

# Acupuncture for chronic migraine and chronic tension-type headache

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**Final evidence report:  
Peer review, comment, and response**

*February 28, 2022*

**Health Technology Assessment Program (HTA)**

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# Acupuncture for Chronic Migraine and Chronic Tension-type Headache

**Provided by:**



**Aggregate Analytics, Inc.**

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***February 28, 2022***

## Responses to clinical and peer reviewers

*Aggregate Analytics Inc. is an independent vendor contracted to produce evidence assessment reports for the Washington Health Technology Assessment (HTA) program. For transparency, all comments received during public comment periods are included in this document and attachments. Comments related to program decisions, process or other matters not pertaining to the evidence report, are acknowledged through inclusion only.*

Specific responses pertaining to peer reviewer comments are included in **Table 1**. Draft report peer reviewers include:

- **Natalia Murinova, MD, MHA**
- **Mark Soddors, DAOM, Dipl. OM (NCCAOM)**
- **Diane Behall, DAOM, LAc**

**Table 1. Responses to Clinical and Peer Reviewers**

Page	Comment	Response
<b>Natalia Murinova, MD, MHA</b>		
Introduction Page 38, Line 10	No cause of migraine mentioned, only tension type headache.	Thank you for your comments. We have added a sentence stating the cause of migraine.
Introduction 3 <sup>rd</sup> paragraph	<p>Technically management of primary headache is divided into pharmacological (medications) and non-pharmacology approaches, and this includes also neuromodulation, as well as procedures such as acupuncture.</p> <p>At least 1/3 of patients prefer non-medications approaches, and many patients with chronic migraine are medication refractory, meaning they failed more than 2 preventive medication options.</p> <p>Non-medication approaches are key for patients with chronic migraine that are medication refractory, but also for patient who can't tolerate medications due to side effects or due to medical illness or other comorbid states like pregnancy or breastfeeding.</p>	We have added information to the background to clarify these points.
Background Page 38	It would be good to add potential mechanism of acupuncture for migraine and tension-type headache.	Please see section 2.3.1.1 for this information. We also added to this section a sentence citing the studies referenced in the comment below regarding mechanism of action (Ke 2021; Jai 2021).
Background Page 45	Epidemiology and Burden of Disease is well characterized.	Thank you for your comments.
Background Page 48, Line 14	<p>Chronic migraine is well summarized.</p> <p>Treatment of migraine on line 14 needs to be updated, there are new anti-CGRP migraine specific treatments. Gepants are small-molecule calcitonin gene-related peptide (CGRP) receptor antagonists primarily developed for the acute treatment of migraine, these include Ubrogepant and Rimegepant. Ditans, another new group of medication (Lasmiditan) has high affinity and selectivity for serotonin 5-HT<sub>1F</sub> receptors and lacks the vasoconstrictor activity inherent with triptans, thereby making lasmiditan a different class of treatment, designated as acute treatment.</p> <p>Neuromodulation devices have been studied as safe and well-tolerated strategies for the acute and preventive treatment of migraine. These devices provide electrical stimulation to extracranial sensory afferent fibers above their depolarization thresholds but below the perceived pain</p>	Thank you for your comments. We have added information regarding anti-CGRP treatments, Lasmiditan, and neuromodulation to the description of common therapies for the prevention/treatment of migraine.

