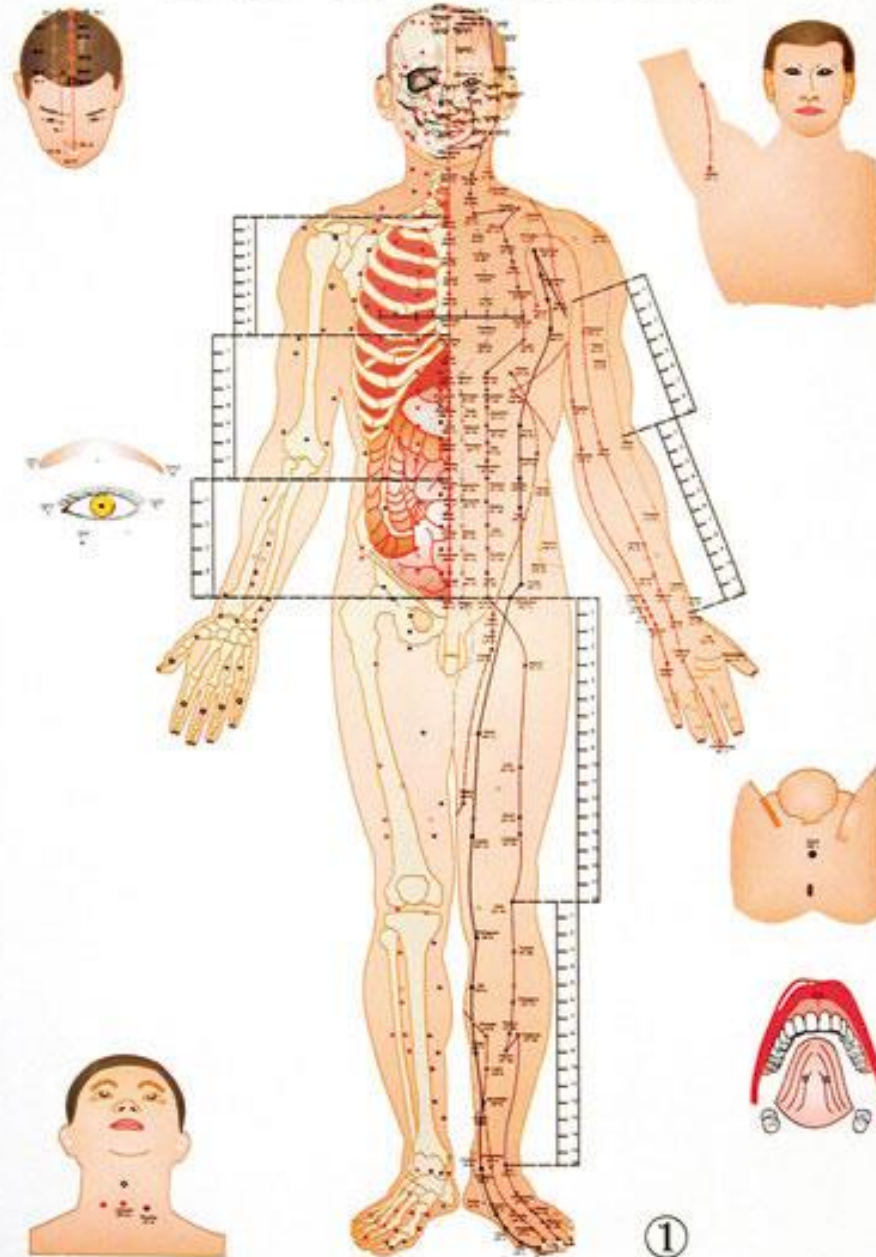
ACUPUNCTURE





THE POINTS AND MERIDIANS OF ACUPUNCTURE

经内针灸挂图



1997 NIH Consensus

“Acupuncture may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program”

- Myofascial pain
- Osteoarthritis
- Low back pain
- Headache
- Menstrual cramps
- Tennis elbow
- Fibromyalgia
- Carpal tunnel syndrome
- Addiction
- Stroke rehabilitation
- Asthma

The NIH Consensus Development Program. Available at:

<http://consensus.nih.gov/1997/1997Acupuncture107html.htm>.

Effectiveness of Acupuncture as Adjunctive Therapy in Osteoarthritis of the Knee

A Randomized, Controlled Trial

Brian M. Berman, MD; Lixing Lao, PhD; Patricia Langenberg, PhD; Wen Lin Lee, PhD; Adele M.K. Gilpin, PhD; and Marc C. Hochberg, MD

Background: Evidence on the efficacy of acupuncture for reducing the pain and dysfunction of osteoarthritis is equivocal.

Objective: To determine whether acupuncture provides greater pain relief and improved function compared with sham acupuncture or education in patients with osteoarthritis of the knee.

