Washington State Health Care Authority

March 18, 2022 Meeting Materials
Health Technology Clinical Committee

Acupuncture for chronic migraine and chronic tension-type headache

Contents

- ☐ HTCC Clinical Expert information
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- ☐ Acupuncture Final Key Questions

Kathleen Lumiere, DAOM, LAc

Education

- 09/1985- 06/1989 **Bachelor of Arts**
  - ***The Evergreen State College****, Olympia, WA*
  - Areas of concentration: Modern Philosophy, Literature, Writing
- 09/1996-06/2000 **Masters of Acupuncture, certificate in Chinese Herbal Medicine**
  - ***Northwest Institute for Acupuncture and Oriental Medicine (NIAOM),*** *Seattle, WA*
- 06/2005-06/2008 **Doctor of Acupuncture and Oriental Medicine**
  - ***Bastyr University****, Juanita, WA*
  - Area of concentration: TCM Oncology

Faculty and Administrative Positions

- 01/2020-present **Bastyr University, Director of Research for Acupuncture and East Asian Medicine Department**, *Seattle, WA*
  - *Developing a research program for the Acupuncture and East Asian Medicine Department*
  - *Assisting doctoral students with research projects*
  - *Collaborating on research projects with the Acute Pain Service at Harborview Medical Center*
  - *Establishing ongoing clinical research projects at the Bastyr Center for Natural Health*
- 09/2016-01/2020 **Bastyr University, Director, DAOM program**, *Seattle, WA*
  - *Planning curriculum and obtaining approval for a modular DAOM program in Advanced Pain Management at Bastyr*
  - *Designing and scheduling weekend modules*
  - *Budgeting in conjunction with administration and staff*
  - *Hiring effective, collaborative assistants*
  - *Recruiting and hiring world-class instructors*
  - *Recruiting and interviewing doctoral candidates*
  - *Working with university staff and administration to frame policy for the DAOM*
  - *Meeting student needs in diverse ways including academic counseling and remediation*
  - *Seeking out feedback from students at multiple junctures to continually enhance their experience and improve the program*
  - *Sharing student feedback and second cohort strategies in cross-departmental meetings*
  - *Setting up the structure for and maintaining a positive programmatic culture*

- *Organizing a preliminary national accreditation site visit (ACAOM)*
- *Following up on site visit findings*
- *Completing an accreditation self-study*

- 09/2010-present **Bastyr University, Core Faculty, Assistant and Associate Professor of Acupuncture and East Asian Medicine**, School of Traditional World Medicines, *Seattle, WA*
  - *2007- present: Clinical supervision and instruction*
  - *2010-present: Coordinating clinical inventory for AEAM acupuncture shifts, at BCNH and off site shifts*
  - *2010-present: Coordinating the preceptor program*
  - *2010-2015: Writing and administering the annual AEAM Clinic Entry Exam*
  - *Development of new curriculum and instruction of: TCM Nutrition; Electroacupuncture and Biophysics; Clinical Theater; Advanced Tongue and Pulse; Advanced Electroacupuncture and Cold Laser Acupuncture; Case Review; Case Report Writing; Case Discussion*
  - *Modification of curriculum and instruction of: Acupuncture Therapeutics; Herbal Therapeutics; Clinic Entry*
  - *Development, and instruction of online, synchronous clinical training for masters and doctoral level students*
  - *Adaptation of curriculum for online, synchronous courses for masters and doctoral level students*

- 09/2012-09/2019 **Bastyr University, Coordinator, AEAM preceptor program**, *Seattle, WA*
  - *Assisting students in setting up and documenting preceptorships with approved, licensed acupuncturists*
  - *Communicating with potential and active preceptors*
  - *Working with staff and administration to ensure fulfillment of preceptorship requirements*

- 03/2014-present **Seattle Institute of Oriental Medicine (SIOM), Adjunct Faculty**, *Seattle, WA*
  - *Development and teaching Biophysics and Electroacupuncture; Acupuncture Techniques; and Auricular Acupuncture, Auricular Acupuncture; Sensitive Points; Case Reports and Research Methods, both in person and online*

- 03/2016-present **Oregon College of Oriental Medicine (OCOM), Guest Lecturer in DAOM program**, *Portland, OR*
  - *Development and teaching a module in TCM Integrated Oncology for doctoral students*
- 05/2020-present **New England School of Acupuncture, Guest Lecturer**
  - *Collaborative online, synchronous instruction of Physiology of Acupuncture course*

- *Development and teaching Physics*

Clinical Experience

- 01/1999-06/2003 **Founder and organizer, Volunteer Acupuncture Program**, 45th St. Clinic (a low-income neighborhood health care facility), *Seattle, WA*
- 06/2000-present **Acupuncturist,** private practice, *Seattle, WA*
- 09/2008-present **Clinical supervisor and instructor** for Bastyr University at the following locations:
  - Bastyr Center for Natural Health, *Seattle, WA*
  - Bastyr University, *Juanita, WA*
  - Harborview Medical Center, *Seattle, WA*
  - Rainier Park Community Clinic/ NeighborCare, *Seattle, WA*
  - Skagit Valley Cancer Center, *Mt. Vernon, WA*
  - Providence Regional Cancer Partnership, *Everett, WA*
  - Highline Cancer Center*, Burien, WA*

Research

- **Capstone research project: "A Review of Chinese Herbal Medicine for the Prevention of Secondary Cancer in Breast Cancer Survivors**," 2008.
- **Community Acupuncture patient demographics: a qualitative, cross-sectional pilot study.** The American Acupuncturist, 2010, authors Kathleen Lumiere (PI), Corey Miller, Tim Miller.
- **Awarded Faculty Seed Grant,** for Scalp electroacupuncture in stroke rehabilitation research : fMRI methodological issues and solutions. Bastyr University, 2013
- **Poster presentation of original research for Scalp electroacupuncture in stroke rehabilitation research : fMRI methodological issues and solutions**. Authors Kathleen Lumiere, Bensheng Qiu and Leanna Standish. The Society for Acupuncture Research, an international conference, University of Michigan, *Ann Arbor, MI*, 2013
- **Poster presentation of original research for Integration of Doctor of Acupuncture & Oriental Medicine (DAOM) Students in an Acute Pain Service.** Authors: Ray Zhang, Kathleen Lumiere, Debra Gordon, Ivan Lesnik, Sara Bayer. The Society for Acupuncture Research, an international conference, University of Vermont, Burlington, VT, 05405, 2019.
- Research article (also listed in Publications): **Integration of Doctor of Acupuncture and Oriental Medicine Students in a Trauma Center's Acute Pain Service: In-Person and Remote Training and Patient Car**e. Kathleen Lumiere, Raymond Zhang, Ivan Lesnik, Sara Bayer, Carol Metcalf, and Debra B. Gordon. *Medical Acupuncture,* 08/25/2021

Publications/interviews

- Book Review: **The Patient-Practitioner Relationship in Acupuncture**. *The American Acupuncturist*. Summer, 2009.
- **Community Acupuncture patient demographics: a qualitative, cross-sectional pilot study.** The American Acupuncturist, 2010, authors Kathleen Lumiere (PI), Corey Miller, Tim Miller
- Book Review: **Treating Autoimmune Disease with Chinese Medicine.** *The American Acupuncturist*. Fall, 2011
- Interview: **Acupuncture and Electroacupuncture for GERD**, e-published March, 2012
- Interview: **Centuries-Old Art of Cupping May Bring Some Pain Relief.** *The Wall Street Journal*, November, 2012
- Book Review: **The Pocket Atlas of Chinese Medicine**. *The American Acupuncturist*. Fall, 2009
- MamaBaby Haiti interview e-published 2014.
- **Bastyr University: On the Front Lines of the Pain Epidemic.** Kathleen Lumiere, Elizabeth Dart, Reshmi Yandipalli, Chaiya Sherman. *Acupuncture Today*, July, 2018.
- **DIY Anxiety Relief with Acupressure**. Bottom Line Inc. e-published March 4, 2019
- **Inside a DAOM Internship at a Level 1 Trauma Center.** *Acupuncture Today.* Interview published August, 2019
- Research article: **Integration of Doctor of Acupuncture and Oriental Medicine Students in a Trauma Center's Acute Pain Service: In-Person and Remote Training and Patient Car**e. Kathleen Lumiere, Raymond Zhang, Ivan Lesnik, Sara Bayer, Carol Metcalf, and Debra B. Gordon. *Medical Acupuncture,* 08/25/2021

Presentations

- **Keynote speaker at the 2009 Cancer Survivor Celebration** in Anacortes, WA
- **Acupuncture and Traditional Chinese Medicine, a view of vibrant age.** World Presidents Organization conference Bastyr University, Juanita WA 2010
- **Acupuncture and electroacupuncture in the treatment of pain.** University of Washington Medical School, Pain Fellows Talk, Seattle, WA 2010
- **East Meets West: Understanding Chinese Medicine & Qi Gong**. Seminar for The Seattle Nursing Association, The Good Shepherd Center, Seattle, WA 2011
- Lecture at Aljoya Retirement Community, Seattle, WA 2014: **Acupuncture and Chinese Medicine for Pain and More**
- Television spot on Q13 Seattle, WA 2014: **Chinese Medicine for Spring Allergies**
- BCNH Living Naturally Talk 2014: **Natural Ways to Ease Spring Allergies**

- Lecture at Aljoya Retirement Community, Seattle WA 2014: **Acupuncture and Chinese Medicine for Aging Well**
- Lecture at Aljoya Retirement Community, Seattle WA 2015: **Acupuncture and Joint Pain**
- Lecture at Ida Culver House, Seattle, WA 2015: **Acupuncture for Aging Joints**
- Lecture at Aljoya Retirement Community, Seattle WA 2016: **Acupuncture for Aching Joints**
- Guest lecturer Oregon College of Oriental Medicine (OCOM), DAOM program: **TCM Oncology**
- **Acupuncture and Advanced Pain Management at a Level One Trauma Center: Conventional Care and Clinical Education."** Presentation 4th American Traditional Chinese Medicine (TCM) Congress, Bellevue, WA, August 4, 2018

Additional training

- 1999 **Japanese Acupuncture**, The Northwest Institute of Acupuncture and Oriental Medicine, Seattle, WA
- 2006 **Certificate in TCM Oncology** with Tai Lahans, *Seattle, WA*
- 2010 **Externship in TCM Integrated Oncology** at Longhua Hospital, *Shanghai, China* and Sichuan People's Hospital, *Chengdu, China*
- 2010 **Teaching the Millennial Student (and Technology)**, *San Francisco, CA*
- 2015 and 2016 **Restorative Justice Training, Community Building**, *Seattle, WA*

Service

- 2000-2003 **Founder and administrator of volunteer acupuncturist program for underserved populations,** The 45th St. Clinic, *Seattle, WA*
- 2013-present **Preceptor of numerous acupuncture students in private practice,** *Seattle, WA*
- 2013-present **Mentor of faculty and alumni within acupuncture and East Asian Medicine**
- 2014 **Volunteer acupuncturist with Oso Mudslide Relief**, *Oso, WA*
- 2014-2016 **Contributor to The Center for Integrated Care**, online international alternative medicine volunteer association
- 2014-present **Representative on Bastyr Faculty Senate**, vice-chair 06/2020-present
- 01/2020-present **Founder for the academic/community group Health and Climate Crisis**, working on developing educational offerings for Bastyr and wider health community members.
- 06/2020-05/2021 **Main organizer for online conference in May 2021, Health in the Climate Crisis, Integrative Approaches for Individuals and Communities**
- 04/2021 -present **Main organizer for Ching Community Gardens,** a local project to protect a site important for local Asian American history and community gardens, *Shoreline, WA*

Professional Memberships

- Member, Washington Acupuncture and Oriental Medicine Association (WEAMA)
- Diplomate, National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM)
- The Society for Acupuncture Research (SAR)
- Acupuncturists Without Borders
- Washington Health Care Climate Alliance

Licensure/Board Certification

- 2000-present NCCAOM Board Certified Acupuncturist
- 2000-present Washington State Licensed Acupuncturist

Health Technology Clinical Committee Conflict of Interest Disclosure

Washington State Health Care Authority

As stewards of public funds, the practicing clinicians who serve (or apply to serve) on the Committee strive to uphold the highest standards of transparency and impartiality. Identifying financial, professional, and other interests contribute to the effective management of perceived, potential, and/or real conflicts of interest/bias that could affect Committee determinations. (WAC 182-55)

This Conflict of Interest form must be completed by an applicant for appointment to the State of Washington Health Technology Clinical Committee (HTCC) or appointment to any of its subcommittees or work groups.

A member of the HTCC or any of its subcommittees or work groups may not participate in discussions or deliberations of any class of drugs or any agenda item for which a conflict of interest is identified and may not vote on any such matter.

If a conflict of interest is so great as to make it difficult for any member to participate meaningfully in the work of the HTCC, that member may be asked to resign.

1 Applicant information

First name: Kathleen

Middle initial:

Last name: Lumiere

Phone number:

Email:

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.

List amounts totaling $1,000 or more from a single source.

Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.

Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.

Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity.

B. Employment including work as an independent contractor, consultant, whether written or unwritten.

C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.

D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.

E. Participating on a company's proprietary governing boards.

F. Participating in a speakers bureau.

G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topics(s):

Not related to headache, but yes, related to acupuncture. Please see CV for details.

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topics(s):

No

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

No

4 Signature

I have read the Conflict of Interest Disclosure form. I understand the purpose of the form and agree to the application of the information to determine conflicts of interest. The information provided is true and complete as of the date the form was signed. If circumstances change, I am responsible for notifying committee staff in order to amend this disclosure. I will complete this form annually by July 1st of each year of committee membership.