Page	Comment	Response
	<p>threshold, which activates the central descending inhibitory pathways to inhibit pain. These devices include remote electrical neuromodulation (REN) device, external trigeminal neurostimulation (eTNS) device, single-pulse transcranial magnetic stimulation (sTMS) device and external vagal nerve stimulation (VNS) device.</p> <p>Common prophylactic treatment is missing CGRP and CGRP receptor antagonist monoclonal antibodies (mAbs): since 2018, mAbs against CGRP or the CGRP receptor have been FDA approved for preventive treatment of both episodic and chronic migraine – erenumab, galcanezumab, fremanezumab, and eptinezumab. The first 3 are intended for self-injection at home.</p>	
Background Page 49	<p>Prophylactic treatment is recommended when patient have more than 4 headache days per month.</p> <p>I would also add that in USA is also consider patients preferences when choosing a preventive agent.</p>	This information has been added to provide additional context to the readers.
Background Page 52 Section 2.3.1.1. Line 7	<p>Proposed benefits of acupuncture now include studies for chronic migraine with discussion of possible decrease in CGRP and regulation of serotonin levels. See:</p> <p>Ke, H.K., Tu, S.H., Shen, Y.J. and Qu, Q.W., 2021. Effect of ZHU Lian's type II inhibition acupuncture on chronic migraine and serum 5-HT, VEGF, CGRP. Zhongguo Zhen jiu= Chinese Acupuncture &amp; Moxibustion, 41(10), pp.1079-1083.</p> <p>Acupuncture has also been shown to have effects on brain connectivity and the default mode network:</p> <p>Jia, J.N., Yan, C.Q., Qi, X.H., Zheng, X.C., Shi, A.Q. and Wang, J., 2021. Effect of acupuncture on default mode network in patients with migraine based on functional Magnetic Resonance Imaging: a preliminary study. Zhongguo zhen jiu= Chinese acupuncture &amp; moxibustion, 41(10), pp.1074-1078.</p>	We have included a couple sentences addressing this new information regarding the potential mechanism of acupuncture.
Objectives Page 39	Objectives -the aim is clearly defined.	Thank you for your comments.
Methods	The methods seem reasonable and adequate.	Thank you for your comments.
Results Page 71-72, Section 4.2.1.2	<p>The heading 4.2.1.2. mentions Description of Study population for Chronic Migraine, however Habibabadi; Musil are not chronic migraine studies.</p> <p>Habibabadi, Mehran Razvani, Fereshteh Ashtari, and Iman Raeisi. "Effect of Auricular Acupuncture with Semi-Permanent Ear Needles on Controlling Migraine Symptoms: A Single-Blind Randomized Clinical Trial." (2021): 58-66.</p>	While chronic headache is currently defined by the International Classification of Headache Disorders, 3rd edition as ≥15 headache days each month for at least 3 months or more than 180 days a year, older studies may have used varied definitions and timeframes (e.g., 28-day period or

Page	Comment	Response																								
	<p>This study listed by (55) is not in chronic migraine.</p> <p>Chronic migraine is defined as <math>\geq 15</math> or more days per month, here is was 3.37 days per month Number of days per week with migraine</p> <table border="1" data-bbox="370 457 1029 653"> <tr> <td>Baseline</td> <td>3.37 <math>\pm</math> 1.25</td> <td>3.25 <math>\pm</math> 1.06</td> <td>0.631</td> </tr> <tr> <td>After treatment</td> <td></td> <td></td> <td></td> </tr> <tr> <td>First week</td> <td>2.50 <math>\pm</math> 0.82</td> <td>2.77 <math>\pm</math> 0.73</td> <td>0.117</td> </tr> <tr> <td>Second week</td> <td>2.47 <math>\pm</math> 0.93</td> <td>2.35 <math>\pm</math> 0.83</td> <td>0.529</td> </tr> <tr> <td>Third week</td> <td>1.72 <math>\pm</math> 0.64</td> <td>2.17 <math>\pm</math> 0.75</td> <td>0.005</td> </tr> <tr> <td>Fourth week</td> <td>1.23 <math>\pm</math> 0.77</td> <td>1.75 <math>\pm</math> 0.59</td> <td>0.001</td> </tr> </table> <p>Musil, F., Pokladnikova, J., Pavelek, Z., Wang, B., Guan, X. and Valis, M., 2018. Acupuncture in migraine prophylaxis in Czech patients: an open-label randomized controlled trial. <i>Neuropsychiatric disease and treatment</i>, 14, p.1221.</p> <p>Not a chronic migraine study. Inclusion was at least 4 days of headaches (not chronic migraine)</p> <p>Vickers, Andrew J., Rebecca W. Rees, Catherine E. Zollman, Rob McCarney, Claire M. Smith, Nadia Ellis, Peter Fisher, and Robbert Van Haselen. "Acupuncture for chronic headache in primary care: large, pragmatic, randomized trial." <i>Bmj</i> 328, no. 7442 (2004): 744.</p> <p>Since this study was done prior to 2005 when chronic migraine was defined as we currently use the term, in this study they lumped TTH and migraine and because of this I don't think you can include this in chronic migraine.</p>	Baseline	3.37 $\pm$ 1.25	3.25 $\pm$ 1.06	0.631	After treatment				First week	2.50 $\pm$ 0.82	2.77 $\pm$ 0.73	0.117	Second week	2.47 $\pm$ 0.93	2.35 $\pm$ 0.83	0.529	Third week	1.72 $\pm$ 0.64	2.17 $\pm$ 0.75	0.005	Fourth week	1.23 $\pm$ 0.77	1.75 $\pm$ 0.59	0.001	<p>30-day period for a month). Given these variations, studies reporting populations with a mean of <math>\geq 12</math> headache days per month or <math>\geq 12</math> headache episodes or attacks per month or equivalent were considered to meet the criteria for chronic headache for this report. We described this approach in the methods under the inclusion/exclusion criteria and included a footnote to this effect Table 4 (PICOTS). This approach is consistent with what was done in the prior report with the intention to be as inclusive as possible.</p> <p>Given the criteria above, both Habbibabadi and Musil meet our criteria for chronic migraine:</p> <ul style="list-style-type: none"> <li>- In Habbibabadi, the mean number of days <i>per week</i> with migraine was 3.37 vs. 3.25; when multiplied by 4 to make it days <i>per month</i> the means are 13.5 vs. 13 days, which meets our cut-off of 12 days per month.</li> <li>- In Musil, the frequency of migraine days per month at baseline was mean 11.97 vs. 12.1 which meets our cut-off of 12 days per month.</li> </ul> <p>Regarding Vickers, this trial's population is comprised of 94% chronic migraine and 6% CTTH; per our inclusion/exclusion criteria (See Exclusion Criteria under Study Design in Table 4, PICOTS), a population comprised of <math>\geq 80\%</math> of the population of interest is includable. This trial is therefore includable under chronic migraine. This is consistent with accepted methodology for SRs and what we have done for other HTAs.</p>
Baseline	3.37 $\pm$ 1.25	3.25 $\pm$ 1.06	0.631																							
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<p>Results Page 72-84</p>	<p>Again above comments, Musil and Vickers studies were included and these are not chronic migraine</p>	<p>Please see comments above.</p>																								