Design: Randomized, controlled trial.

Setting: Two outpatient clinics (an integrative medicine facility and a rheumatology facility) located in academic teaching hospitals and 1 clinical trials facility.

Patients: 570 patients with osteoarthritis of the knee (mean age [\pm SD], 65.5 \pm 8.4 years).

Intervention: 23 true acupuncture sessions over 26 weeks. Controls received 6 two-hour sessions over 12 weeks or 23 sham acupuncture sessions over 26 weeks.

Measurements: Primary outcomes were changes in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain and function scores at 8 and 26 weeks. Secondary outcomes were patient global assessment, 6-minute walk distance, and physical health scores of the 36-Item Short-Form Health Survey (SF-36).

Results: Participants in the true acupuncture group experienced greater improvement in WOMAC function scores than the sham acupuncture group at 8 weeks (mean difference, -2.9 [95% CI, -5.0 to -0.8]; $P = 0.01$) but not in WOMAC pain score (mean difference, -0.5 [CI, -1.2 to 0.2]; $P = 0.18$) or the patient global assessment (mean difference, 0.16 [CI, -0.02 to 0.34]; $P > 0.2$). At 26 weeks, the true acupuncture group experienced significantly greater improvement than the sham group in the WOMAC function score (mean difference, -2.5 [CI, -4.7 to -0.4]; $P = 0.01$), WOMAC pain score (mean difference, -0.87 [CI, -1.58 to -0.16]; $P = 0.003$), and patient global assessment (mean difference, 0.26 [CI, 0.07 to 0.45]; $P = 0.02$).

Limitations: At 26 weeks, 43% of the participants in the education group and 25% in each of the true and sham acupuncture groups were not available for analysis.

Conclusions: Acupuncture seems to provide improvement in function and pain relief as an adjunctive therapy for osteoarthritis of the knee when compared with credible sham acupuncture and education control groups.

Ann Intern Med. 2004;141:901-910.

www.annals.org

For author affiliations, see end of text.

See related articles on pp 911-919 and pp 920-928.

ACUPUNCTURE FOR ARTHRITIS

- **Randomized, controlled trial. 570 patients with osteoarthritis of the knee**
- **23 true acupuncture sessions over 26 weeks. Controls received 6 two-hour sessions over 12 weeks or 23 sham acupuncture sessions over 26 weeks.**
- **At 26 weeks, the true acupuncture group experienced significantly greater improvement than the sham group in the WOMAC function score WOMAC pain score and patient global assessment**
- **Berman et al. Effectiveness of Acupuncture as Adjunctive Therapy in Osteoarthritis of the Knee. *Ann Intern Med.* 2004;141:901-910**

ACUPUNCTURE FOR MIGRAINE

- Randomized controlled trial of acupuncture for patients with migraine, n=302
- Real vs. sham vs. waitlist
- Primary outcome measure: reduction in headache days $\geq 50\%$
- Results:
 - 51% improved in the acupuncture group
 - 53% improved in the sham acupuncture group,
 - 15% improved in the waiting list group
- Linde K. et al **Acupuncture for Patients With Migraine: A Randomized Controlled Trial** JAMA. 2005 May 4;293(17):2118-25.

ACUPUNCTURE FOR MIGRAINE

- Patients were randomly allocated to receive up to 12 acupuncture treatments over three months or to a control intervention offering usual care (n=401)
- **Results** Headache score at 12 months, the primary end point, was lower in the acupuncture group (16.2, SD 13.7, n = 161, 34% reduction from baseline) than in controls (22.3, SD 17.0, n = 140, 16% reduction from baseline).
- Patients in the acupuncture group experienced the equivalent of 22 fewer days of headache per year (8 to 38).
- Compared with controls, patients randomised to acupuncture used 15% less medication (P = 0.02), made 25% fewer visits to general practitioners (P = 0.10), and took 15% fewer days off sick (P = 0.2).
- Vickers AJ et al Acupuncture for chronic headache in primary care: large, pragmatic, randomised trial BMJ 2004;328:744

ACUPUNCTURE FOR BACK PAIN: COCHRANE 2004

- **Thirty-five RCTs covering 2861 patients were included in this systematic review.**
- **For chronic low-back pain, results show that acupuncture is more effective for pain relief than no treatment or sham treatment, in measurements taken up to three months.**
- **The results also show that for chronic low-back pain, acupuncture is more effective for improving function than no treatment, in the short-term.**
- **When acupuncture is added to other conventional therapies, it relieves pain and improves function better than the conventional therapies alone.**
- Furlan AD. van Tulder M. Cherkin D. Tsukayama H. Lao L. Koes B. Berman B. Acupuncture and dry-needling for low back pain: an updated systematic review within the framework of the cochrane collaboration. *Spine*. 30(8):944-63, 2005 Apr 15.