Signature	Date
	Kathleen Lumiere 12/17/21

please return form to **shtap @hca.wa.gov**, or:

Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

Washington State Health Care Authority

Agency medical director comments

Acupuncture for Chronic Headache: Re-review

Emily Transue, MD, MHA
Medical Director for Employee and Retiree Benefits
WA Health Care Authority

March 18, 2022

Chronic headache

- Headache disorders are a leading cause of disability and diminished quality of life
- Common reason for patient visits in primary care, neurology, and emergency departments
- Chronic headache (15+ days/month) less common (1-2% of population each for chronic tension and chronic migraine) but very high impact
- Costs of chronic headache are high
  - Estimated medical costs of chronic migraine $8500-$9500/year*
  - High impact on absenteeism/presenteeism

*Polson et all, American Journal of Managed Care, Feb 2020

Acupuncture for Chronic Headache

- Thin, solid needles inserted at specific acupuncture points
- Placement and technique can vary
  - Arms, legs, back, head or face
  - Generally left in 10-20 minutes
  - "Auricular acupuncture:" distinct, sites on ear, dart-shaped needles left in 2-5 days
  - Electrical stimulation is sometimes but not always used
- Mechanism:
  - Traditional understanding in Eastern medicine: Adjusts flow and balance of xi (vital energy) in the body
  - May stimulate nerves, muscles, and connective tissue; may release endorphins and modulate immune response
- Use in headache is common (approx. 10% of acupuncture users)

Acupuncture for headache: 2017 HTCC review

- The Health Technology Clinical Committee reviewed a number of modalities for treatment of chronic headache in 2017
  - Botulinum toxin, acupuncture, massage, trigger point injections, transcranial magnetic stimulation, manipulation/manual therapy
- Botox was covered with conditions, all others non-covered
- Rationale for non-coverage of acupuncture: Evidence not felt to be sufficient to justify coverage

Acupuncture for Chronic Headache: 2022 HTCC re-review

- Selected for re-review on the basis of newly available evidence and petition/public comment
- New evidence includes:
  - 3 new RCTs evaluating chronic migraine
  - No new studies for chronic tension-type headache
  - No studies for chronic daily headache

Washington State Health Care Authority

Current state agency policy: Acupuncture for chronic headache

Agency	Policy
ERB*/UNIFORM MEDICAL PLAN (UMP)	Non-Covered
MEDICAID	Non-Covered
LABOR AND INDUSTRIES	Non-Covered

*Employee and Retiree Benefits (ERB), the HCA program encompassing the Public Employees Benefits Board (PEBB) and School Employees Benefits Board (SEBB)

Current state agency policy: Acupuncture (any indication)

- Uniform Medical Plan (PEBB/SEBB):
  - Covers up to 24 visits per calendar year for any indication other than chronic headache
- Medicaid (FFS and Managed Care):
  - Currently not covered in FFS; MCOs may cover at their discretion
  - New benefit created in 2022 legislation, to begin in 2023
  - Specifics not yet determined
- Labor and Industries:
  - Covers for low back pain only, up to 10 visits/claim

Washington State Health Care Authority

Current utilization
Acupuncture: Migraine or other headache

	2017	2018	2019	2020
Medicaid FFS	NR	NR	NR	NR
Medicaid MCO				
Members	16	16	15	23
Sessions/Member	9	6	11	13
Total sessions	150	94	160	276
ERB/UMP				
Members	314	161	166	186
Sessions/Member	20	18	16	19
Total sessions	6,180	2,900	2,726	3,874
LNI	NR	NR	NR	NR

NR: Member numbers under 11 not reported

Cost Experience
(Cost per member; Total cost)

	2017	2018	2019	2020
Medicaid FFS	N/A	N/A	N/A	N/A
Medicaid MCO	$124 $1,980	$30 $480	$334 $5,012	$370 $8,508
UMP	$691 $216,886	$670 $107,877	$584 $96,875	$537 $111,785
LNI	NR	NR	NR	NR

Average amounts paid per individual, paid amounts >0$

Agency medical director concerns

Safety = Low

Efficacy = Medium/High

Cost = Low/Medium

Key questions

- In adults with chronic migraine, chronic tension-type headache, or chronic daily headache:
  - What is the evidence of the short- and long-term efficacy and effectiveness of acupuncture, compared with standard alternative treatment options, placebo, sham, waitlist or no treatment?
  - What is the evidence regarding short- and long-term harms and complications of acupuncture with standard alternative treatment options, placebo, sham, waitlist or no treatment?
  - Is there evidence of differential efficacy, effectiveness, or safety of acupuncture compared with standard alternative treatment options, placebo sham, waitlist or no treatment? Include consideration of age, sex, race, ethnicity, socioeconomic status, payer, and worker's compensation.
  - What is the evidence of cost-effectiveness of acupuncture compared with standard alternative treatment options, placebo, sham, waitlist or no treatment?

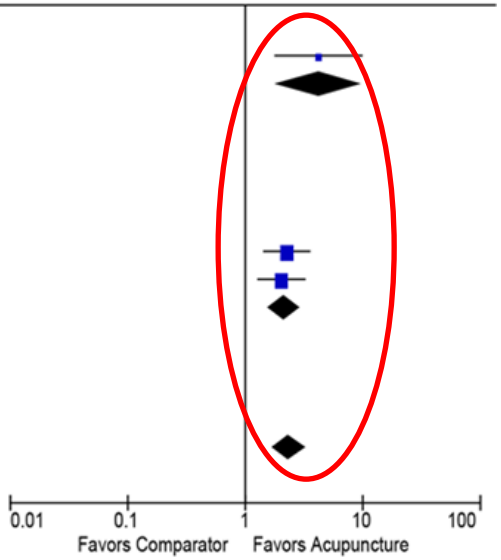
Data considerations

- Funding for research on health technologies tends to rely heavily on for-profit model, with heavy investment by companies that stand to benefit from marketing expensive new technologies (drugs, devices)
- While some funding is available for research into alternative therapies through the National Institutes of Health (NIH)'s National Center for Complementary and Integrative Health (NCCIH) and elsewhere, funds are limited (in 2019, NCCIH received 0.3% of NIH budget)
- This impacts size and number of studies, design expertise, etc.
- Generally low quality of evidence in studies reviewed per GRADE methodology; need to consider this particularly in the setting of research environment
  - Consider likelihood of systematic bias skewing results, vs lower impact methodological concerns

Efficacy: Chronic Migraine

Treatment responders: % with ≥50% ↓ mean HA days

Study or Subgroup	Comparator	F/U (wks)	Acupuncture Events	Acupuncture Total	Comparator Events	Comparator Total	Weight	Risk Ratio M-H, Random, 95% CI
Short-term								
Yang 2011	Topiramate	1	21	33	5	33	13.7%	4.20 [1.80, 9.80]
Subtotal (95% CI)				**33**		**33**	**13.7%**	**4.20 [1.80, 9.80]**
Total events			**21**		**5**			
Heterogeneity: Not applicable								
Test for overall effect: Z = 3.32 (P = 0.0009)								
Long-term								
Musil 2018	WL + UC	24	30	37	14	39	44.0%	2.26 [1.44, 3.53]
Vickers 2004	UC	36	49	161	21	140	42.2%	2.03 [1.28, 3.21]
Subtotal (95% CI)				**198**		**179**	**86.3%**	**2.14 [1.56, 2.95]**
Total events			**79**		**35**			
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.11$, df = 1 (P = 0.74); $I^2 = 0\%$								
Test for overall effect: Z = 4.67 (P < 0.00001)								
Total (95% CI)				**231**		**212**	**100.0%**	**2.35 [1.70, 3.24]**
Total events			**100**		**40**			
Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 2.24$, df = 2 (P = 0.33); $I^2 = 11\%$								
Test for overall effect: Z = 5.21 (P < 0.00001)								
Test for subgroup differences: $Chi^2 = 2.12$, df = 1 (P = 0.15), $I^2 = 52.8\%$								



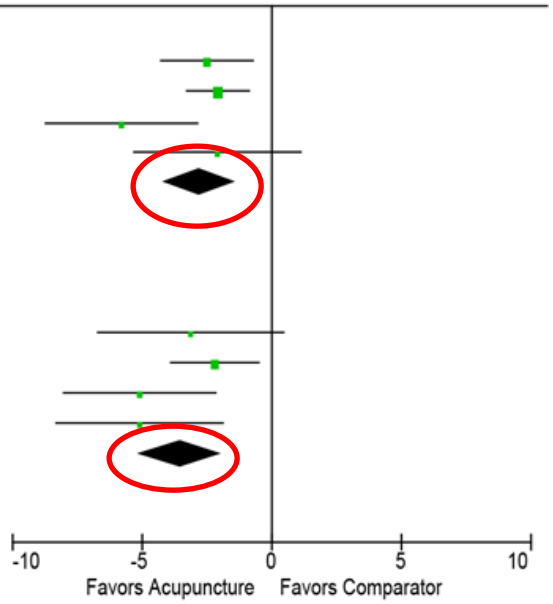
Absolute differences in % responders:

- 64% vs 15% (Yang, short term)
- 81% vs 35% (Musil), 30% vs 15% (Vickers) (both long term)
- Low strength of evidence (SOE)

Efficacy: Chronic Migraine

Mean ↓ in any headache days/month

Study or Subgroup	Comparator	F/U(wks)	Acupuncture Mean	Acupuncture SD	Acupuncture Total	Comparator Mean	Comparator SD	Comparator Total	Weight	Mean Difference IV, Random, 95% CI
Short-term										
Yang 2011	Topiramate	1	10.6	3.23	33	13.1	4.09	33	17.4%	-2.50 [-4.28, -0.72]
Habibabadi 2021	Sham+UC	4	4.92	3.08	40	7	2.36	40	25.1%	-2.08 [-3.28, -0.88]
Naderinabi 2017	Sodium valproate	8	7.6	6.8	25	13.4	4.4	50	8.8%	-5.80 [-8.73, -2.87]
Naderinabi 2017 Botox	Botox	8	7.6	6.8	25	9.7	6.5	50	7.6%	-2.10 [-5.32, 1.12]
Subtotal (95% CI)					**123**			**173**	**58.9%**	**-2.80 [-4.19, -1.42]**
Heterogeneity: Tau² = 0.85; Chi² = 5.39, df = 3 (P = 0.15); I² = 44%										
Test for overall effect: Z = 3.98 (P < 0.0001)										
Long-term										
Musil 2018	WL + UC	24	4.97	6.6	37	8.1	9.2	39	6.4%	-3.13 [-6.72, 0.46]
Vickers 2004	UC	36	11.4	7.5	161	13.6	7.5	140	18.3%	-2.20 [-3.90, -0.50]
Naderinabi 2017	Sodium valproate	12	8	6.8	25	13.1	4.4	50	8.8%	-5.10 [-8.03, -2.17]
Naderinabi 2017 Botox	Botox	12	8	6.8	25	13.1	6.5	50	7.6%	-5.10 [-8.32, -1.88]
Subtotal (95% CI)					**248**			**279**	**41.1%**	**-3.54 [-5.15, -1.94]**
Heterogeneity: Tau² = 0.82; Chi² = 4.27, df = 3 (P = 0.23); I² = 30%										
Test for overall effect: Z = 4.32 (P < 0.0001)										



Absolute reduction in HA days:

- 2.8 HA days/month short term (Low SOE)
- 3.5 HA days/month long term (Moderate SOE)

SUMMARY: Efficacy – Chronic Migraine

Outcome	Timing	CM – Acupuncture vs. sham and active control
Responders: ≥50% reduction in *any* headache days from baseline	Short term (1 wk.)	**↑, large effect, Low SOE** (1, N=66; vs. topiramate)
	Long term (24-36 wks.)	**↑, large effect, Moderate SOE** (2, N=377; vs. topiramate, WL/UC)
Responders: ≥50% reduction in *moderate/severe* headache days from baseline	Short (1 wk.) and Long term (36 wks.)	**↑, large effect (short term), small effect (long term), Low SOE** (2, N=367; vs. topiramate, UC)
Responders: ≥50% reduction in *mild* headache days from baseline	Long term (36 wks.)	**↑, small effect, Low SOE** (1, N=301; vs. UC)
Responders: ≥35% improvement in headache score from baseline	Long term (36 wks.)	**↑, small effect, Low SOE** (1, N=301; vs. UC)
Reduction (mean Δ) in *any* headache days/month	Short term (1-8 wks.)	**↑, 2.8 days, Low SOE** (3, N=296; vs. sham+UC, topiramate, sodium valproate, Botox)
Reduction (mean Δ) in *any* headache days/month	Long term (12-36 wks.)	**↑, 3.5 days, Low SOE** (3, N=527; vs. UC, WL+UC, topiramate, sodium valproate, Botox)
Reduction (mean Δ) in *moderate/severe* headache days/month	Short (1 wk.) and Long term (36 wks.)	**↑, 2.3 days (short term), 1.5 days (long term), Low SOE** (2, N=367; vs. topiramate, UC)
Reduction (mean Δ) in *mild* headache days/month	Long term (36 wks.)	**↑, 1.6 days, Low SOE** (1, N=301; vs. UC)
Reduction in headache episodes/attacks per month	Short term (4 wks.)	**Insufficient evidence** (1, N=80; vs. sham/UC)
	Long term (24 wks.)	**Θ Low SOE** (1, N=76; vs. WL/UC)
MIDAS	Short (1 wk.) and Long term (24 wks.)	**↑, MD −12.0 (short term), −13.6 (long term), Low SOE** (2, N=124; vs. topiramate, WL/UC)

nalytics

↑ = Acupuncture favored ↓ = Comparator favored Θ = no diff. b/w groups

Effectiveness: Chronic tension-type headache (TTH)

- No new evidence since prior review
- All evidence deemed to be of “insufficient” quality
- Pooled evidence on short term impact does not show statistically significant difference from sham; only one long term study, which did not report data

Effectiveness: Chronic daily headache

- No evidence identified

Safety

- Serious adverse events (AEs): None reported in any studies (though sizes small)
- Non-serious adverse events:
  - Broadly lower risk for acupuncture than for comparator treatments such as topiramate or botulinum toxin
  - Generally related to needle insertion
- Review of acupuncture AEs (all indications): BMJ*, 7679 studies (Not part of the evidence report)
  - Serious AEs approx. 8 per million treatments
  - AEs requiring treatment 1 per 1000
  - “Acupuncture can be considered among the safer treatments in medicine.”