Page	Comment	Response
	And Habibabadi is not chronic migraine with baseline headache count at $3.37 \pm 1.25$	
Results Page 88	<p>Chronic Tension Type Headache. – no new studies were mentioned. The data presented appears accurate and representative of the articles.</p> <p>I do question whether the 1990 article (#35; Carlsson J, Augustinsson LE, Blomstrand C, Sullivan M. Health status in patients with tension headache treated with acupuncture or physiotherapy. Headache 1990;30:593-9.) is fully applicable since the diagnosis of headache has changed significantly since 1990.</p>	Thank you. We understand that this is a limitation of the available evidence. We did not limit by publication date.
General Page 116	The strength of evidence summary is helpful, although my previous concerns about some of the studies listed as being of chronic migraine (Habibabadi 2021, Musil 2018) stand and make up a significant amount of the data being summarized, as well as the significantly older studies (Carlsson 1990, Vickers 2004).	Thank you. As stated previously, these trials do meet our a priori inclusion criteria for chronic migraine. We are at the mercy of the literature and recognize that a number of the included trials were older and this is a noted limitation of the evidence, especially for CTTH.
General Page 120	<p>As a side note, I did not see that the circle-and-cross symbols used in the strength of evidence tables are explained anywhere and at least in one row they seem inconsistent; page 120, the entry for Habibabi (2021), where the paper gets three crosses but is listed as INSUFFICIENT. Without an explanation of these symbols, I cannot tell if this is a typo or has some greater significance.</p> <p>See earlier comments about the executive summary, which appears to mirror the rest of the report closely.</p>	Thank you for catching this copy and paste error; it has been fixed. The more crosses, the greater the strength of evidence (i.e., High = 4 crosses; Moderate = 3 crosses and 1 empty circle; Low = 2 crosses and 2 empty circles; Insufficient = 1 cross and three empty circles). We do not typically provide a legend for these symbols as the SOE (high, moderate, low, insufficient) is also provided.
General	<p>The review is well structured and organized. The introduction is dated and does not reflect the state of the art in headache medicine. In addition, multimodal treatment is very common in the treatment of chronic headaches, which is not well reflected in the studies considered.</p> <p>The generalizability and applicability of this report may be limited by the small number of studies that are considered. Many of these studies have been performed outside the USA with populations, and in health care systems, that are significantly different from the Washington headache patient population. These are obviously issues beyond the scope of this report.</p>	Thank you for your thoughtful review and comments. The introduction and background have been updated to reflect current understanding and approaches to headaches and their treatment per your comments. Regarding generalizability and applicability, your comments/concerns are well taken; unfortunately, we are at the mercy of the peer-reviewed published literature.
<b>Mark Soddors, DAOM, Dipl. OM (NCCAOM)</b>		