GERMAN ACUPUNCTURE TRIALS (GERAC)

- Studies acupuncture in a “naturalistic” setting
- Funded by six large health insurers
- Studies patients declining randomization as well as those accepting
- Evaluates cost outcomes as well as clinical outcomes
- Looks at back pain, headache, dysmenorrhea, osteoarthritis, etc.

ACUPUNCTURE FOR BACK PAIN: GERAC

- randomized controlled trial plus a nonrandomized cohort, chronic LBP
- effectiveness and costs of acupuncture in addition to routine care in the treatment of chronic low back pain and assessed whether the effects of acupuncture on function, pain and QOL differed in randomized and nonrandomized patients.
- 11,630 patients; 1,549 randomized to the acupuncture group and 1,544 to control
- 8,537 were included in the nonrandomized acupuncture group.
- Witt CM. Jena S. et al Pragmatic randomized trial evaluating the clinical and economic effectiveness of acupuncture for chronic low back pain. *American Journal of Epidemiology*. 164(5):487-96, 2006

ACUPUNCTURE FOR BACK PAIN: GERAC

- **At 3 months, back function improved by 12.1 points in the acupuncture group and by 2.7 points among controls (difference=9.4 points (95% confidence interval 8.3, 10.5); $p < 0.001$).**
- **Nonrandomized patients had more severe symptoms at baseline and showed improvements in back function similar to those seen in randomized patients.**
- **incremental cost-effectiveness ratio was euro10,526 (euros) per quality-adjusted life year.**
- **Acupuncture plus routine care was associated with marked clinical improvements in these patients and was relatively cost-effective.**
- Witt CM. Jena S. et al Pragmatic randomized trial evaluating the clinical and economic effectiveness of acupuncture for chronic low back pain. *American Journal of Epidemiology*. 164(5):487-96, 2006

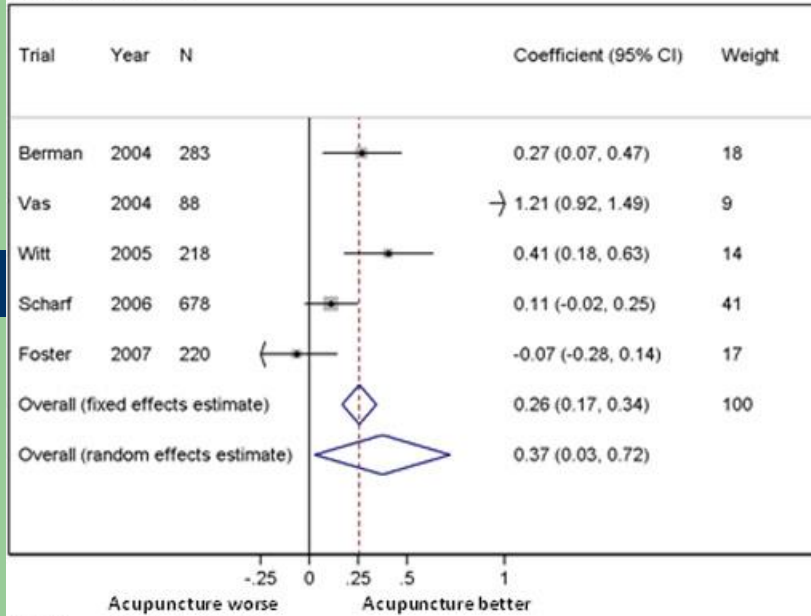
META-ANALYSIS 2012

- systematic review using data from 29 of 31 eligible RCTs, with a total of 17 922 patients analyzed.
- acupuncture was superior to both sham and no-acupuncture control for back and neck pain, osteoarthritis, and chronic headache ($P < .001$ for all comparisons).. These results were robust to a variety of sensitivity analyses, including those related to publication bias.
- Acupuncture is effective for the treatment of chronic pain and is therefore a reasonable referral option. Significant differences between true and sham acupuncture indicate that acupuncture is more than a placebo. However, these differences are relatively modest, suggesting that factors in addition to the specific effects of needling are important contributors to the therapeutic effects of acupuncture.
- Vickers AJ1, Cronin AM, Maschino AC, Lewith G, MacPherson H, Foster NE, Sherman KJ, Witt CM, Linde K; Acupuncture Trialists' Collaboration. Acupuncture for chronic pain: individual patient data meta-analysis. Arch Intern Med. 2012 Oct 22;172(19):1444-53