*BMJ Open 2021;11:e045961. doi:10.1136/ bmjopen-2020-045961

Differential effectiveness

- Limited data on subgroups
- 1 RCT (Acupuncture vs usual care) suggests that those with more severe symptoms had more improvement with acupuncture
- 1 RCT (acupuncture vs topiramate) suggests those with higher baseline showed greater improvement with acupuncture
- Both “insufficient” strength of evidence
- No evidence for other differential impact

Costs/Cost-effectiveness:

- No new evidence since prior review
- Very limited data
- UK studies on acupuncture for chronic migraine suggests cost-effective, with incremental cost-effectiveness ratio (ICER) ranging from 810-12,333 pounds ($1088-16,403)/quality adjusted life year (QALY)
  - However, generalizability to US experience is limited

Coverage comparisons

Medicare	Aetna	Cigna	Kaiser	Regence
Non-covered for headache (low back only)	Covered for chronic headache (12+ weeks); Non-covered for tension headache	Covered for migraine and tension; general medical necessity standard applies	Covered for chronic headache; self-referral up to plan-defined limit, then with PA	Non covered for headache in book of business (follows eviCore guidelines)

Guidelines:

- 4/5 guidelines reviewed support use; VA/DoD neither for nor against
- **National Institute for Health and Care Excellence (NICE) (2012, updated May 2021):**
  - Tension-type: Consider a course of up to 10 sessions over 5-8 weeks for prophylaxis
  - Migraine: If propranolol and topiramate are unsuitable or effective, consider up for 10 sessions over 5-8 weeks according to the person's preference, comorbidities, and risk of adverse effects

Agency Medical Director Group
Recommendation:

Scope: This decision applies to adults (age 18 and older). This decision supersedes the 2017 HTCC "Treatment of chronic migraine and chronic tension-type headache" decision for acupuncture only; otherwise the 2017 decision is unaffected.

- **For Chronic Migraine:** Acupuncture is a covered benefit with conditions
  - Must meet criteria for chronic migraine, i.e., headache occurring on 15 or more days/month for more than 3 months, which, on at least 8 days/month, has the features of migraine headache
  - Must have a referral from a qualified provider (qualified to diagnose per Washington State, includes MD, PA, ARNP, etc.)
  - Up to 24 sessions over the course of up to 12 weeks (per approval)
- **For Chronic Tension-type Headache:** Acupuncture is non-covered
- **For Chronic Daily Headache:** Acupuncture is non-covered

Agency Medical Director Group
Recommendation:

- Rationale:
  - For chronic migraine:
    - Evidence suggests a modest but significant benefit
    - Risks are low, and costs are modest particularly relative to the disability and expense of the condition
    - While quality of evidence is generally low, evidence is felt to be adequate for a coverage decision
    - Definition (12 vs 15 days): matched definitions used for study inclusion, slightly more liberal than International Classification of Headache Disorders
  - For chronic tension-type headache, evidence does not suggest an impact
  - For chronic daily headache, no evidence available

Washington State Health Care Authority

Questions?

More Information:

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AGENCY MEDICAL DIRECTOR GROUP
Appendix

Definition of Chronic Migraine (International Classification of Headache Disorders, 3rd edition)

- Headache occurring on 15 or more days/month for more than 3 months, which, on at least 8 days/month, has the features of migraine headache.

Diagnostic criteria:

A. Headache (migraine-like or tension-type-like) on ≥15 days/month for >3 months, and fulfilling criteria B and C

B. Occurring in a patient who has had at least five attacks fulfilling: *Criteria B-D for 1.1 Migraine without aura and/or* criteria B and C for 1.2 *Migraine with aura (see next page)*

C. On ≥8 days/month for >3 months, fulfilling any of the following[2]:

1. Criteria C and D for 1.1 *Migraine without aura*
2. Criteria B and C for 1.2 *Migraine with aura*
3. Believed by the patient to be migraine at onset and relieved by a triptan or ergot derivative

D. Not better accounted for by another ICHD-3 diagnosis[3;4;5].

AGENCY MEDICAL DIRECTOR GROUP
Recommendation:

Criteria B-D for 1.1 Migraine without aura:

B. Headache attacks lasting 4-72 hr (untreated or unsuccessfully treated)

C. Headache has at least two of the following four characteristics:

- *unilateral location*
- *pulsating quality*
- *moderate or severe pain intensity*
- *aggravation by or causing avoidance of routine physical activity (eg, walking or climbing stairs)*

D. During headache at least one of the following:

- *nausea and/or vomiting*
- *photophobia and phonophobia*

Criteria B and C for 1.2 *Migraine with aura*

- *B. One or more of the following fully reversible aura symptoms:*
  - *visual*
  - *sensory*
  - *speech and/or language*
  - *motor*
  - *brainstem*
  - *retinal*
- *C. At least three of the following six characteristics:*
  - *at least one aura symptom spreads gradually over ≥5 minutes*
  - *two or more aura symptoms occur in succession*
  - *each individual aura symptom lasts 5-60 minutes1*
  - *at least one aura symptom is unilateral2*
  - *at least one aura symptom is positive3*
  - *the aura is accompanied, or followed within 60 minutes, by headache*

Washington State Health Care Authority

Acupuncture for chronic migraine and chronic tension-type headache

Order of scheduled presentations:

No scheduled comments

Day of comments:

	Name
1	
2	
3	
4	
5	
6	

Acupuncture for Chronic Migraine and Chronic Tension-type Headaches

Presentation to

Washington State Health Care Authority
Health Technology Clinical Committee

Erika D. Brodt, BS
March 18, 2022

Report prepared by:
Erika D. Brodt, BS
Shelby Kantner, BA
Mark Junge, BS
Andrea C. Skelly, PhD, MPH

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Previous Reports and Rationale

2017 Report –

Various treatments for chronic migraine (CM), chronic tension-type headache (CTTH), and chronic daily headache (CDH), to include acupuncture (*focus of this re-review*):

- **CM:** 2 RCTs (acupuncture vs. UC [1 RCT], vs. topiramate [1 RCT])
- **CTTH:** 4 RCTs (acupuncture vs. sham [2 RCTs], vs. physical training and vs. relaxation [1 RCT], vs. physiotherapy [1 RCT]
- **CDH:** No evidence identified.

Conclusions related to acupuncture:

- Effectiveness: Primarily low strength of evidence (SOE) that acupuncture may be effective for treatment of CM; Insufficient evidence for CTTH.
- Safety: Adverse events poorly reported; Low SOE suggesting that acupuncture may be as safe or safer than other active treatments for CM.

Re-review Rationale: newly available published evidence

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Background – Epidemiology & Burden of Disease

- Headache disorders combined are the second highest cause of years lost to disability globally
- In 2018, the age-adjusted prevalence of migraine or severe headache was 15.9% across all U.S. adults:
  - Chronic migraine: 1.4%–2.2%
  - Chronic tension-type headache: 0.9%–2.2%
- Usual care treatments
  - Pharmacological: NSAIDs, Triptans, Ergotamine, Lasmiditan, anti-calcitonin gene-related peptide (CGRP) treatments*, beta-blockers, anticonvulsants
  - Nonpharmacological: neuromodulation, trigger management, lifestyle changes, psycho-behavioral training
- **Focus for chronic headache:** preventative treatment

Aggregate Analytics

Background – General Headache Classification

- **Primary vs. Secondary**
  - **Primary:** are not caused by an underlying disease; migraine and tension-type headache are the most common
  - **Secondary:** are a result of a recognized disease process or other medical condition (e.g., from musculoskeletal disorders)
- **Frequency**
  - **Chronic:** ≥ 15 days per month or ≥ 180 days per year
  - **Episodic:** 0-14 days per month
- **Diagnosis of 1° HA**
  - Combination of clinical history, headache diary, exclusion of causes for secondary headache

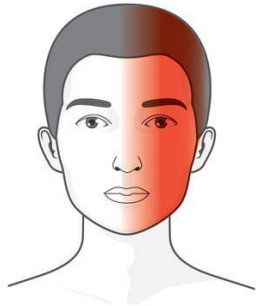
International Classification of Headache Disorders 3rd edition

Aggregate Analytics

Background – Characteristics

➢ Chronic Migraine

- Symptoms occurring unilaterally in a pulsating quality
- Attacks of moderate to severe in intensity ranging from 4 to 72 hours
- Attacks associated with nausea, sensitivity to light, and/or sensitivity to noise
- With or without aura (i.e., a disturbance caused by hyper-excited nerves in the brain resulting in visual, sensory, speech, and/or language, motor, brainstem, or retinal symptoms)


Migraine

➢ Chronic Tension-Type Headache (TTH)

- Symptoms characterized as a dull, non-pulsatile, diffuse, band-like bilateral pain in the head, scalp, or neck
- Mild to moderate intensity, last 30 minutes to several days
- Does not generally involve nausea, sensitivity to noise and light, or unilateral pain

➢ **Chronic Daily Headache:** for purposes of this report, classified as coexistence of migraine and TTH in combination, occurring >15 days/month. This is not listed as an official classification.

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Background – Acupuncture

- Used for thousands of years, a part of TCM
- Holistic medicine with roots in Eastern philosophy
- Focuses on activating and balancing qi
  - Qi is a difficult word to translate and is therefore often left untranslated; “vital energy” source in humans
- Uses solid, filiform needles that are thin and flexible and inserted into the body at specific acupuncture points
  - Manual or electrical needle stimulation
- Individualized, semi-standardized, or standardized technique
- No FDA guidance for acupuncture as an intervention
  - Several different types of needles have received FDA approval
- Commonly used in headache disorders
  - 2006 survey: 9.9% of patients that had used acupuncture used it to treat headache disorders

Aggregate Analytics

Key Questions

In adults with chronic migraine and chronic tension-type headache:

1. What is the evidence of the short- and long-term **efficacy and effectiveness** of acupuncture compared with standard active treatment options, placebo, sham, waitlist, or no treatment?
2. What is the evidence regarding short- and long-term **harms and complications** of acupuncture compared with standard active treatment options, placebo, sham, waitlist, or no treatment?
3. Is there evidence of **differential efficacy, effectiveness, or safety** of acupuncture compared with standard active treatment options, placebo, sham, waitlist, or no treatment?
4. What is the evidence of **cost-effectiveness** of acupuncture compared with standard active treatment options, placebo, sham, waitlist, or no treatment?

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Inclusion Criteria

Population - Patients with

- Chronic migraine, chronic tension headache [and chronic daily headache]
  - Chronic defined as **≥15 days/month** for at least 3 months (ICHD, 3rd edition); **mean ≥12 headache days**/episode/attacks per month considered to meet the criteria for chronic headache for this report.

Interventions:

- Acupuncture

Comparator(s)

- Placebo, sham, usual care/treatments, waitlist, no treatment

Study design

- RCTs, observational studies (for safety only), full economic studies; focus on studies with least potential for bias

Publication

- Full-length studies published in English in peer-reviewed journals, FDA reports (no meeting abstracts, proceedings)

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Inclusion Criteria, cont.

Primary Outcomes *(prioritized via clinical expert input)*

- **Efficacy**
  - Proportion of treatment responders
  - Complete cessation/prevention of HA
  - Reduction in number of episodes
  - Reduction in number of HA days/HA-free days
  - Validated Function/Disability Measures
- **Adverse events or complications**
- **ICER/other measures of cost-effectiveness**

Follow-up Definitions

- Short-term: ≤ 8 weeks post-treatment
- Intermediate-term: > 8 to < 12 weeks post-treatment
- Longer-term: ≥12 weeks post-treatment

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Strength of Evidence (SoE)

SoE for overall body of evidence for primary outcomes was assessed based on:

- **Risk of bias**: the extent to which the individual included studies protect against bias
  - Appropriate randomization
  - Allocation concealment
  - Intention to treat analysis
  - Blind assessment of outcomes
  - Co-interventions applied equally
  - Adequate follow-up (≥80%) and <10% follow-up difference between groups
  - Controlling for confounding
- **Consistency**: degree to which estimates are similar in terms of range and variability.
- **Directness**: whether the evidence is directly related to patient health outcomes.
  NOTE: None were considered indirect.
- **Precision**: level of certainty surrounding the effect estimates.
- **Publication/report bias**: selective reporting or publishing.

