

Safety and Efficacy of Complementary Therapies in Children and Adults

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• Faculty Disclosure Information

- In the past 12 months, I have not had a significant financial interest or other relationship with the manufacturer(s) of the product(s) or provider(s) of the service(s) that will be discussed in my presentation.



Objectives

- Become familiar with the mechanisms of action, appropriate indications, safety and evidence to support the use of complementary therapies.
- Learn the role of complementary therapies in children/ adolescents including aromatherapy, acupuncture, biofeedback and hypnosis, massage and homeopathy.
- Obtain practical guidance on how to incorporate complementary therapies into a pediatric/adolescent practice.

Case Study

- 16 yo female with history of idiopathic thoracic scoliosis s/p fusion today. She is admitted to the PICU for routine post operative care the night of surgery. She has had considerable post op nausea, anxiety and pain. Her parents own a lavender farm and were wondering if they could bring some lavender for her to smell overnight? How about homeopathy?

Aromatherapy

- Aromatherapy acts upon holistic principles to awaken and strengthen energies and to promote self-healing
- Anti-inflammatory (chamomile, lavender)
- Antiseptic (thyme, ylang ylang)
- Appetite stimulator (citrus oils)
- Carminitive (rosemary, cascarilla bark)
- Choleric (wild thyme)
- Circulation stimulator (eucalyptus)
- Deodorizer (patchouli)
- Expectorant (tea tree, eucalyptus)
- Insecticide (citronella)
- Sedative (valerian)

Types of Oils

- Essential oils
 - Fragrant oils extracted from herbs, flowers, and trees considered to be the “essence” of the plant
 - Examples
 - Lavender, camphor, eucalyptus, citronella, patchouli
- Infused oils
 - Produced from plant materials that are extracted with heat into a carrier oil medium
 - used for plants that yield very small amounts
 - Examples: aloe vera, arnica, calendula

Storage

- Store in amber bottles
- Avoid extreme temperature
- Avoid exposure to air
- Most oils may lose potency after one year

Aromatherapy Research

- Víctor López, Birgitte Nielsen, Maite Solas, María J. Ramírez, Anna K. Jäger. Exploring Pharmacological Mechanisms of Lavender (*Lavandula angustifolia*) Essential Oil on Central Nervous System Targets. *Front Pharmacol.* 2017; 8: 280.