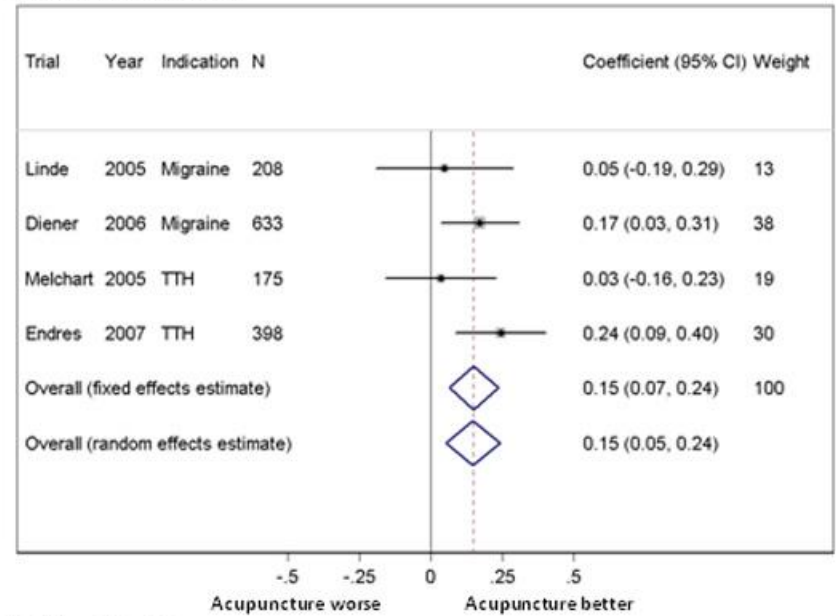
Forest plots for the comparison of true and sham acupuncture. Acupuncture for chronic pain: individual patient data meta-analysis

Arch Intern Med. 2012 October 22;172(19):1444-1453.