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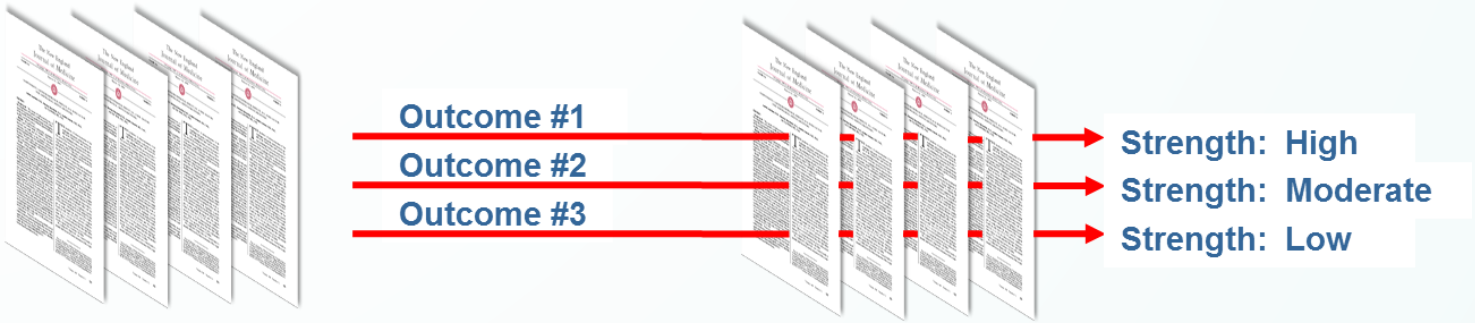
Systematic Review Process

Studies meeting eligibility criteria
- Efficacy: RCTs (effectiveness)
- Harms: RCTs, observational studies
- Economic studies

Risk of Bias Appraisal (Study)
- Low ROB, Mod. Low ROB, or Mod. High ROB)

Synthesis/analysis

Overall Strength of Evidence Determination (GRADE/AHRQ)



Strength of Evidence Ratings	
High	Very confident that effect is true.
Moderate	Moderately confident.
Low	Limited confidence.
Insufficient	No evidence or no confidence in effect.

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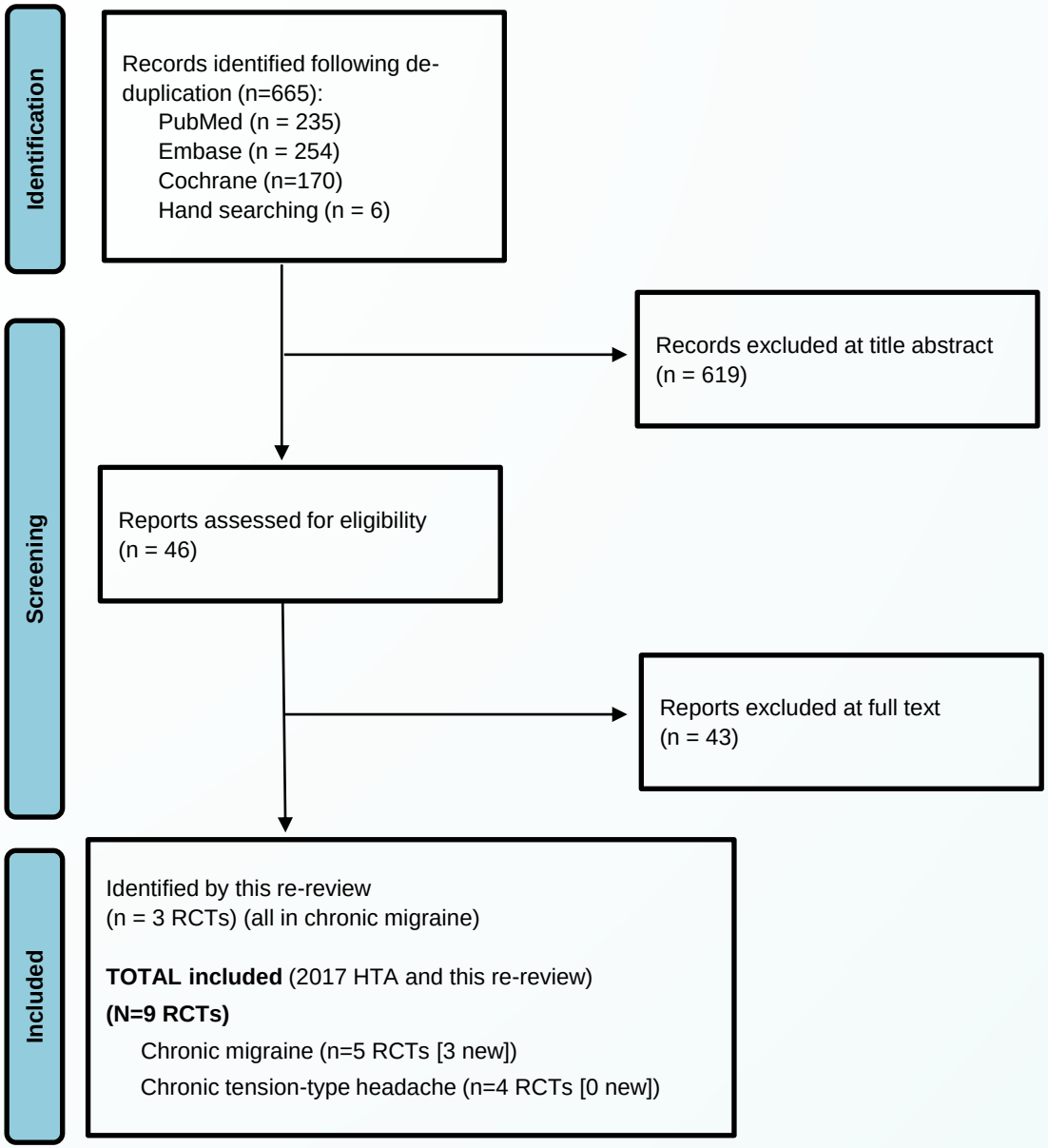
Literature Search Results



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Number of studies for each comparison of efficacy

Comparisons	2017 Report	2022 Update	Total
CHRONIC MIGRAINE			
Acupuncture vs. **UC/Sham/WL**	1 RCT[112,113]	2 RCTs[60,80]	3 RCTs (across 4 publications)[60,80,112,113]
Acupuncture vs. **Pharmacological treatment***	1 RCT[123,124]	1 RCT[81]	2 RCTs (across 3 publications)[81,123,124]
Acupuncture vs. **Botulinum toxin***	None identified.	1 RCT[81]	1 RCT[81]
TOTAL			5 RCTs (across 7 publications) [60,80,81,112,113,123,124]
CHRONIC TENSION-TYPE HEADACHE			
Acupuncture vs. **Sham**	2 RCT[67,109]	None identified.	2 RCTs[67,109]
Acupuncture vs. **Physical Training†**	1 RCT (2 publications)[101,103]	None identified.	1 RCT (across 2 publications) [101,103]
Acupuncture vs. **Physiotherapy**	1 RCT[38]	None identified.	1 RCT[38]
Acupuncture vs. **Relaxation Training†**	1 RCT (across 2 publications)[101,103]	None identified.	1 RCT(2 publications)[101,103]
TOTAL			4 RCTs (across 5 publications)[38,67,101,103,109]
CHRONIC DAILY HEADACHE			
	None identified.	None identified.	None identified.

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Efficacy/Effectiveness: Primary Outcomes Reported

(as prioritized via clinical expert input)

Headache

Measure	MCID
HA *days†, *episodes*** (responders, mean Δ)	3 days* 4 days†
HA-free *days*, *periods* (mean Δ) [CTTH]	NR
Headache Index (HI) (responders) [CTTH]	NR
Headache score (responders) [CM]	NR

*Chronic Migraine population (Mathew 2005)
†Chronic Migraine population (Silberstein 2021)

Function/Disability

Measure	MCID
MIDAS (scale 0-21+) (mean Δ) [CM] 0-5: little/no disability 6-10: mild disability 11-20: moderate disability 21+: severe disability	NR
SIP (scale 0-100) (mean Δ) [CTTH]	NR

MIDAS = Migraine Disability Assessment
SIP = Sickness Impact Profile

Aggregate Analytics

KQ 1: Efficacy and Effectiveness: Chronic Migraine

Chronic Migraine
Acupuncture vs. Sham, Usual Care or Waitlist
(3 RCTs across 4 publications)

	Vickers 2004[††]		Habibabadi 2021		Musil 2018	
	N = 401		N = 80		N = 86	
	Acupuncture	**UC[*]**	**Acupuncture**	**Sham+UC[†]** adhesive tape on the inactive points of the ears	**Acupuncture**	**WL+UC[§]**
Randomized	n=205	n=196	n=40	n=40	n=42	n=44
Mean Age, years	46.4	46.2	37.1	36.7	45.6	46.5
Female, %	83%	86%	80%	78%	88%	89%
Mean Chronicity of Headache (years)	21.3	21.9	10.7	10.5	26.9	23.0
Mean No. Migraine days/month	15.6	16.2	13.5	13.0	12.0	12.1
Medication use (mean)	16.5 (pain), 9.0 (prophylactic) per week	14.3 (pain), 13.3 (prophylactic) per week	NR	NR	14.8 (ATC/DDD)	11.5 (ATC/DDD)
Medication overuse, %	0%[‡‡]	0%[‡‡]	NR	NR	NR	NR
Prior acupuncture	0%[***]	0%[***]	0%[†††]	0%[†††]	0%[§§§]	0%[§§§]
Acupuncture type	**TCM**	NA	**Auricular, semi-permanent**	NA[†]	**TCM**	NA
No. treatment sessions	**Maximum 12**	NA	**2**	2	**14**	NA
Duration of treatment	**12 weeks**	12 weeks	**2 weeks**	2 weeks	**12 weeks**	12 weeks
Co-interventions	Standard care from GP (NOS)	NR – "avoid acupuncture"	propranolol 20 mg every 12 hours.; rescue meds. prn‡	propranolol 20 mg every 12 hours.; rescue meds. prn‡	Prophylactic meds. prn[****]	Standard pharmacologic treatment[††††]

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Chronic Migraine
Acupuncture vs. Pharmacological treatment and vs. Botulinum toxin A (Botox)
(2 RCTs across 3 publications)

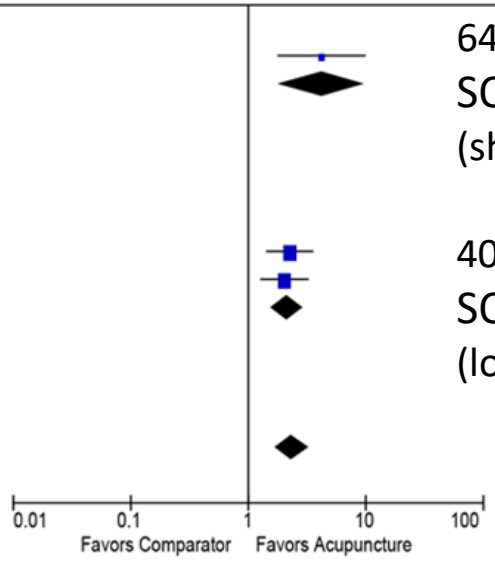
	Yang 2011		Naderinabi 2017		
Population	**N = 66**		**N = 150**		
	Acupuncture	**Topiramate**	**Acupuncture**	**Sodium valproate**	**Botox**
Randomized	n=33	n=33	n=50 (treated)	n=50 (treated)	n=50 (treated)
Mean Age, years	47.6	48.1	37.2	37.6	36.8
Female, %	91%	88%	58%	66%	54%
Mean Chronicity of Headache (years)	13.2	13.5	10.3	9.2	9.2
Mean No. Migraine days/month	21.3	21.0	21.3	21.0	23.6
Duration of drug use	NR	NR	4.2 years	3.2 years	4.1 years
Medication overuse, %	73%	76%	0%	0%	0%
Prior acupuncture	0%‡	0%‡	0%	0%	0%
Acupuncture type	**TCM** [fixed and classic acupuncture points]	NA	**TCM** [10-12 sites]	NA	NA
Number of treatment sessions / Medication dosage	**24**	4-week titration; 25mg/day increased by 25mg/day weekly to maximum 100mg/day for 8 weeks	**30**	500 mg/day	Total dose 155 U; 31 fixed-site, fixed-dose, IM injections at 7 specific head/ neck muscle areas
Duration of treatment	**12 weeks**	12 weeks	**8 weeks**	8 weeks	8 weeks
Co-interventions	None** ;acute HA meds allowed	NR; acute HA meds allowed	NR; acute HA meds allowed (Novafen)	NR; acute HA meds allowed (Novafen)	NR; acute HA meds allowed (Novafen)

Aggregate Analytics

KQ1: Chronic Migraine - Treatment Responders

Proportion with **≥50%** ↓ in mean headache days

Study or Subgroup	Comparator	F/U (wks)	Acupuncture Events	Acupuncture Total	Comparator Events	Comparator Total	Weight	Risk Ratio M-H, Random, 95% CI
Short-term								
Yang 2011	Topiramate	1	21	33	5	33	13.7%	4.20 [1.80, 9.80]
Subtotal (95% CI)				**33**		**33**	**13.7%**	**4.20 [1.80, 9.80]**
Total events			**21**		**5**			
Heterogeneity: Not applicable								
Test for overall effect: Z = 3.32 (P = 0.0009)								
Long-term								
Musil 2018	WL + UC	24	30	37	14	39	44.0%	2.26 [1.44, 3.53]
Vickers 2004	UC	36	49	161	21	140	42.2%	2.03 [1.28, 3.21]
Subtotal (95% CI)				**198**		**179**	**86.3%**	**2.14 [1.56, 2.95]**
Total events			**79**		**35**			
Heterogeneity: Tau² = 0.00; Chi² = 0.11, df = 1 (P = 0.74); I² = 0%								
Test for overall effect: Z = 4.67 (P < 0.00001)								
Total (95% CI)				**231**		**212**	**100.0%**	**2.35 [1.70, 3.24]**
Total events			**100**		**40**			
Heterogeneity: Tau² = 0.01; Chi² = 2.24, df = 2 (P = 0.33); I² = 11%								
Test for overall effect: Z = 5.21 (P < 0.00001)								
Test for subgroup differences: Chi² = 2.12, df = 1 (P = 0.15), I² = 52.8%								



64% vs. 15%
SOE: Low
(short term)

40% vs. 20%
SOE: Moderate
(long term)

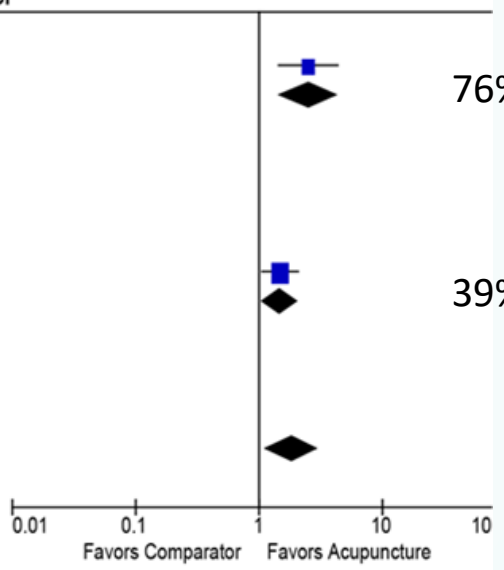
- More acupuncture patients with ≥50% reduction in mean headache days over short and long term versus active controls
- Large effects

Aggregate Analytics

KQ1: Chronic Migraine - Treatment Responders, cont.