Aromatherapy Research

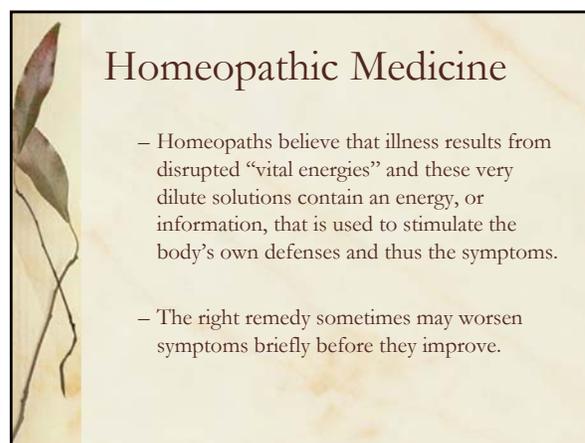
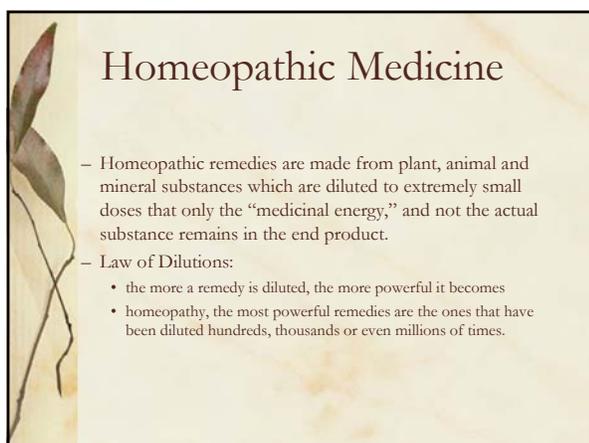
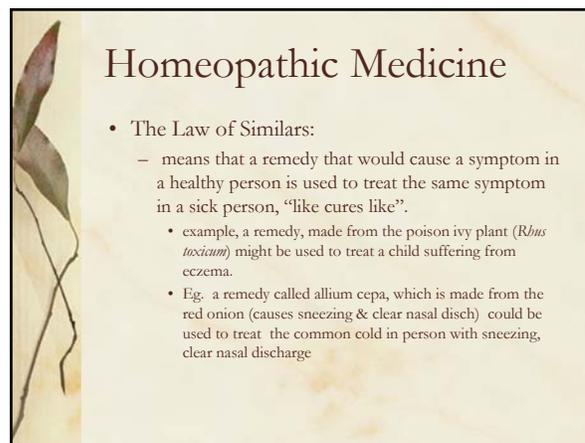
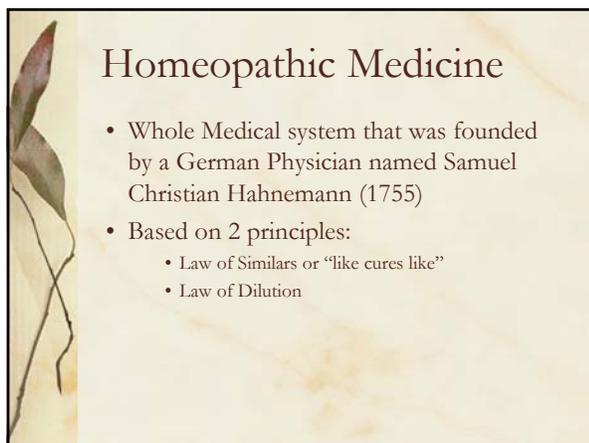
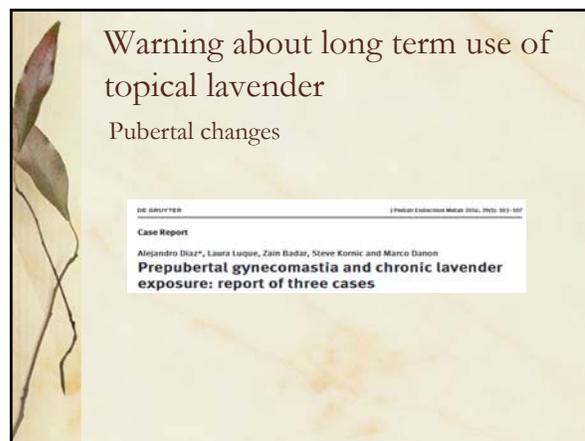
- [Kim JT.](#) Treatment with lavender aromatherapy in the post-anesthesia care unit reduces opioid requirements of morbidly obese patients undergoing laparoscopic adjustable gastric banding. *Obes Surg.* 2007 Jul;17(7):920-5.
- [Kim JT.](#) Evaluation of aromatherapy in treating postoperative pain: pilot study. *Pain Pract.* 2006;6(4):273-7.



- Soltani R et al. Evaluation of the effect of aromatherapy with lavender essential oil on post-tonsillectomy pain in pediatric patients: a randomized controlled trial. *Int J Pediatr Otorhinolaryngol.* 2013;77(9):1579-81.
- Results: In 48 patients use of lavender essential oil caused statistically significant reduction in daily use of acetaminophen in all three post-operative days but had not significant effects on pain intensity and frequency of nocturnal awakening.
- Conclusion: Aromatherapy with lavender essential oil decreases the number of required analgesics following tonsillectomy in pediatric patients.

Aromatherapy Research

- [Hines S, Steels E, Chang A, Gibbons K.](#)
- Aromatherapy for treatment of postoperative nausea and vomiting. *Cochrane Database Syst Rev.* 2018 Mar 10;3:CD007598.



Homeopathic Medicine

- Homeopathic remedies have been evaluated in children in small randomized controlled trials & shown to provide improvement in some common conditions (e.g., allergic rhinitis, diarrhea, and ADHD).

(Jacobs J, Jonas WB, et.al. "Homeopathy for childhood diarrhea: combined results and meta-analysis from three randomized, controlled clinical trials." *Pediatr Infect Dis J.* 2003;22:229-34.)
 (Taylor, MA, Reilly, D, et.al. "Randomized controlled trial of homeopathy versus placebo in perennial allergic rhinitis with overview of four trial series." *BMJ* 2000; 321:471.)