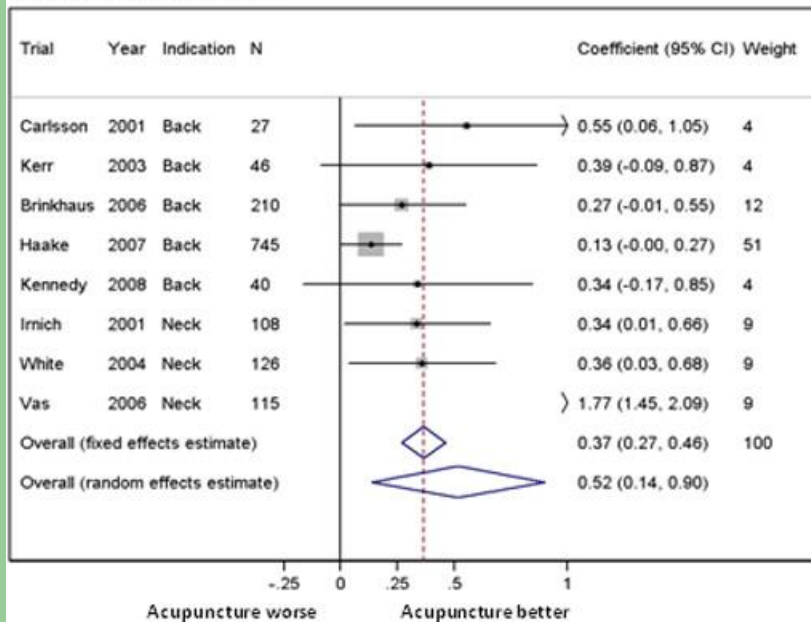
A. Osteoarthritis



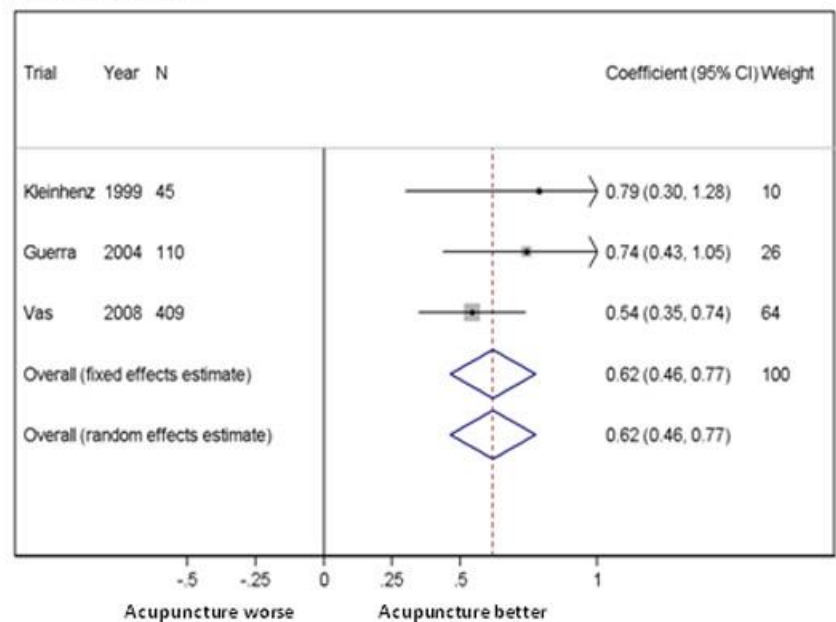
B. Chronic Headache



C. Musculoskeletal Pain



D. Shoulder Pain



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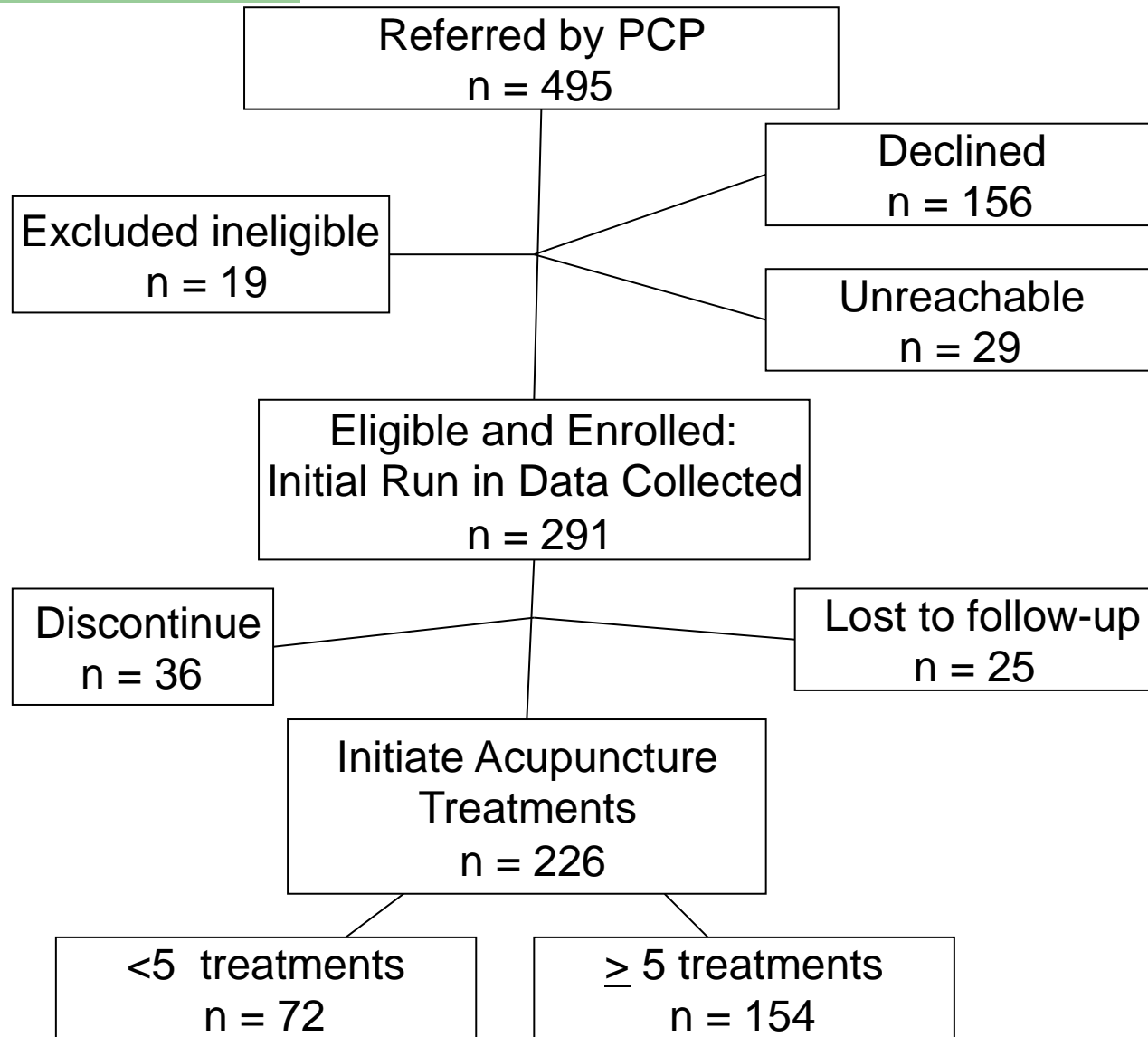
ADDOPT: ACUPUNCTURE TO DECREASE DISPARITIES IN PAIN TREATMENT

PURPOSE

- To describe the outcome of the NIH-funded Acupuncture to Decrease Disparities in Outcomes of Pain Treatment (ADDOPT) trial, testing acupuncture as an adjunct to usual treatment for chronic pain in four urban health centers. These health centers belong to New York City Research and Improvement Networking Group (NYC RING), a practice-based research network dedicated to decreasing health disparities through primary care research and quality improvement in the urban safety net setting.