Proportion with **≥50% ↓** in mean *moderate/severe* headache days

Study or Subgroup	Comparator	F/U (wks)	Acupuncture Events	Acupuncture Total	Comparator Events	Comparator Total	Weight	Risk Ratio M-H, Random, 95% CI
Short-term								
Yang 2011	Topiramate	1	25	33	10	33	40.9%	2.50 [1.44, 4.34]
Subtotal (95% CI)				**33**		**33**	**40.9%**	**2.50 [1.44, 4.34]**
Total events			**25**		**10**			
Heterogeneity: Not applicable								
Test for overall effect: Z = 3.25 (P = 0.001)								
Long-term								
Vickers 2004	UC	36	63	161	37	140	59.1%	1.48 [1.06, 2.07]
Subtotal (95% CI)				**161**		**140**	**59.1%**	**1.48 [1.06, 2.07]**
Total events			**63**		**37**			
Heterogeneity: Not applicable								
Test for overall effect: Z = 2.28 (P = 0.02)								
Total (95% CI)				**194**		**173**	**100.0%**	**1.83 [1.11, 3.04]**
Total events			**88**		**47**			
Heterogeneity: Tau² = 0.08; Chi² = 2.53, df = 1 (P = 0.11); I² = 60%								
Test for overall effect: Z = 2.35 (P = 0.02)								
Test for subgroup differences: Chi² = 2.52, df = 1 (P = 0.11), I² = 60.3%								



76% vs. 30%

39% vs. 26%

SOE: Low (short and long term)

- More acupuncture patients with ≥50% reduction in mean *moderate/severe* headache days over short (large effect) and long (smaller effect) term versus active controls

Aggregate Analytics

KQ1: Chronic Migraine - Treatment Responders, cont.

	Outcome	Results	Conclusion SOE
1 RCT (N=301) Vickers 2004 Acupuncture vs. UC 36 weeks	% with **≥50% ↓** in *mild* headache days	35% (56/161) vs. 18% (25/140) RR 1.9 (95% CI 1.3, 2.9)	More acupuncture patients with **≥50% ↓** in *mild* headache days and **≥35% improvement** in *headache score* compared with UC over the long term ⊕⊕◯◯ LOW
	% with **≥35% improvement** in *headache score**	54% (87/161) vs. 32% (45/140) RR 1.7 (95% CI 1.3, 2.2)	

*Headache Score: Defined as the summed total of headache severity recorded 4x/day on a 6-point Likert scale; this was the study protocol definition of responder

- Small to moderate effects

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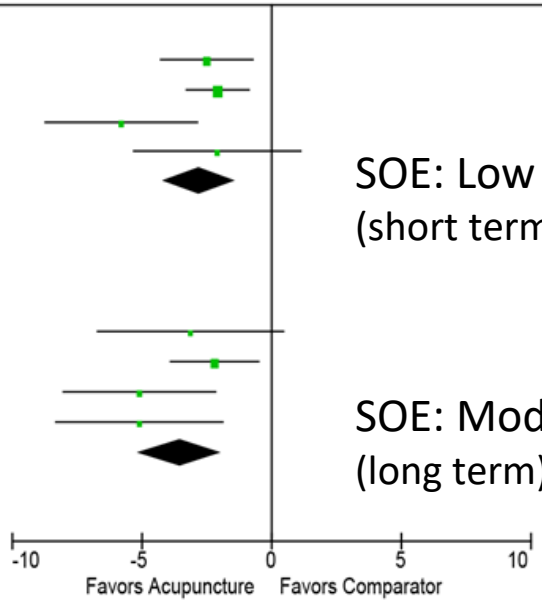
Chronic Migraine – Reduction in HA Frequency

Mean ↓ in any headache days/month

Study or Subgroup	Comparator	F/U(wks)	Acupuncture Mean	Acupuncture SD	Acupuncture Total	Comparator Mean	Comparator SD	Comparator Total	Weight	Mean Difference IV, Random, 95% CI
Short-term										
Yang 2011	Topiramate	1	10.6	3.23	33	13.1	4.09	33	17.4%	-2.50 [-4.28, -0.72]
Habibabadi 2021	Sham+UC	4	4.92	3.08	40	7	2.36	40	25.1%	-2.08 [-3.28, -0.88]
Naderinabi 2017	Sodium valproate	8	7.6	6.8	25	13.4	4.4	50	8.8%	-5.80 [-8.73, -2.87]
Naderinabi 2017 Botox	Botox	8	7.6	6.8	25	9.7	6.5	50	7.6%	-2.10 [-5.32, 1.12]
Subtotal (95% CI)					**123**			**173**	**58.9%**	**-2.80 [-4.19, -1.42]**
Heterogeneity: Tau² = 0.85; Chi² = 5.39, df = 3 (P = 0.15); I² = 44%										
Test for overall effect: Z = 3.98 (P < 0.0001)										
Long-term										
Musil 2018	WL + UC	24	4.97	6.6	37	8.1	9.2	39	6.4%	-3.13 [-6.72, 0.46]
Vickers 2004	UC	36	11.4	7.5	161	13.6	7.5	140	18.3%	-2.20 [-3.90, -0.50]
Naderinabi 2017	Sodium valproate	12	8	6.8	25	13.1	4.4	50	8.8%	-5.10 [-8.03, -2.17]
Naderinabi 2017 Botox	Botox	12	8	6.8	25	13.1	6.5	50	7.6%	-5.10 [-8.32, -1.88]
Subtotal (95% CI)					**248**			**279**	**41.1%**	**-3.54 [-5.15, -1.94]**
Heterogeneity: Tau² = 0.82; Chi² = 4.27, df = 3 (P = 0.23); I² = 30%										
Test for overall effect: Z = 4.32 (P < 0.0001)										



SOE: Low (short term)

SOE: Moderate (long term)

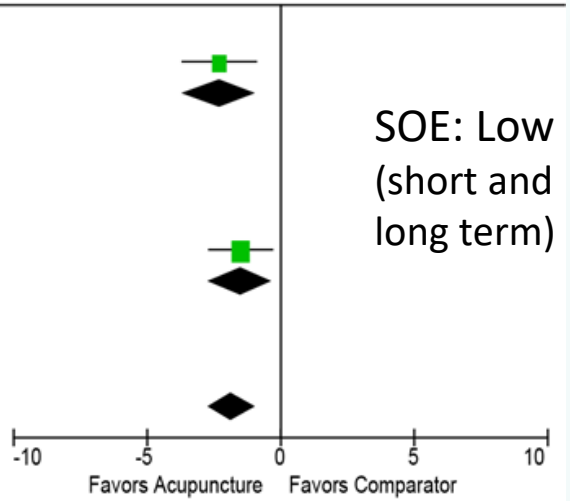
- Acupuncture associated with a greater reduction in number of headache days/month in pooled estimates across comparators and timepoints; may be clinically significant

Aggregate Analytics

Chronic Migraine – Reduction in HA Frequency, cont.

Mean ↓ in *moderate/severe* headache days/month

Study or Subgroup	Comparator	F/U(wks)	Acupuncture Mean	Acupuncture SD	Acupuncture Total	Comparator Mean	Comparator SD	Comparator Total	Weight	Mean Difference IV, Random, 95% CI
Short-term										
Yang 2011	Topiramate	1	9.7	3.23	33	12	2.44	33	42.5%	-2.30 [-3.68, -0.92]
Subtotal (95% CI)					**33**			**33**	**42.5%**	**-2.30 [-3.68, -0.92]**
Heterogeneity: Not applicable										
Test for overall effect: Z = 3.26 (P = 0.001)										
Long-term										
Vickers 2004	UC	36	5.4	4.8	161	6.9	5.6	140	57.5%	-1.50 [-2.69, -0.31]
Subtotal (95% CI)					**161**			**140**	**57.5%**	**-1.50 [-2.69, -0.31]**
Heterogeneity: Not applicable										
Test for overall effect: Z = 2.48 (P = 0.01)										
Total (95% CI)					**194**			**173**	**100.0%**	**-1.84 [-2.74, -0.94]**
Heterogeneity: Tau² = 0.00; Chi² = 0.74, df = 1 (P = 0.39); I² = 0%										
Test for overall effect: Z = 4.01 (P < 0.0001)										
Test for subgroup differences: Chi² = 0.74, df = 1 (P = 0.39), I² = 0%										



SOE: Low (short and long term)

- Acupuncture associated with a greater reduction in number of *moderate/severe* headache days/month across both active comparators and timepoints

Aggregate Analytics

Chronic Migraine – Reduction in HA Frequency, cont.

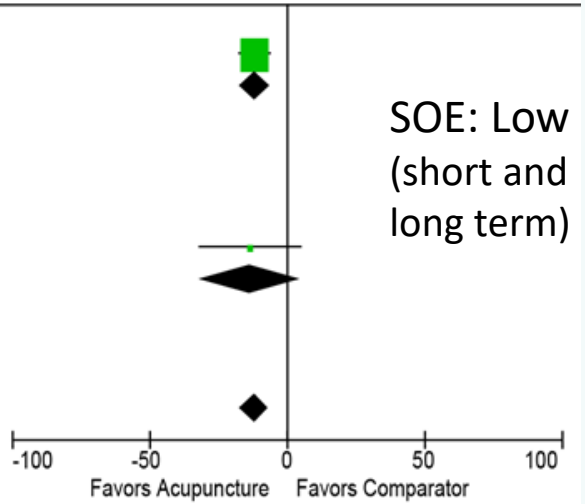
Outcome	Trial	Results	Conclusion SOE
Mean ↓ in *mild* headache days/month	1 RCT (N=301) Vickers 2004 vs. UC 36 weeks	MD –1.6 (95% CI –2.6, –0.5)	Greater ↓ in *mild* headache days with acupuncture vs. UC long term. ⊕⊕◯◯ LOW
Mean ↓ in headache *episodes/ attacks* per month	1 RCT (N=76) Musil 2018 vs. WL+UC 24 weeks	MD –0.9 (95% CI –2.1, 0.3)	No difference between groups in headache episodes/attacks long term. ⊕⊕◯◯ LOW
	1 RCT (N=80) Habibabadi 2021 vs. Sham+UC 4 weeks	MD –6.1 (95% CI –9.9, –2.3)	Insufficient evidence to draw conclusions [ROB (-2), imprecision (-1)] ⊕⊕⊕◯ INSUFFICIENT

Aggregate Analytics

Chronic Migraine – Disability

Improvement in mean Migraine Disability Assessment (**MIDAS**) scores

Study or Subgroup	Comparator	F/U(wks)	Acupuncture Mean	Acupuncture SD	Acupuncture Total	Comparator Mean	Comparator SD	Comparator Total	Weight	Mean Difference IV, Random, 95% CI
Short-term										
Yang 2011	Topiramate	1	22.2	12.34	33	34.2	10.73	33	91.6%	-12.00 [-17.58, -6.42]
Subtotal (95% CI)					**33**			**33**	**91.6%**	**-12.00 [-17.58, -6.42]**
Heterogeneity: Not applicable										
Test for overall effect: Z = 4.22 (P < 0.0001)										
Long-term										
Musil 2018	WL + UC	24	33.1	38.1	29	46.7	33.26	29	8.4%	-13.60 [-32.01, 4.81]
Subtotal (95% CI)					**29**			**29**	**8.4%**	**-13.60 [-32.01, 4.81]**
Heterogeneity: Not applicable										
Test for overall effect: Z = 1.45 (P = 0.15)										
Total (95% CI)					**62**			**62**	**100.0%**	**-12.13 [-17.47, -6.80]**
Heterogeneity: Tau² = 0.00; Chi² = 0.03, df = 1 (P = 0.87); I² = 0%										
Test for overall effect: Z = 4.45 (P < 0.00001)										
Test for subgroup differences: Chi² = 0.03, df = 1 (P = 0.87), I² = 0%										



SOE: Low (short and long term)

- Acupuncture associated with a greater reduction in mean MIDAS scores, suggesting improved function, compared to active controls over the short, but not the long term; may be a clinically important difference.