Homeopathic Medicine

- Cochrane review was done to assess the safety and effectiveness of homeopathy as a treatment for ADHD
- Results:** studies done to date do not suggest significant treatment effects for the global symptoms, core symptoms of inattention, hyperactivity or impulsivity, or related outcomes such as anxiety in ADHD.
- There is currently little evidence for the efficacy of homeopathy as a sole tx for ADHD.

(Coulter MK, Dean ME. Homeopathy for attention deficit/hyperactivity disorder or hyperkinetic disorder. *Cochrane Database of Systematic Reviews* 2007, Issue 4.)

Case Study

- John is an 8 year old youth who you see frequently for migraine headaches and associated nausea. He is taking Topamax and not doing well.
- Family wants to try acupuncture, biofeedback or hypnosis.

Acupuncture: Regulation



- ~12,000 acupuncturists in 2017
- ~10 million visits/year
- 48 accredited acupuncture schools
- Acupuncturists is recognized in 44 states including the District of Columbia
- 1/3 are MDs (300 hours) vs. non-MD (1000-3000 hours, 3-4 yr Master's program)
- 40-80% insurers pay for some treatments

Acupuncture: Needles (US)



- Metallic
- Solid
- 36-38 gauge
- Disposable

What is acupuncture?



- Acupuncture is one of the key components of traditional Chinese medicine (TCM).
- In TCM, the body is seen as a delicate balance of two opposing and inseparable forces: yin and yang.
- Yin represents cold, slow, or passive aspects of the person, while yang represents hot, excited, or active aspects.
- A major theory is that health is achieved through balancing yin and yang.

What is acupuncture?

- Disease is caused by an imbalance leading to a blockage in the flow of qi along pathways known as meridians.
- Qi can be unblocked by using acupuncture at certain points on the body that connect with these meridians.
- Meridians (14-20 pathways) can include up to 20,000 acupuncture points in a weblike interconnecting matrix.

Acupuncture Clinical Studies

Children 2014, 7, 134-141, doi:10.3390/children020134

Review
Acupuncture for Pediatric Pain
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Abstract: Chronic pain is a growing problem in children, with prevalence as high as 30.8%. Acupuncture has been found to be useful in many chronic pain conditions, and may be of clinical value as a multidisciplinary treatment program. The basic principles of acupuncture are reviewed, as well as studies exploring basic mechanisms of acupuncture and clinical efficacy. Conditions commonly treated in the pediatric pain clinic, including headache, abdominal pain, fibromyalgia, juvenile arthritis, complex regional pain syndrome, cancer pain, as well as perioperative pain studies are reviewed and discussed. Areas in need of further research are identified, and procedural aspects of acupuncture practice and safety studies are reviewed. Acupuncture can be an effective adjunct in the care of pediatric patients with painful conditions, both in a chronic and an acute setting. Further studies, including randomized controlled trials, as well as trials of comparative effectiveness are needed.

Reindl, T.K., Geilen, W., Hartmann, R. et al. Acupuncture against chemotherapy-induced nausea and vomiting in pediatric oncology. Support Care Cancer (2006) 14: 172.

- Eleven children receiving several courses of highly emetogenic chemotherapy for treatment of solid tumors were included.
- Randomization allocated patients to start chemotherapy either with antiemetic medication plus acupuncture or antiemetic medication alone.
- During all study courses, patients continued to receive their programmed and additional antiemetic medication as needed. Acupuncture was given at day 1 of chemotherapy and at subsequent days on patient's demand.
- Acupuncture enabled patients to experience higher levels of alertness during chemotherapy and reduced nausea and vomiting. Except for needle pain, no side effects were noted. Patient's acceptance of acupuncture was high.

Grissa MH et al. Acupuncture more effective than IV MS in relief of acute pain with less SE's. Am J Emerg Med. 2016 Nov; 34(11):2112-2116.

Table 3
 Treatment adverse effects.

	Morphine n = 150	Acupuncture n = 150	P
Minor, n			
Drowsiness	2	0	>.156
Chills/rigors	64	0	<.001
Nausea and vomiting	36	0	<.001
Pruritus	2	0	>.156
Fatigue	3	0	.082
Headache/bruising	0	1	.082
Fainting	4	1	>.176
Major, n	0	1	>.176
Total, n	85	4	<.001

- Denise Adams, Florence Cheng, HsingJou, Steven Aung, Yutaka Yasui, Sunita Vohra. The Safety of Pediatric Acupuncture: A Systematic Review. Pediatrics. November 2011.