Page	Comment	Response
Introduction Page 1, Section 1.1	"Eastern philosophy of activating or correcting qi, the believed vital energy source in humans." Qi is a difficult word to translate and is often left untranslated. While many dictionaries support the definition used, the term "energy" is non-specific and has many interpretations. Instead, the authors are encouraged to combine the two sentences and indicate that "Acupuncture has been used for thousands of years and involves the insertion of ...."	Thank you for this clarification. We have eliminated the part of the sentence you suggested and added additional context in section 2.3.1 concerning qi.
Introduction Page 2, Section 1.2	It is unclear how we get from sections 1.1.2 to 1.2 for an interest in short-term efficacy. In the objectives (1.1.2), the authors indicate that the focus is on chronic headaches. However, the key questions indicate the review is examining evidence for short-term efficacy of acupuncture compared to a control. Is short-term efficacy as used here to mean the effect of acupuncture on isolated headache episodes? If not, how does examining short-term efficacy answer the objective for outcomes related to chronic headaches?	The Key Questions say we are looking at both short-term and long-term efficacy. The follow-up term has nothing to do with isolated headache episodes – the focus is still on chronic headaches. For the purposes of this report and consistent with the scope of the prior report, short term was defined as follow-up 1-8 weeks <i>post-treatment</i> , intermediate term >8 to <12 weeks <i>post-treatment</i> , and long term ≥12 weeks <i>post-treatment</i> . Given that these are chronic headaches, our focus was on intermediate and long-term outcomes <i>posttreatment</i> (as stated in our Methods and in our PICOTS table (Table 4) under timing) to assess the lasting effects of acupuncture once treatment had ended. Trials reported short- and long-term data as defined above, but no/very little intermediate term data.
Introduction Page 4, Table 1	Table 1 seems out of place for an introduction section and appears to belong in the results section. The authors are encouraged to provide a statement of why it is necessary to include this information in the introduction, and if it remains, consider adding a column to show how these instruments map to the key objectives.	Thank you for your comments. It is standard to include a table of outcome measures in our reports for the Healthcare Authority. The reason is stated in the text preceding the table.
Introduction Page 5, Table 1	The MIDAS components indicate five items, but only four are listed. MSEP indicates only five items for Contentment, but seven are listed. MACL- it might be helpful to clarify if the term "bipolar" has a contrasting meaning or means something else. VAS- the abbreviation ED is not defined.	Thank you for your comments. We've made the necessary changes.
Background Page 8, Section 2.1	The abbreviation of GBD is not defined and is assumed to mean "Global Burden of Disease."	We have now defined GBD within the text.



Page	Comment	Response
Background Page 9, Section 2.2	<p>The draft presents information on TTH first and then on CM. However, in paragraph 1 of section 2.2, CM is presented first (as it tends to be throughout the paper). It might be beneficial to be consistent on which headache type is discussed first throughout the paper.</p> <p>The first paragraph details how the terminology and definitions of headaches evolved. As such, the fifth paragraph, sentence 1, under section 2.2, is redundant and disrupts the reading flow. It is also a little difficult to understand the relationship at first between the last two paragraphs. Both of these paragraphs point to different headache definitions. Therefore, consider pointing out in the last paragraph that the topic is now on chronic daily headaches first before indicating that a non-standard classification has to be used to define chronic daily headaches (which is defined as the coexistence of tension and migraine headaches).</p>	<p>Thank you for your comments. We have ensured that throughout the entirety of the report information and data on CM is presented first followed by TTH.</p> <p>The paragraph you stated as being redundant has been eliminated.</p> <p>The first and final paragraphs of section 2.2 have also been edited to increase clarity around the definition of chronic daily headache as defined for the purposes of this report.</p>
Background Page 14, Section 2.3.1	<p>See previous comment about defining Qi.</p> <p>Acupuncture needles are also thin and flexible in addition to being solid.</p>	<p>Thank you for this clarification. We have eliminated the part of the sentence you suggested and added additional context concerning qi, as well as added additional information regarding needles.</p>
Background Page 15, Section 2.3.1.2	<p>The first sentence indicates that infections, organ injuries, and tissue injuries are common. Context is needed for this statement. In relation to reporting adverse events (AE), "common" means an occurrence of <math>\geq 1/100</math> and <math>&lt; 1/10</math> (according to the CIOMS). The cited article included only case reports specifically reporting complications or adverse events for acupuncture, moxibustion, and cupping. Also, this paragraph cites a 2021 systematic review and meta-analysis of adverse events. For context, it might be beneficial to point out that most of the reported AEs were considered minor and transitory, and some events were possibly even part of the therapy. Of note, this systematic review also did not identify any significant adverse events (SAE) reported from traumatic injuries of inner organs or systemic infections.</p>	<p>Thank you for your comments. We have removed the word common from the sentence and updated the verbiage based on your suggestion.</p>
Background Page 16-18, Table 2	<p>Abbreviation NR not defined.</p>	<p>Abbreviations have been added.</p>
Objectives Page 20, Sections 3.1.1 Objectives	<p>The aims and objectives address the relevant policy/clinical issue under study. The population, intervention, comparators, and outcomes are outlined and defined. Key questions are generally defined clearly and adequately for achieving the aims. For clarity in the key questions, the</p>	<p>For the purposes of this report and consistent with the scope of the prior report, short term was defined as follow-up 1-8 weeks <i>post-treatment</i>, intermediate term</p>