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Chronic Migraine – Secondary Outcomes (no SOE)

(as prioritized via clinical expert input)

- Acupuncture was associated with a greater improvement versus sham and/or active comparators in:
  - **Pooled VAS pain scores** (0-10 scale) for headache intensity/severity at short (2 RCTs, N=230, 4-8 wks.) and long term (2 RCTs, N=219, 12-24 wks.)
  - **Health related quality of life** (8 domains of the SF-36) at short (1 RCT, N=66, 1 wk.) and long term (1 RCT, N=301, 36 wks.)
  - **Proportion of patients requiring rescue or prophylactic medication** at short (1 RCT, N=150, 8 wks.) and long term (2 RCTs, N=451, 12-36 wks.)
  - **Frequency of analgesic use** at short (2 RCTs, N=216, 1-8 wks.) and long term (3 RCTs, N=522, 12-36 wks.)
  - **Depression and anxiety** (BDI-II and HADS) at short term (1 RCT, N=66, 1 wk.)
  - **Patient satisfaction** at short term (1 RCT, N=80, 4 wks.)
  - **Headache scores** at long term (1 RCT, N=301, 36 wks.)
- No difference in:
  - **Loss of working days or social activities** at short (1 RCT, N=150, 8 wks.) or long term (2 RCTs, N=451, 12-36 wks.)
  - **Resource use** at long term (1 RCT, N=301, 36 weeks)

KQ 1: Efficacy and Effectiveness: Chronic Tension-type Headache (TTH)

No new trials of CTTH meeting inclusion criteria identified. Results from the 2017 report were re-evaluated for accuracy and edits have been made for consistency with this updated review.

Aggregate Analytics

Chronic TTH
Acupuncture vs. Sham (2 RCTs)

	Karst 2000		Tavola 1992	
	N = 39		N = 30	
	Acupuncture	**Sham** Blunt placebo needle, simulated puncturing sensation (no insertion)	**Acupuncture**	**Sham** Same treatment, but needles were inserted into non-acupoints
Randomized	n=21	n=18	n=15	n=15
Mean Age, years	50.4	47.3	32.5	33.3
% Female	38%	61%	87%	87%
Mean Chronicity of Headache (years)	NR	NR	7.5	8.1
Mean # HA days/month	26.9	27.2	NR	NR
Mean # HA attacks/month	NR	NR	18.3 crises	16.8 crises
Mean analgesics/mo.	8.3	10.2	11.6	11.5
Medication overuse, %	NR**	NR**	NR	NR
Prior acupuncture, %	NR	NR	NR	NR
Acupuncture type	**TCM**	NA	**TCM**	NA
No. of acupuncture sites, needles	10 points (max 15 needles)	NA	6-10 needles	6-10 needles
Manipulation of needles	NR	NR	No use of any manual or electrical stimulation	NA
No. of treatment sessions	**10**	NR	**8**	8
Duration of treatment	**5 weeks**	5 weeks	**8 weeks**	8 weeks
Co-interventions	NR; analgesics and rescue medication allowed	NR; analgesics and rescue medication allowed	None; non-narcotic analgesics allowed	None; non-narcotic analgesics allowed

Chronic TTH
Acupuncture vs. Active Controls
(2 RCTs across 3 publications)

	Carlsson, 1990		Söderberg, 2006 & 2011		
	N = 62		**N = 90**		
	Acupuncture	**Physiotherapy‡**	**Acupuncture**	**Physical Training§**	**Relaxation Training****
Randomized	n=31	n=31	n=30	n=30	n=30
Mean Age, years	34		Median 35.0	Median 35.0	Median 43.0
% Female	100%		77%	77%	90%
Mean Chronicity of Headache (years)	9.0		Median 10.0	Median 5.0	Median 10.0
Mean # HA days/month	NR – "occurs almost daily"		Minimum 15 days/month (inclusion criteria)		
Medication overuse, %	NR		NR (use of analgesics, triptans >10 days/mo. Exclusion)		
Prior acupuncture, %	NR	NR	NR	NR	NR
Acupuncture type	**TCM**	NA	**NR**	NA	NA
Number of acupuncture sites, needles	3 points, 3 needles, twilled by hand 3x per session	NA	10-12 needles, twilled by hand, electrical stim.	NA	NA
Number of treatment sessions	**Variable***	1-2 sessions per week, 10-12 sessions over 8-12 weeks	**10-12**	10	8-10
Duration of treatment			**10-12 weeks**	10-12 weeks	10-12 weeks
Co-interventions	NR†	NR†	None	None	None

‡ Specific for each patient, including: relaxation techniques, auto-massage, cryotherapy and transcutaneous electrical nerve stimulation.
§ Sessions were a combination of in-clinic and home-training but all focused on neck and shoulder muscles (Medical Training Therapy).
** Combination of neuromuscular and self-hypnotic techniques, as well as breathing techniques, stress coping mechanisms, and how to relax during the day and during

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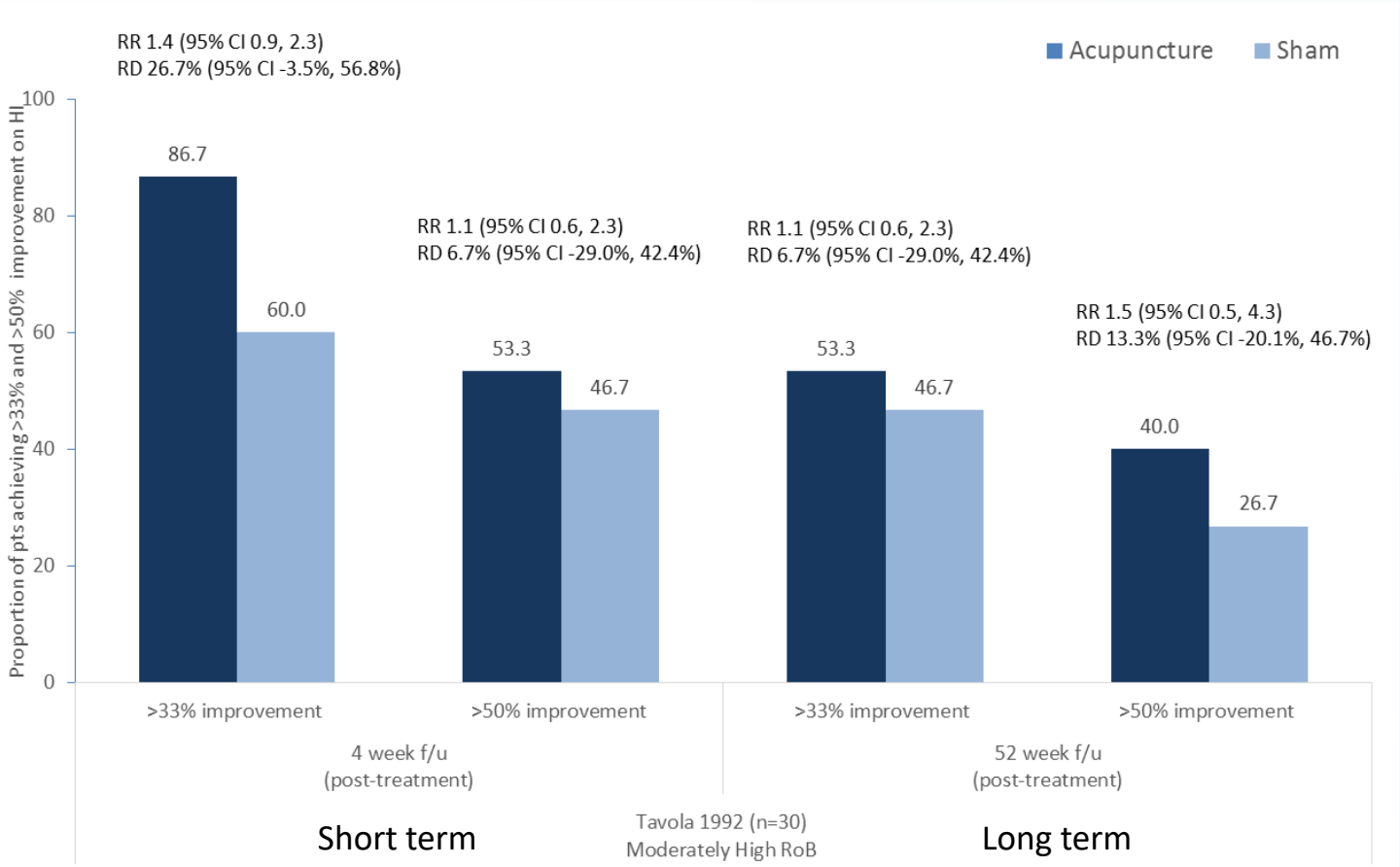
Chronic TTH – Acupuncture vs. Sham

Treatment Responders

- Proportion of patients achieving >33% and >50% improvement from baseline on the Headache Index (HI)



SOE: Insufficient

1 small RCT, moderately high ROB, consistency unknown, small sample size

Chronic TTH – Acupuncture vs. Sham

Reduction in headache episodes

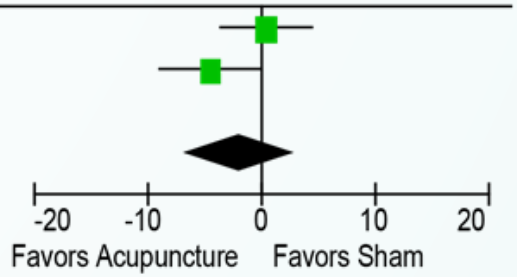
- Mean change from baseline in number of *headache episodes*/month (**SOE: Insufficient**)

Short term (4-6 weeks), 2 small, RCTs; moderately high ROB:

	Acupuncture			Sham				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Karst 2000	-4.8	6.53	21	-5.2	6.27	18	52.2%	0.40 [-3.62, 4.42]
Tavola 1992	-8.1	6.37	15	-3.6	6.2	15	47.8%	-4.50 [-9.00, -0.00]
Total (95% CI)			**36**			**33**	**100.0%**	**-1.94 [-6.74, 2.85]**

Heterogeneity: $Tau^2 = 7.26$; $Chi^2 = 2.53$, df = 1 (P = 0.11); $I^2 = 61\%$

Test for overall effect: Z = 0.79 (P = 0.43)



Long term (26-52 weeks), 1 small RCT, moderately high ROB:

- Frequency of headache episodes continued to decrease through long term follow-up, difference NS between groups; no data provided.

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Chronic TTH – Acupuncture vs. Physical Training/Exercise and vs. Relaxation

	Outcome	F/U	Results	Conclusion SOE
1 RCT (N=90; 30 per group) Soderberg 2006, 2011 Mod. High ROB	Headache-free *days* per week	12 wks.	**Acupuncture**: mean 1.18, median 0 (range, 0.00–7.00) **Exercise**: mean 1.23, median 0.50 (range, 0.00–7.00) **Relaxation**: mean 1.58, median 0.13 (range, 0.00–7.25)	p=NS for all comparisons Firm conclusions are not possible ⊕◯◯◯ **INSUFFICIENT** 1 small RCT, moderately high risk of bias, serious imprecision
		26 wks.	**Acupuncture**: mean 1.56, median 0 (range, 0.00–7.00) **Exercise**: mean 1.66, median 1.00 (range, 0.00–7.00) **Relaxation**: mean 1.73, median 0.13 (range, 0.00–7.25)	
	Headache-free *periods* per week	12 wks.	**Acupuncture**: mean 6.25, median 0.25 (range, 0.00–28.00) **Exercise**: mean 7.46, median 5.00 (range, 0.00–28.00) **Relaxation**: mean 7.67, median 2.0 (range, 0.00–29.00)	
		26 wks.	**Acupuncture**: mean 7.58, median 0 (range, 0.00–28.00) **Exercise**: mean 9.37, median 9.38 (range, 0.00–28.00) **Relaxation**: mean 8.29, median 2.0 (range, 0.00–29.00)	

Chronic TTH – Acupuncture vs. Physiotherapy

	Outcome	Results	Conclusion SOE
1 RCT (N=62) Carlsson 1991 Mod. High ROB 4-9 wks.	Reduction in headache episodes	Headache frequency significantly (<0.001) reduced in both groups; no data provided and no information regarding the between group difference provided.	Firm conclusions are not possible ⊕◯◯◯ **INSUFFICIENT** 1 small RCT, moderately high ROB, serious imprecision
	Sickness Impact Profile (SIP)	Acupuncture associated with greater improvement (p<0.05) vs. PT in the SIP category Sleep and Rest but less improvement in the psychosocial categories Emotional Behavior, Work, Eating, and Recreation and Pastimes; overall SIP score and the Psychosocial dimension were improved in both groups but between group differences are unclear. No data was provided to support these statements.	