Medical Acupuncture

- <http://www.medicalacupuncture.org/For-Physicians/Education>
- <https://hmieducation.com/course-description>

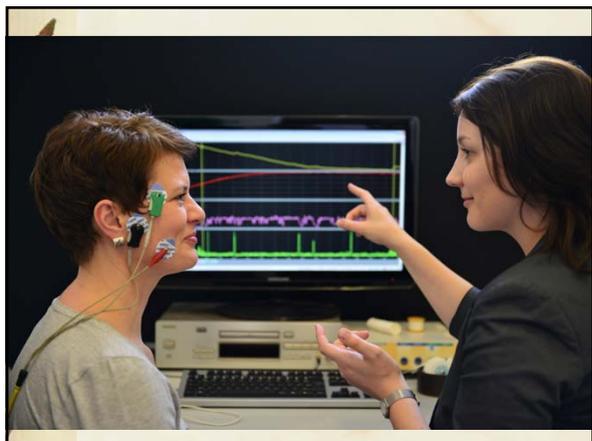
Fees for Fall 2019 - Spring 2020 Course	*Through 12 Nov.	After 12 Nov.
Tuition		
300-hour course tuition for the introductory Session, Clinical 1, and Clinical 2 - paid by credit card	\$11,000	\$11,500
300-hour course tuition for the 3 sessions - paid by check	\$10,750	\$11,250
Discounts for residents and fellows (Applicant must be a full-time resident or fellow through the conclusion of the course and pay his/her own tuition.) 300-hour course tuition for residents - paid by credit card	\$9,000	\$9,300
300-hour course tuition for residents - paid by check	\$8,750	\$9,050

Biofeedback

- Technique intended to teach patients self-regulation of physiologic processes, such as muscle tension, heart rate, and skin temperature
- Learn mental techniques to affect the physiologic variable being monitored → while practicing, able to see when that variable is successfully altered

What is biofeedback?

- Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under regulatory control.
- Patients are taught modify physiologic functions by being connected through electrical sensors to a computer.
- A typical program consists of 5- 20 training sessions of 30 – 60 minutes each. Through learning specific techniques patients learn to control their heart rate, breathing, muscle tension, galvanic skin response and skin temperature.



BIOFEEDBACK MODALITIES

- EMG
- Skin Temperature
- GSR
- Respiratory rate
- Cardiac rate
- Heart Rate Variability
- Neurofeedback



Blume HK, Brockman LN, Breuner CC. Biofeedback therapy for pediatric headache: factors associated with response. Headache. 2012 Oct;52(9):1377-86.

- 132 children who attended ≥ 2 biofeedback sessions.
- Median headache frequency dropped from 3.5 to 2 headache days/week between the first and last visits. Response-58% overall; 48% for chronic headaches and 73% episodic headaches.
- In multivariate analysis, ability to raise hand temperature by $>3^{\circ}\text{F}$ at the last visit and use of selective serotonin reuptake inhibitors (SSRIs) were associated with a positive response, and preventive medication use was associated with nonresponse.
- Anxiety, depression, and somatization were not significantly associated with response

Nestoriuc, Y, Rief, W, Martin, A. Meta-analysis of biofeedback for tension-type headache: Efficacy, specificity, and treatment moderators. *Journal of Consulting and Clinical Psychology*. 2008 : 76(3): 379-96.

- 74 outcome studies, of which 53 were selected according to predefined inclusion criteria.
- Meta-analytic integration resulted in a significant medium-to-large effect size ($d = 0.73$; 95% confidence interval = 0.61, 0.84) that proved stable over an average follow-up phase of 15 months. Biofeedback was more effective than headache monitoring, placebo, and relaxation therapies.
- The strongest improvements resulted for frequency of headache episodes. Further significant effects were observed for muscle tension, self-efficacy, symptoms of anxiety, depression, and analgesic medication.
- Moderator analyses revealed biofeedback in combination with relaxation to be the most effective treatment modality; effects were particularly large in children and adolescents.
- It is concluded that biofeedback constitutes an evidence-based treatment option for tension-type headache

Doobin A. Randomised controlled trial of brief intervention with biofeedback and hypnotherapy in patients with refractory irritable bowel syndrome. *J R Coll Physicians Edinb*. 2013;43(1):15-23.