METHODS

- **Population:** primary care patients (>18 years) with chronic pain due to osteoarthritis, neck or back pain at four hospital owned safety net community health centers in the Bronx NY. The patient population was ethnically diverse and low income in a medically underserved area of the Bronx.
- **Intervention:** weekly acupuncture treatments for up to 14 weeks. The acupuncture team was free to adapt and change the treatment approach from week to week based on the condition of the patient and response to treatment.
- **Outcome measures:** Pain and functional status were assessed during a 6-week run-in period before acupuncture, during treatment and post treatment up to 24 weeks. Outcome measures were the Brief Pain Inventory (BPI), and the Chronic Pain Grading Scale (CPGS) for pain, and the Short Form-12 (SF-12) for quality-of-life status.

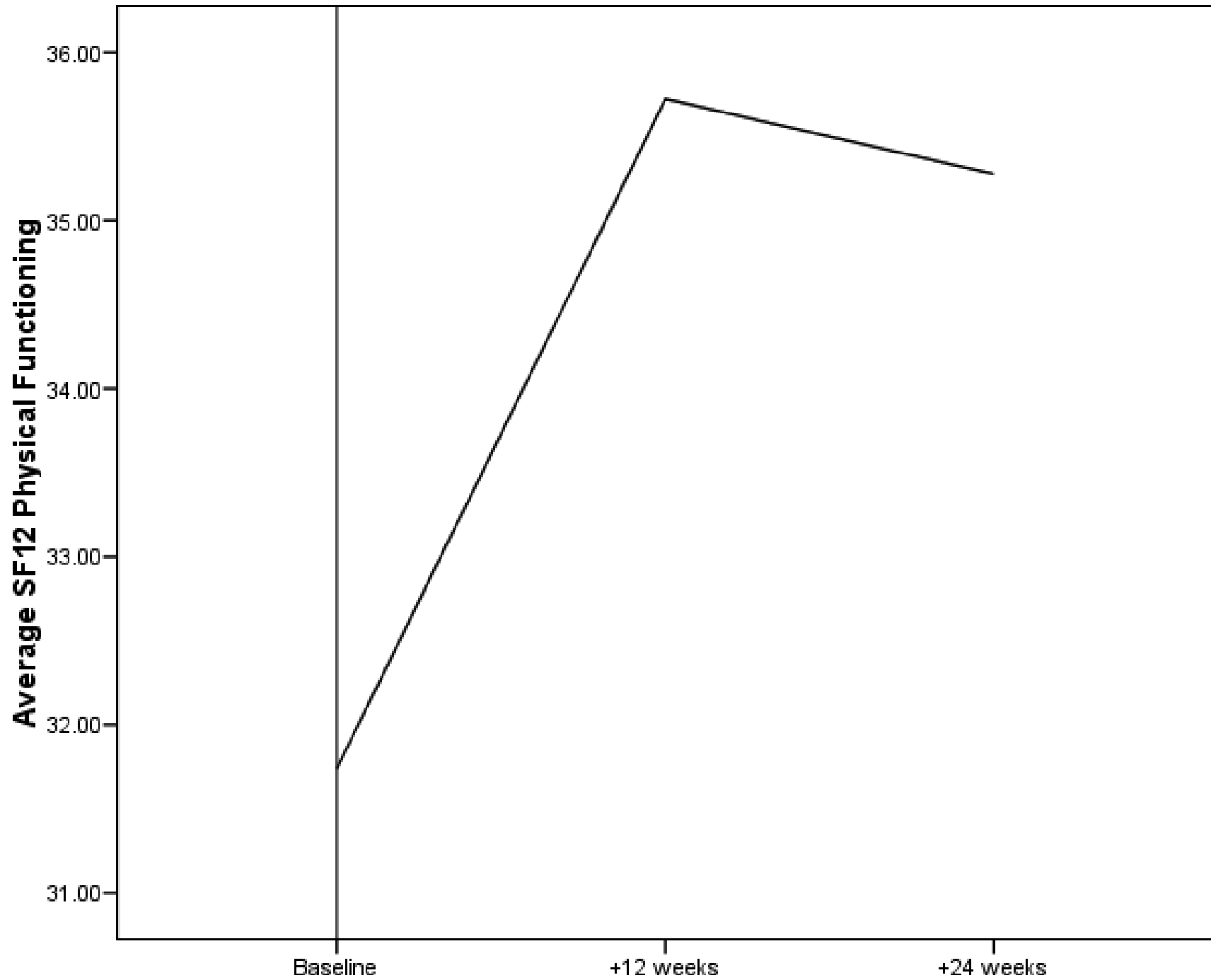


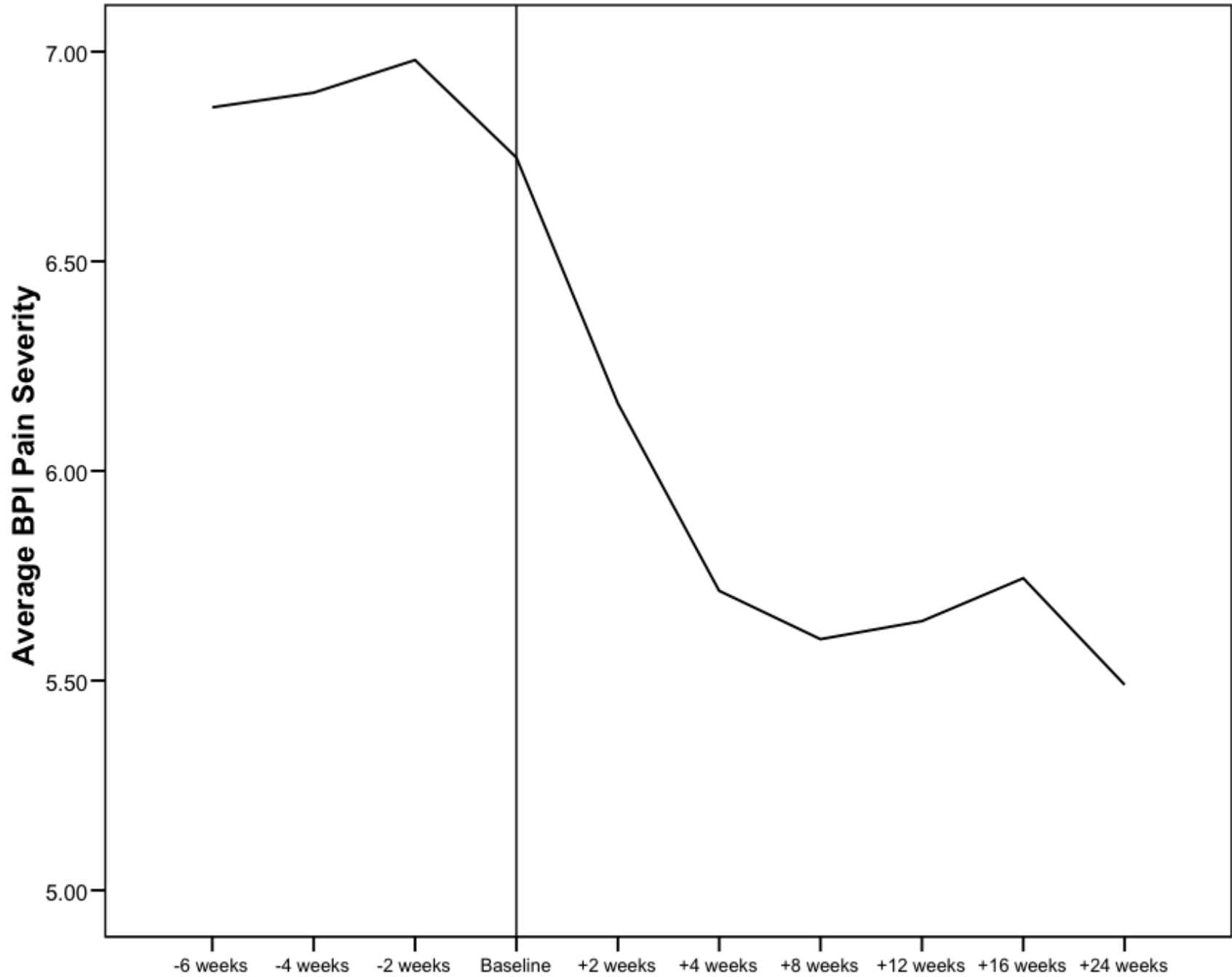
RESULTS

- Of 495 referred patients, 226 (47%) initiated acupuncture.
- Back pain was the most common referring diagnosis (59.5%) followed by osteoarthritis (16.3%).
- Patients were older (mean age 54.3), mostly Medicaid insured (60.4%), often on disability insurance (38.3%), often (46.7%) in poor or fair overall health, and had high baseline levels of pain (mean BPI pain severity 6.8; mean days with pain, 12.3 of 14 days).
- Mean number of treatments was 8.0 (SD 4.7).

RESULTS

- Pain severity improved from baseline (6.8 vs 5.6 at 12 weeks and 5.5 at 24 weeks) as did physical well-being (31.8 vs 35.7 at 12 weeks and 35.3 at 24 weeks).
- Reduction in pain severity between baseline and treatment phase was significant ($p < .001$). Improvements in physical well-being were significant at 12 and 24 weeks post-baseline ($p < .001$).
- 30.3% experienced a 30% or greater improvement in pain—the generally accepted threshold for clinically significant change.