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Chronic TTH – Secondary Outcomes (no SOE)

(as prioritized via clinical expert input)

- Acupuncture vs. Sham
  - Acupuncture associated with greater increase in **Pressure Point Thresholds (PPTs)**, clinical significance unclear
  - NS difference between groups:
    - **VAS HA intensity (0-10) scores, quality of life (various measures), patient perception of improvement** at short term (1 RCT, N=39, 6 wks.)
    - **Analgesic consumption** at short (2 RCTs, N=69, 4-6 weeks) or long term (1 RCT, N=30, 24-36 weeks)
    - **Headache Index** scores at short (4 weeks) and long term (24-36 weeks) (1 RCT, N=30)
- Acupuncture vs. Active comparators:
  - **Quality of Life:** mixed results; some improvement with acupuncture vs. physiotherapy, no difference or less improvement with acupuncture versus physical training/exercise and relaxation.
  - **VAS HA intensity (0-100) scores**: mixed results; less improvement with acupuncture vs. physiotherapy short-term, no differences between acupuncture and relaxation training or physical training/exercise longer term.

KQ 2: Safety

Chronic Migraine – Serious AEs

Outcome	Author	Comparator	F/U post-tx	Results, % (n/N)		p-value
				Acupuncture	Comparator	
Serious AEs (NOS)	Yang 2011	Topiramate	1 wk.	0% (0/33)	0% (0/33)	-----
	Vickers 2004	UC	36 wks.	0% (1/161)	0% (0/140)	-----
Death	Yang 2011	Topiramate	1 wk.	0% (0/33)	0% (0/33)	-----
AEs leading to treatment withdrawal	Yang 2011	Topiramate	1 wk.	0% (0/33)	9.1% (3/33)	0.079
	Vickers 2004	UC	12 wks.	0.6% (1/161)	0% (0/140)	0.351

SOE: Insufficient (firm conclusions are not possible)

- Without knowing what constitutes a serious AE and the rarity of such events, unclear whether there was sufficient sample size to detect such events

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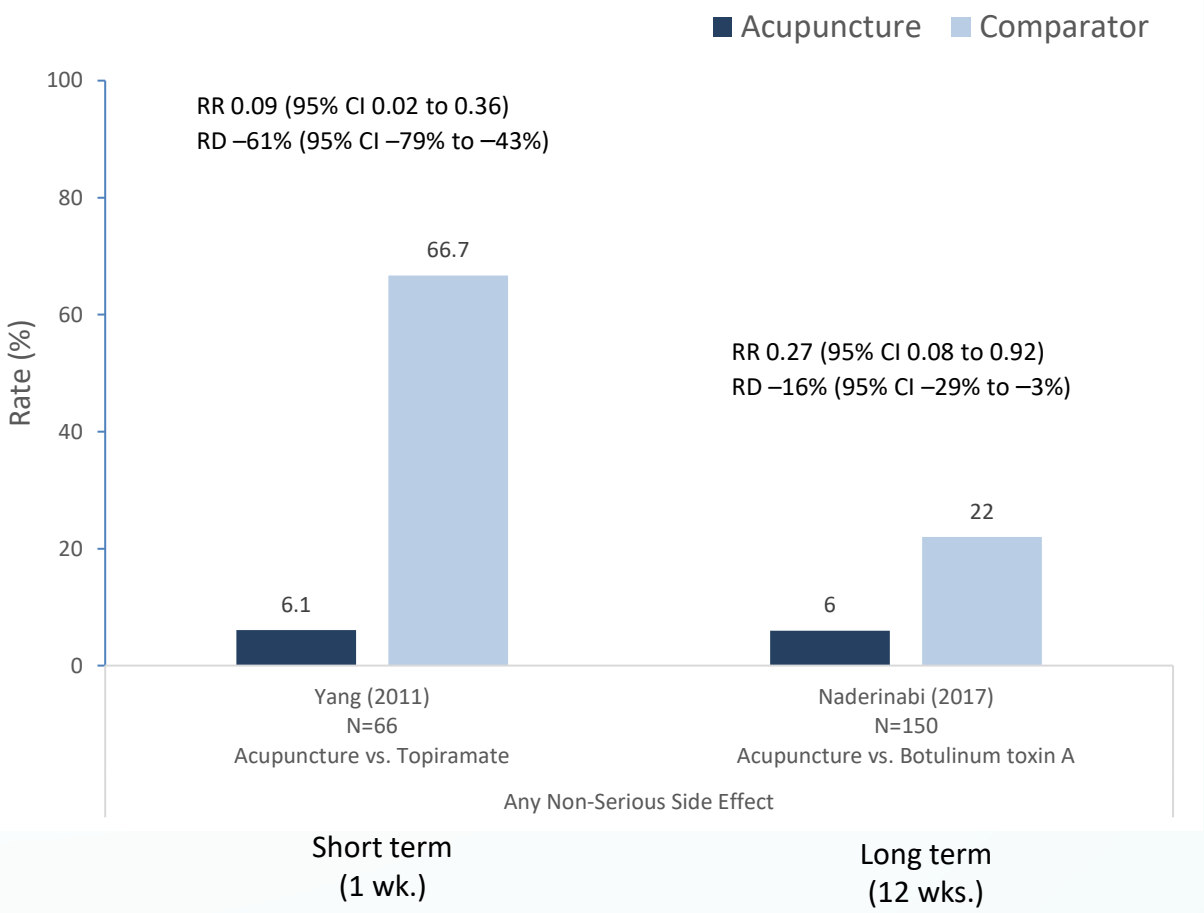
Chronic Migraine – Any Non-Serious AE

Risk of any non-serious AE (SOE: Low)



Acupuncture: ↓ **risk** of any non-serious AEs over short and long term, 2 RCTs.

Most AEs were mild and self-limiting.

Acupuncture = primarily related to local insertion of needles, i.e., local pain and paresthesia, bleeding, subcutaneous hematoma

Topiramate, most common (≥ 12%) = paresthesia, memory, dyspepsia, fatigue, dizziness, somnolence, nausea

Botulinum, most common = ptosis, facial masking or asymmetry

Aggregate Analytics

Chronic Migraine –Non-Serious AEs, cont.

- **Treatment-related headache; 1 RCT (SOE: Low):**
  - No difference with acupuncture vs. UC: 2.5% (4/161) [5 cases]) vs. 0% (0/140)

- **Hematoma, facial hematoma; 2 RCTs (SOE: Insufficient):**
  - Facial hematoma: 1.3% (1/79) in acupuncture group; NA to WL/UC (1 RCT)
  - No cases of hematoma in acupuncture or sham group in 1 RCT (N=80); however, *patients were excluded if they developed redness or infection at the site of the needle implant*

- **Ear swelling, pain, erythema or infection; 1 RCT (SOE: Insufficient)**
  - Ear swelling ranged from 3% (1/40) to 10% (4/40) and ear pain from 5% (2/40) to 18% (7/40) with auricular acupuncture over 4 weeks.
  - No cases of erythema or ear infection; however, *patients were excluded if they developed redness or infection at the site of the needle implant*
  - No events occurred in sham/UC group

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Chronic TTH – Safety

- **Serious AEs** were not reported by any trial

- Only 1 RCT (N=62) – acupuncture vs. physiotherapy – provided data on **Nonserious AEs**
  - Authors state that a few patients in the acupuncture group had a slight vasovagal reaction at the first treatment; no other complications were noted.
  - **SOE: Insufficient**

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KQ 3: Differential Effectiveness or Safety

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Chronic Migraine – Differential Effectiveness or Safety

Acupuncture vs. Usual care (1 RCT, N=301, longer term):

Insufficient Evidence

- Patients with more severe baseline symptoms had greater improvement with acupuncture vs. usual care (interaction p-value 0.004, no data provided)

- No interaction observed
    - Headache type (CM vs. CTTH)
    - Age
    - Sex
    - Chronicity

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Chronic Migraine – Differential Effectiveness or Safety, cont.

Acupuncture vs. Topiramate (1 RCT, N=66, longer term):

Insufficient evidence

- Patients with more HA days (≥20 vs. <20 days/month) – any (interaction p-value 0.002) and moderate/severe (interaction p-value 0.007) – showed more improvement following acupuncture vs. topiramate

- No interaction observed: other characteristics including
    - Demographic factors
    - Baseline functional measures
    - Headache characteristics
    - Treatment expectations

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KQ 4: Cost-effectiveness

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Chronic Migraine – Cost-effectiveness

	Vickers 2004 (QHES Sore 71)
Population	255 adult (aged 16-65 years); Vickers RCT
Funding	Government (National Health Service, HTA Programme)
ICER	**£ 9,951/QALY (UK NHS perspective) £ 9,180/QALY(societal)**
SA	ICERs range: £801/QALY (for a 10 year time horizon) to £12,333/QALY if GP provided the service (Payer); Cost-effective on 84% to 92% of the time at ceiling of £30,000
AUTHOR'S CONCLUSION	**Incremental cost-effectiveness was favorable and below the willingness-to-pay threshold. The estimated improvement in quality of life correlates with the observed reductions in headache severity and frequency.**
STUDY LIMITATIONS	• Controls group: "usual care to avoid acupuncture", no detail provided; no comparison to more active treatments • Generalizability across settings and health systems is unclear • Limited time horizon (1 year) • The need for continued or periodic treatment: unclear • Limited sensitivity analyses for economic model inputs • Lack of long term follow-up data for benefits and harms.

SUMMARY

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SUMMARY: Efficacy – Chronic Migraine

Outcome	Timing	CM – Acupuncture vs. sham and active control
Responders: ≥50% reduction in *any* headache days from baseline	Short term (1 wk.)	**↑, large effect, Low SOE** (1, N=66; vs. topiramate)
	Long term (24-36 wks.)	**↑, large effect, Moderate SOE** (2, N=377; vs. topiramate, WL/UC)
Responders: ≥50% reduction in *moderate/severe* headache days from baseline	Short (1 wk.) and Long term (36 wks.)	**↑, large effect (short term), small effect (long term), Low SOE** (2, N=367; vs. topiramate, UC)
Responders: ≥50% reduction in *mild* headache days from baseline	Long term (36 wks.)	**↑, small effect, Low SOE** (1, N=301; vs. UC)
Responders: ≥35% improvement in headache score from baseline	Long term (36 wks.)	**↑, small effect, Low SOE** (1, N=301; vs. UC)
Reduction (mean Δ) in *any* headache days/month	Short term (1-8 wks.)	**↑, 2.8 days, Low SOE** (3, N=296; vs. sham+UC, topiramate, sodium valproate, Botox)
Reduction (mean Δ) in *any* headache days/month	Long term (12-36 wks.)	**↑, 3.5 days, Low SOE** (3, N=527; vs. UC, WL+UC, topiramate, sodium valproate, Botox)
Reduction (mean Δ) in *moderate/severe* headache days/month	Short (1 wk.) and Long term (36 wks.)	**↑, 2.3 days (short term), 1.5 days (long term), Low SOE** (2, N=367; vs. topiramate, UC)
Reduction (mean Δ) in *mild* headache days/month	Long term (36 wks.)	**↑, 1.6 days, Low SOE** (1, N=301; vs. UC)
Reduction in headache episodes/attacks per month	Short term (4 wks.)	**Insufficient evidence** (1, N=80; vs. sham/UC)
	Long term (24 wks.)	**Θ Low SOE** (1, N=76; vs. WL/UC)
MIDAS	Short (1 wk.) and Long term (24 wks.)	**↑, MD –12.0 (short term), –13.6 (long term), Low SOE** (2, N=124; vs. topiramate, WL/UC)

↑ = Acupuncture favored ↓ = Comparator favored Θ = no diff. b/w groups

SUMMARY: Efficacy – Chronic TTH

Outcome	Timing	CTTH – SOE, Conclusion
Acupuncture vs. Sham		
Responders: ≥33% and >50% improvement on the Headache Index (HI)	Short (4 wks.) and Long term (52 wks.)	**Insufficient evidence** (1, N=30, sham: non-acupoints)
Reduction (mean Δ) in headache episodes/month	Short (4-6 wks.)	**Insufficient evidence** (2, N=69, sham: non-acupoints, blunt needle/simulated insertion)
	Long term (26-52 wks.)	**Insufficient evidence** (1, N=30, sham: non-acupoints)
Acupuncture vs. Exercise or Relaxation		
Headache-free *days* per week	Long term (12-26 wks.)	**Insufficient evidence** (1, N=90)
Headache-free *periods* per week		
Acupuncture vs. Physiotherapy		
Reduction (mean Δ) in headache *episodes*	Short to intermediate term (4-9 wks.)	**Insufficient evidence** (1, N=62)
Sickness Impact Profile (SIP)		

- Single, small trials at moderately high ROB, unknown or serious inconsistency, serious imprecision

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SUMMARY: Safety – Acupuncture

6 RCTs (5 in CM and 1 in CTTH) compared Acupuncture with sham or active control and reported limited data on AEs.

LOW evidence of:

- Any side effect: significantly less common with acupuncture (vs. topiramate, sodium valproate, or Botox; 2 RCTs, CM)
- NS difference for discontinuation due to AEs (vs. topiramate, UC; 1 RCT, CM)
- NS difference between groups for treatment-related headache (vs. usual care, 1 RCT, CM)

INSUFFICIENT evidence:

- No Serious AEs or deaths reported (vs. topiramate, UC; 2 RCTs, CM)
- Hematoma, facial hematoma (vs. sham/UC, WL/UC; 2 RCTs, CM)
- Ear swelling, pain, erythema or infection (vs. sham/UC; 1 RCT, CM)
- Vasovagal reaction - “a few” in the acupuncture group (vs. physiotherapy, 1 RCT, CTTH)

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SUMMARY: Differential Efficacy or Harm

Chronic Migraine

- **Greater improvement with Acupuncture vs. Active Controls in patients with the following baseline characteristics:**
  - **More severe symptoms (not specified further)** (versus Usual Care, 1 RCT)
  - **More HA days (≥ 20 vs. < 20 days)** (versus Topiramate, 1 RCT)
- **No modification by other factors in either trial**
- **All evidence INSUFFICIENT**

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SUMMARY: Cost-Effectiveness

Chronic Migraine, Acupuncture vs. Usual care

1 poor to moderate quality study (UK):

- Suggests cost-effectiveness of acupuncture is favorable; limitations no active treatment comparator, limited time horizon, limited sensitivity analyses

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Questions?