- 97 patients randomized into the study, 21 failed to attend the therapy session; 15 of 76 patients who attended for therapy dropped out before week 12 post-therapy.
- 128 IBS patients suitable for the study declined to consider nonpharmacological therapy; 29 patients did not attend beyond the first session.
- Biofeedback group had greater decrease in symptom severity scores $p=0.029$.
- 61 patients with refractory IBS, biofeedback and hypnotherapy were equally effective at improving IBS symptom severity scores, total non-gastrointestinal symptom scores and anxiety and depression ratings during 24 weeks follow-up.

Biofeedback for Musculoskeletal Pain Does it Work and What Factors are Associated with Successful Outcomes?

Cori Collette Brimmer MD, MPH, Ryan Anders MD, MPH, Wanda Bonwick PhD, Tom Ayoob MS, BCIA, Marisa Bruckner MD, MS

Seattle Children's

UW Medicine
UW SCHOOL OF MEDICINE

Chart review of patients who underwent biofeedback at a large urban center between January 2008 to April 2016.

Selection criteria:
1) diagnosis of chronic musculoskeletal pain,
2) completed 26 sessions of biofeedback.

Primary Outcome: "Success", defined as decrease in pain score of ≥ 3 points or $\geq 50\%$ on a self-reported 1-10 scale.

Secondary outcomes:
1) proportion achieving any decrease in average pain score in the past week compared with pre-treatment,
2) proportion with decrease in the number of pain days per week compared with pre-treatment,
3) proportion that were completely pain free by end of biofeedback treatment.

Linear and logistic regressions were performed to determine if demographic (gender, age, race/ethnicity), historical (prior medication/non-medication treatments), or psychosocial (depression and anxiety symptoms, sleep latency/duration) factors were associated with treatment success or secondary outcomes.

1) Biofeedback appears to be effective for some patients with musculoskeletal pain, particularly those who:

- have not undergone prior physical therapy, massage, chiropractic or acupuncture,
- those who have high pain scores prior to treatment.

2) Gender (male) may also influence some aspects of response.

3) More research and larger cohorts are needed to confirm the findings and better understand which pediatric patients with MSK pain will respond best to biofeedback.

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Other Information

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Association for Applied Psychophysiology and Biofeedback, Inc.

About Biofeedback

Biofeedback has evolved from a technique in the 1920s and '30s to a mainstream methodology today for treating acute and chronic pain and improving human performance. This scientific-based approach has been shown to be effective in a wide range of conditions, from chronic pain to stress management, from anxiety to depression, from insomnia to ADHD, and from substance abuse to weight management. Biofeedback is a non-invasive, non-pharmaceutical approach to health and performance. It is a safe, effective, and evidence-based approach to health and performance.

The Association for Applied Psychophysiology and Biofeedback (AAPB), the Biofeedback Certification International Alliance (BCIA), and the International Society for Biofeedback and Self-regulation (ISBS) are the leading organizations in the field of biofeedback. We are committed to the advancement of this science and to the education of the public. We are committed to the advancement of this science and to the education of the public. We are committed to the advancement of this science and to the education of the public.

History of Hypnosis in Medicine

- Milton Erickson and Ernest Hilgard were among the first investigators in the United States to undertake a modern, systematic approach to hypnosis.
- American Medical Association acknowledged hypnosis as a valuable tool in medical treatment in 1958: **Council on Mental Health. Medical use of hypnosis. JAMA.1958.**
- National Institutes of Health Technology Assessment Panel report in 1996 judged hypnosis to be a viable and effective intervention for alleviating pain with cancer and other chronic pain: **NIH Technology Assessment Panel on Integration of Behavioral and Relaxation Approaches Into the Treatment of Chronic Pain and Insomnia. JAMA.1996.**

Hypnosis

- Altered state of consciousness or awareness.
- Resembles various meditative states.
- A heightened concentration on a particular idea or image.
- Guided imagery used most often used where, specific images, sounds and smells are suggested for the purpose of altering some symptom.