Outcomes of Acupuncture for Chronic Pain in Urban Primary Care

M. Diane McKee, MD, MS, Benjamin Kligler, MD, MPH, Jason Fletcher, PhD, Francesca Biryukov, LAc, William Casalaina, LAc, Belinda Anderson, PhD, LAc, and Arthur Blank, PhD

Purpose: The purpose of this study was to describe outcomes of the Acupuncture to Decrease Disparities in Outcomes of Pain Treatment (ADDOPT) trial, testing acupuncture as an adjunct to usual treatment for chronic pain in urban health centers.

Method: We conducted a quasi-experimental trial. Primary care patients (>21 years old) with chronic pain caused by osteoarthritis or neck or back pain at 4 hospital-owned safety net health centers in the Bronx, New York, received weekly acupuncture treatments provided by supervised acupuncture students for up to 14 weeks. Pain and functional status were assessed during a 6-week run-in period before acupuncture, during treatment, and after treatment.

Results: Of 495 referred patients, 226 (47%) initiated acupuncture. Back pain was the most common referring diagnosis (59.5%) followed by osteoarthritis (16.3%). Patients were older (mean age, 54.3 years), mostly insured by Medicaid (60.4%), often receiving disability (38.3%), and often in poor or fair overall health (46.7%). They had high baseline levels of pain (mean severity per the Brief Pain Inventory, 6.8; mean days with pain, 12.3 of 14). The mean number of treatments was 9.7 (standard deviation, 7.3). Pain severity improved from baseline (6.8 vs. 5.6 at 12 weeks and 5.5 at 24 weeks), as did physical well-being (31.8 vs. 35.7 at 12 weeks and 35.3 at 24 weeks). Using hierarchical linear modeling methods, reduction in pain severity between baseline and the treatment phase was significant ($P < .001$). Improvements in physical well-being were significant at 12 and 24 weeks after baseline ($P < .001$).

Conclusions: Referred primary care patients experienced high levels of pain and pain-related disability. Weekly acupuncture was associated with short-term improvements in pain and quality of life. (J Am Board Fam Med 2013;26:692–700.)

CONCLUSION

- Referred primary care patients experienced high levels of pain and pain-related disability.
- Weekly acupuncture resulted in improvements in pain and quality of life.
- It is feasible and effective to incorporate acupuncture in the primary care setting into the approach to chronic pain for an ethnically diverse, medically underserved, socioeconomically underprivileged population.

RE: The Joint Commission Standards and Non pharmacological Strategies for Pain Management

Dear Drs. Nielsen, Kligler and Ms. Handel:

Thank you for your email regarding non-pharmacologic treatment options for pain as they relate to The Joint Commission pain management standards. The Joint Commission never intended for our pain management standards to focus exclusively on pharmacologic treatments. In the greater than 10 years that this standard has been part of accreditation, it has been a persistent misperception that these standards applied exclusively to pharmacological treatments.

The Joint Commission is in the process of exploring ways to both correct the misconceptions concerning our standards and also to investigate the need to modify these standards so as to keep them contemporary. This will require clarifying the original intent of the standards to emphasize the expectation that both pharmacological and non-pharmacological methods of treatment be considered in pain management

Daniel J Castillo,MD,MBA

Medical Director Division of Healthcare Quality Evaluation JACHO

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JOINT COMMISSION

Effective January 1, 2015: For ambulatory care, critical access hospital, home care, hospital, nursing care center, and office-based surgery accreditation programs.

Standard PC.01.02.07: The [organization] assesses and manages the [patient's] pain.

[Revised] Rationale for PC.01.02.07 [New for ambulatory care and office-based surgery practice]

The identification and management of pain is an important component of [patient]-centered care. [Patients] can expect that their health care providers will involve them in their assessment and management of pain. Both pharmacologic and nonpharmacologic strategies have a role in the management of pain. The following examples are not exhaustive, but strategies may include the following:

- Nonpharmacologic strategies: physical modalities (for example, acupuncture therapy, chiropractic therapy, osteopathic manipulative treatment, massage therapy, and physical therapy), relaxation therapy, and cognitive behavioral therapy
- Pharmacologic strategies: nonopioid, opioid, and adjuvant analgesics

EP 4: The [organization] either treats the [patient's] pain or refers the [patient] for treatment.

[New] Note: Treatment strategies for pain may include pharmacologic and nonpharmacologic approaches. Strategies should reflect a [patient]-centered approach and consider the patient's current presentation, the health care providers' clinical judgment, and the risks and benefits associated with the strategies, including potential risk of dependency, addiction, and abuse.

Session Objectives

- Describe the integrative approach to treatment of pain
- Discuss the current evidence and proposed mechanisms for the use of mind-body therapies for pain management
- Discuss the current evidence for the use of acupuncture for pain management