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HTCC Coverage and Reimbursement Determination
Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.

[1] Based on Legislative mandate: RCW 70.14.100(2).
[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm
[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. *Availability of evidence:*

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. *Sufficiency of the evidence:*

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

3. *Factors for Consideration - Importance*

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

Clinical committee findings and decisions

Efficacy considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next step: Cover or no cover

If not covered, or covered unconditionally, the chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next step: Cover with conditions

If covered with conditions, the committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.
2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical committee evidence votes

First voting question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Discussion document: What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

Safety outcomes	Importance of outcome	Safety evidence/ confidence in evidence
Adverse events leading to tx withdrawal		
Serious AEs (NOS- not otherwise specified)		
Death		
Headache		
Hematoma		
Ear swelling, pain, other		

Efficacy – effectiveness outcomes	Importance of outcome	Efficacy / Effectiveness evidence
Headache (HA) days, episodes		
HA-free days, periods		
Headache index (HI)		
Headache score		
MIDAS (0-21 scale) Migraine disability index		
SIP (0-100 scale)		

Cost outcomes	Importance of outcome	Cost evidence
Cost		
Cost effectiveness		

Special population / Considerations outcomes	Importance of outcome	Special populations/ Considerations evidence
Age		
Race		
Gender		
Ethnicity		
Chronicity		
Headache type		

For safety:

Is there sufficient evidence that the technology is safe for the indications considered?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all (yes)

For efficacy/ effectiveness:

Is there sufficient evidence that the technology has a meaningful impact on patients and patient care?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all (yes)

For cost outcomes/ cost-effectiveness:

Is there sufficient evidence that the technology is cost-effective for the indications considered?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all (yes)

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective

- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not covered _____ Covered unconditionally _____ Covered under certain conditions

Discussion item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Next step: proposed findings and decision and public comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?
2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: final determination

Following review of the proposed findings and decision document and public comments:

Final vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome chair will lead discussion to determine next steps.

Medicare Coverage
[see page 11 of the final report]

No Medicare National Coverage Determination (NCD)

Clinical Practice Guidelines
[see page 9 of the final report]

Guideline	Evidence Base	Recommendation	Rating/Strength of Recommendation
European Academy of Neurology (EFNS) 2010[24] (Included in prior report) *EFNS guideline on the treatment of tension-type headache – Report of an EFNS task force* Denmark	17 studies, type NR	Acupuncture may be a valuable option for patients with frequent TTH*, although there is no robust scientific evidence for efficacy.	NR
National Institute for Health and Care Excellence (NICE) 2012 (updated in May 2021)[13] (Included in prior report) *Headaches in over 12s: diagnosis and management* United Kingdom	Tension-type headache: 4 RCT Migraine: 4 RCTs†	Tension-type headache: Consider a course of up to 10 sessions of acupuncture over 5 to 8 weeks for the prophylactic treatment of chronic tension-type headache. Migraine with or without aura: If both topiramate and propranolol are unsuitable or ineffective, consider a course of up to 10 sessions of acupuncture over 5 to 8 weeks according to the person's preference, comorbidities, and risk of adverse events	NR
Institute for Health Economics & Towards Optimized Practice 2016[116] *Primary care management of headache in adults: clinical practice guideline.* Canada	Chronic migraine: 2 guidelines, Institute of Health Economics Database Tension-type headache: 2 guidelines	Chronic Migraine: Acupuncture can be considered in the prophylactic treatment of patients with migraine. Treatment should consist of at least one to two sessions per week for several (two or more) months, with each treatment lasting approximately 30 minutes Tension-type headache: Acupuncture may be considered for patients with frequent tension-type headaches.	NR

VA/DoD 2021[47] *VA/DoD Clinical Practice Guideline for the Primary Care Management of Headache* USA	3 SRs, 1 RCT‡	There is insufficient evidence to recommend for or against acupuncture for the treatment of headaches.	Neither for nor against
Study Group for Chronic Headache Clinical Practice Guideline Development and The Japanese Headache Society 2019[18] *Clinical practice guideline for chronic headache 2013* Japan	NR	Non-pharmacotherapies for chronic tension-type headache include psycho-behavioral therapy, physical therapy, acupuncture, and Tiger Balm®, and those with proven usefulness warrant recommendation as treatment.	Grade A (Strongly recommend)
China Association of Chinese Medicine 2019[98] *Report of guidelines for diagnosis and treatment of common internal diseases in Chinese medicine: Headache* China	Migraine: 2 comparative studies (study design NR) Tension-type headache: 1 comparative study (study design NR)*	NR	Migraine: - Quality of Evidence (GRADE): C (Low) - Strength of recommendation: 1 (Strong) Tension-Type Headache: - Quality of Evidence (GRADE): B (Moderate) - Strength of recommendation: 1 (Strong)
National Clinical Guidelines for Qatar 2016[17] *Clinical Guidelines for the State of Qatar: Headaches in adults* Qatar	2 guidelines	Non-pharmacological treatment of chronic TTH and chronic Migraine should always be considered and should include acupuncture – consider a course of up to 10 sessions over 5-8 weeks	Chronic Tension-Type Headache: Recommendation Grade A2: Evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. Chronic Migraine: Recommendation Grade A1: demonstrates at least moderate certainty of at least moderate net benefit.

Washington State Health Care Authority

Final Key Questions

Acupuncture for Chronic Migraine and Chronic Tension-type Headache

September 30, 2021

Background

Headaches are among the most common reasons for patient visits in primary care and neurology settings. Headache is considered primary when a disease or other medical condition does not cause the headache. Tension-type headache is the most common primary headache and accounts for 90% of all headaches; it is characterized by a dull, non-pulsatile, diffuse, band-like (or vice-like) pain of mild to moderate intensity in the head, scalp or neck. There is no clear cause of tension-type headaches even though it has been associated with muscle contraction and stress. Migraines are the second most frequently occurring primary headaches. Migraine headache is characterized by recurrent unilateral pulsatile headaches lasting 4-72 hours; nausea, vomiting and sensitivity to light and sound are frequent co-existent symptoms. The two major subtypes are common migraine (without aura) and classic migraine (with aura or neurological symptoms). Migraine and tension headache attacks are classified as episodic if they occur less than 15 days per month. Headaches are considered chronic if they occur 15 or more days each month for at least 3 months or more than 180 days a year. Episodic migraine and tension-type headache may evolve to become chronic. Chronic tension-type headache (CTTH) and chronic migraine (CM) features differ but the two may coexist. CCTH and CM will be evaluated in this report. Both chronic tension-type headache and chronic migraine are associated with substantial impact on the physical, psychological, and social well-being of patients as well as healthcare costs. They are a leading cause of disability and diminished quality of life.

Usual (standard) management of tension-type headache includes pharmacotherapy, psychological therapy and physical therapy. Migraine management generally focuses on pharmacological therapy. While abortive therapy for acute episodes is necessary for both CTTH and CM, the focus of management for CCTH and CM is on preventive treatments. Primary goals of preventive therapy are to reduce the number, severity and/or duration of acute episodes and reduce disability. Some of the treatments that are used in the acute setting are also employed for prevention/long term treatment.

A variety of interventions may be used to manage chronic migraine and chronic tension-type headache, many of which were covered in a 2017 health technology assessment, including the use of acupuncture. Acupuncture has been used for thousands of years and is based in the Eastern philosophy of activating or correcting qi, the believed vital energy source in humans. Acupuncture involves the insertion of solid, filiform needles into the body (with or without manual or electrical stimulation) to directly or indirectly stimulate acupuncture points, including trigger points and other tissues, to promote health and treat organic or functional disorders.

Policy context/ reason for selection

Acupuncture for chronic migraine or chronic tension type headache has been selected for re-review by the Health Care Authority Director. Technologies are selected for re-review when new evidence may be available that could change a previous determination. Acupuncture was originally reviewed together

with other interventions for prevention of chronic migraine and chronic tension type headache. Those interventions will not be part of this re-review.

Objective:

The aim of this report is to update the acupuncture portion of the 2017 HTA on Treatment of Chronic Migraine and Chronic Tension-type Headache by systematically reviewing, critically appraising and analyzing new research evidence comparing the efficacy and safety of acupuncture with usual (standard) treatments, placebo or sham treatments, no treatment or waitlist controls. This re-review will follow the same Key Questions, definitions, and scope as the prior report as they apply to acupuncture.

Research Key Questions:

In adults with chronic migraine or chronic tension-type headache:

1. What is the evidence of the short- and long-term efficacy and effectiveness of acupuncture, compared with standard alternative treatment options, placebo, sham, waitlist or no treatment?

2. What is the evidence regarding short- and long-term harms and complications of acupuncture with standard alternative treatment options, placebo, sham, waitlist or no treatment?

3. Is there evidence of differential efficacy, effectiveness, or safety of acupuncture compared with standard alternative treatment options, placebo sham, waitlist or no treatment? Include consideration of age, sex, race, ethnicity, socioeconomic status, payer, and worker's compensation.

4. What is the evidence of cost-effectiveness of acupuncture compared with standard alternative treatment options, placebo, sham, waitlist or no treatment?

Scope:

Population: Adults with chronic migraine (with or without aura) or chronic tension-type headache. Chronic headache is defined as 15 or more days each month for at least 3 months or more than 180 days a year (International Classification of Headache Disorders, 3rd edition definition). Studies reporting populations with a mean of ≥12 headache days per month or ≥12 headache episodes or attacks per month were considered to meet the criteria for chronic headache in the original report and chronic daily headache was defined as combined migraine and tension headache.

Interventions: Acupuncture.

Comparators: Standard/usual alternative treatment(s), sham, placebo, waitlist or no treatment.

Outcomes: Primary/critical outcomes are 1) the proportion of treatment responders, 2) complete cessation/prevention of headache, 3) function/disability (based on validated outcomes measures), 4) treatment related adverse events/harms, 5) quality of life. Economic outcomes are cost-effectiveness (e.g., cost per improved outcome), cost-utility (e.g., cost per quality adjusted life year (QALY), incremental cost effectiveness ratio (ICER) outcomes.

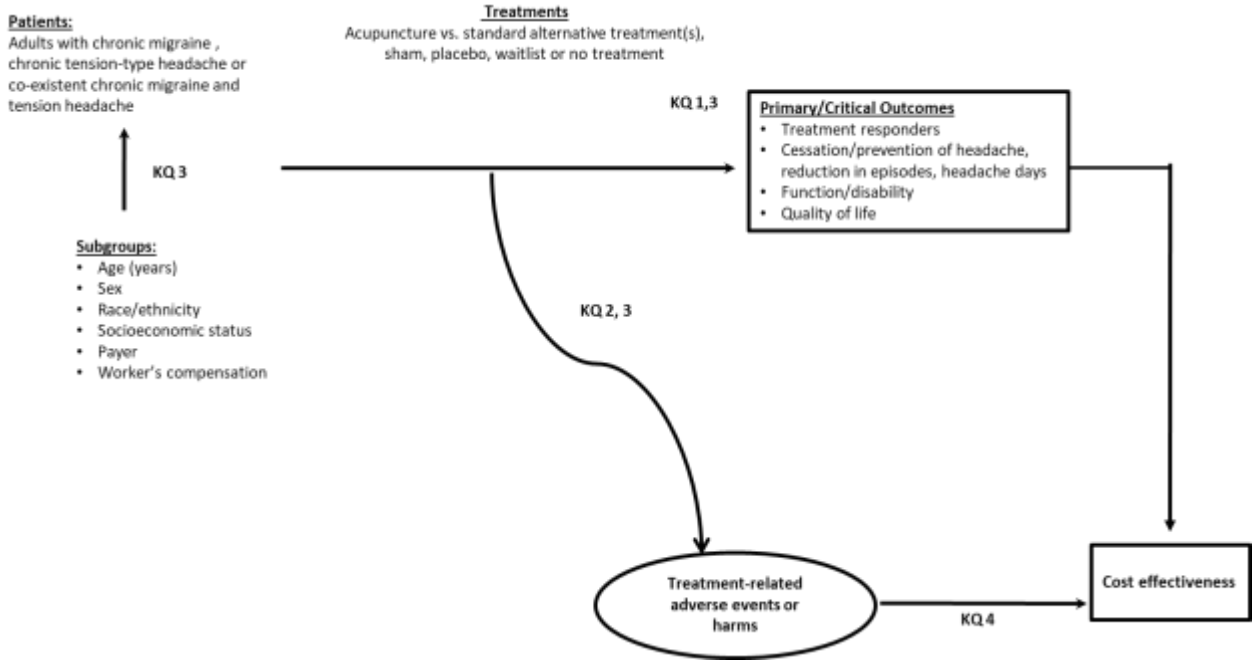
Studies:

Studies must report at least one of the primary outcomes**.** Focus will be on studies with the least potential for bias such as high-quality systematic reviews of randomized controlled trials which focus on the population of interest for this review and randomized controlled trials and full economic studies.

Timing:

Focus will be on intermediate (>6 months) and long term (> 12months) for efficacy outcomes, particularly cessation/ prevention; any timeframe for harms.

Analytic framework



Public comment and response:

All comments received regarding the draft key questions have been published in a separate document.