Sawni A, Breuner CC. Clinical Hypnosis, an Effective Mind-Body Modality for Adolescents with Behavioral and Physical Complaints. Children. 2017 Mar 24;4(4). E19

Training in Hypnosis

- Society for Developmental & Behavioral Pediatrics: <http://www.sdbp.org>
703-556-9222
- Society for Clinical & Experimental Hypnosis: <http://www.sceh.us>
617-469-1981
- American Society for Clinical Hypnosis: www.asch.net

Case Study

- 14-yo girl who had two surgeries for gastro-esophageal reflux disease (GERD) and who had continued chest, back and abdominal pain, as well as vomiting, difficulty eating, weight loss, and anxiety.
- What other options are there for her?

Massage



- **Swedish massage:** long strokes are used to knead and apply friction to the muscles and move the joints to aid flexibility.
- **Deep tissue massage:** patterns of strokes and deep finger pressure on parts of the body where muscles are tight or knotted, focusing on layers of muscle deep under the skin.
- **Trigger point massage** (pressure point massage): a variety of strokes applied deeper with more focused pressure on myofascial trigger points
- **Shiatsu massage:** the therapist applies varying, rhythmic pressure from the fingers on parts of the body that are believed to be important for the flow of a vital energy called qi.

Massage Research

- Jennie C.I. Tsao. Evid Based Complement Alternat Med. Effectiveness of Massage Therapy for Chronic, Non-malignant Pain: A Review. 2007 ; 4(2): 165–179.
- Beider S. Randomized controlled trials of pediatric massage: a review. Complement Alternat Med. 2007;4(1):23-34.

Yoga Therapy

- Increasingly popular as an adjunctive treatment to conventional medicine practices.
- Approximately 16 million people in the US practice yoga
 - Recent poll results:
 - 63% for wellness, 48% for a specific health condition
 - 90% feel it is helpful for their health



Clinical Studies

- Carei, T, Fyfe- Johnson A, Breuner CC. Randomized Controlled Clinical Trial of Yoga in the Treatment of Eating Disorders Mar2010 Journal of Adolescent Health
- Smith C. A randomized comparative trial of yoga and relaxation to reduce stress and anxiety. 2007. Complement Ther Med;15(2):77-83.
- Gurjeet S. Birdee,. Clinical Applications of Yoga for the Pediatric Population: A Systematic Review. Acad Pediatr. 2009 Jul–Aug; 9(4): 212–220.e1-9.



Case Study

- 10 yo male sustained closed head injury playing baseball. He had an epidural which was evacuated but unfortunately has a poor prognosis.
- He is doing poorly and seems to be in pain.

Music Therapy

- Caprilli S et al. Interactive Music as a Treatment for Pain and Stress in Children During Venipuncture: A Randomized Prospective Study. Journal of Developmental & Behavioral Pediatrics. 2007;28(5): 399-403.
- Hartling L. Music for medical indications in the neonatal period: a systematic review of randomised controlled trials. Arch Dis Child Fetal Neonatal Ed 2009;94:F549-F554.
- Stouffer JW. Practice guidelines for music interventions with hospitalized pediatric patients. J Pediatr Nurs. 2007;22(6):448-56.
- Karlene Treurnicht. The Effectiveness of Music in Pediatric Healthcare: A Systematic Review of Randomized Controlled Trials. Evid Based Complement Alternat Med. 2011



- Bradt J, Dileo C, Magill L, Teague A.
- Music interventions for improving psychological and physical outcomes in cancer patients. Cochrane Database Syst Rev. 2016 Aug 15;(8):CD006911.

Animal Therapy




- Cole KM, Gawlinski A. Animal-assisted therapy in the intensive care unit. A staff nurse's dream comes true. *Nurs Clin North Am.* 1995;30(3):529-37.
- Wohlfarth R . Dogs motivate obese children for physical activity: key elements of a motivational theory of animal-assisted interventions. *Frontiers in Psychology.* 2013. 1-7.
- Nahm N. Therapy Dogs in the Emergency Department. *West J Emerg Med.* 2012; 13(4): 363–365.

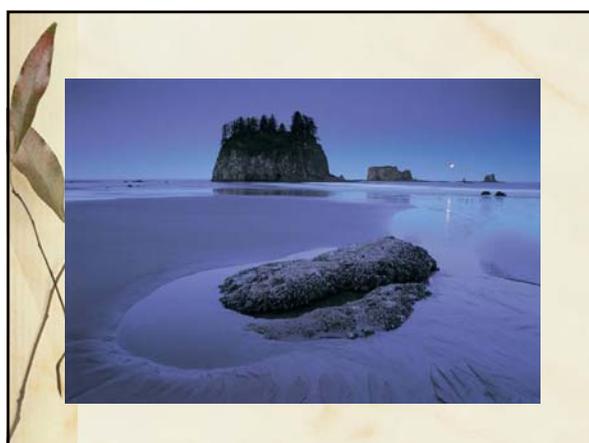
Valeria Calcaterra et al. Post-Operative Benefits of Animal-Assisted Therapy in Pediatric Surgery: A Randomised Study. PLoS One. 2015; 10(6): e0125813. Published online 2015 Jun 3.

AAP Section on Integrative Medicine (SOIM)

- To support the mission of the AAP "to attain optimal physical, mental, and social health and well being for all infants, children, adolescents, and young adults" by:
- promote policies to enhance patient-centered care;
- integrate evidence-based, safe and effective complementary therapies into high quality pediatric practice;
- educate clinicians and families; advocating for appropriated payment for safe and effective services; and
- respectfully collaborate with diverse health professionals dedicated to enhancing the health of infants, children, and adolescents.

Questions?

- cora.breuner@seattlechildrens.org
- (206) 999- 1208



- SECTION ON INTEGRATIVE MEDICINE. Mind-Body Therapies in Children and Youth. *Pediatrics,* 2016 Sep;138(3). 2016 Aug 22.

Case Study

- A 14 year old girl diagnosed with functional abdominal pain is brought into your clinic by her mother. They are frustrated because despite multiple medications and dietary modifications, she continues to complain of abdominal pain several times each month and has missed a lot of school.
- Mom wants to discuss other options for her daughter. How could you advise her?

The effectiveness of hypnosis for reducing procedure-related pain in children and adolescents: a comprehensive methodological review. Accardi MC, Milling LS. *J Behav Med.* 2009;32(4):328-39.

- Review of studies looking at the effectiveness of hypnosis for reducing procedure-related pain in children and adolescents (<19 years).
- Hypnosis was compared with a control condition or an alternative intervention in reducing the procedure-related pain.
- Conclusion: Hypnosis found to be more effective than control conditions in alleviating discomfort associated with bone marrow aspirations, lumbar punctures, voiding cysto-urethograms, pectus excavatum surgery and post-surgical pain

Kohen, D.P. Zajac, R. Self-hypnosis training for headaches in children and adolescents. *J Pediat.* 2007, 150 (6): 635.

- Retrospective review of 144 children/ adolescents referred to a behavioral pediatric program for recurrent headaches
- Reported reduction in frequency of headaches, intensity and duration of headaches.
- Conclusion: training in self-hypnosis had significant improvement of chronic recurrent headaches in children & adolescents

Rutten J. Gut-directed hypnotherapy for functional abdominal pain or irritable bowel syndrome in children: a systematic review. *Arch Dis Child.* 2013; 98(4):252-7.

- 3 RCT comparing HT to a control treatment were included with sample sizes ranging from 22 to 52 children.
- 2 studies examined HT performed by a therapist, one examined HT through self-exercises on audio CD.
- All showed statistically significantly greater improvement in abdominal pain scores among children receiving HT.
- 1 trial reported beneficial effects sustained after 1 year of follow-up.
- 1 trial reported statistically significant improvement in quality of life in the HT group.
- 2 trials reported significant reductions in school absenteeism after HT.

Biology of Hope



- Endorphins, enkephalins released by expectancy and belief (placebo effect)
- Cholecystokinin release blocked by expectancy & belief
- Expectancy + Belief = Hope
- HCPs can reinforce beliefs about medication and treatment efficacy and solidify expectations via words and gestures

Groopman, J. *How people prevail in the face of illness: The anatomy of hope.* New York, NY. Random House, 2004.



Roots of Empathy

- Started in 1996, Roots of Empathy is an evidence-based classroom program that has shown significant effect in reducing levels of aggression among schoolchildren while raising social/emotional competence and increasing empathy.
- At the heart of the program are a neighborhood infant and parent who engage students in their classroom.
- Over the school year, a trained Roots of Empathy Instructor guides the children as they observe the relationship between baby and parent, understanding the baby's intentions and emotions.
- The baby is the "Teacher" and a catalyst, helping children identify and reflect on their own feelings and the feelings of others.