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and 3.1.2 Key Questions	authors should support in the introduction why we are interested in short-term efficacy and effectiveness when our population is adults with chronic headache. As mentioned in the earlier comments, is this short-term efficacy and effectiveness about acupuncture's effect on isolated headache episodes? Clarity could also be added by explicitly defining the difference and importance of efficacy and effectiveness in the introduction section.	>8 to <12 weeks <i>post-treatment</i> , and long term $\geq 12$ weeks <i>post-treatment</i> . Given that these are chronic headaches, our focus was on intermediate and long-term outcomes <i>posttreatment</i> (as stated in our Methods and in our PICOTS table (Table 4) under timing) to assess the lasting effects of acupuncture once treatment had ended. Trials reported short- and long-term data as defined above, but no/very little intermediate term data. We clarified efficacy and effectiveness where relevant in our opinion.
Methods	Absent from the methods is the search strategy used, which appears to be listed in Appendix B. Also absent from the methods section is the application of the inclusion/exclusion criteria in the study flow, which appears to be listed in Appendix C. In the absence of this information, it is unclear if the methods are adequate for identifying studies relevant to the study objectives and key questions. Methodologies for assessing risk of bias and strength of evidence are good. There are some inconsistencies throughout the methods section related to the inclusion/exclusion criteria, RoB assessments, and data abstraction. Comments related to this are below.	There are different ways to format reports/HTAs. It is standard to include the full search strategy as well as a list of studies excluded at full text with the reason for exclusion in the Appendix of these reports. These HTAs are very large and it allows the reader to focus on the results while still ensuring that the full methodological details are available for review for transparency.
Methods  Page 20-22, Section 3.1.3	<p>The inclusion/exclusion criteria is listed in duplicate.</p> <p>See previous comments about highlighting why the population includes a mean <math>\geq 12</math> headache days or <math>\geq 12</math> episodes monthly and how this is different from the ICHD definition of chronic headache is for 15 or more days.</p> <p>Outcomes- continue serializing the outcomes to include (5) for the economic outcomes. As it stands, it appears that the economic outcomes are included with the safety information.</p>	<p>We always list an abbreviated, bulleted version of the inclusion/exclusion criteria that highlights the key criteria; additional details are available in the PICOTS table that follows.</p> <p>This information is highlighted both in the abbreviated, bulleted version of the inclusion/exclusion criteria (under Population) as well as by a footnote (*) at the bottom of the PICOTS table. The footnote further describes the rationale for the different criteria.</p> <p>The outcomes serialized are primary outcomes (efficacy or harms) and studies must report at least one of them to be included. Economic studies and their</p>

Page	Comment	Response
	<p>Studies- use of high-quality studies is reported as a criterion, but the report needs to add clarity on how and when in the study flow the authors determine if a study is considered high quality from the identification through the data synthesis process.</p> <p>Timing- the introduction sets up the study to focus on chronic headache, so the justification is not clear for reporting on 8 to 12 weeks in this study, and the authors should include information as to why this period of time is important to examine since the condition under study is for chronic headache. Also, in this section and throughout the paper, the authors should highlight the difference between efficacy and effectiveness, and use consistency when reporting on these two different types of study-related concepts.</p> <p>Table 4. The exclusion for episodic migraine occurring &lt; 15 days per month- there is no mention of tension-type headaches occurring &lt; 15 days per month. There is also no exclusion for a mean of &lt; 12 headache episodes per month for chronic daily headache. The criteria should be clarified.</p>	<p>outcomes stand alone and those do not have a number.</p> <p>Only RCTs were considered for inclusion, consistent with the prior report, as they represent the highest quality evidence available. No RCT was excluded (at title/abstract review or FT review) based on study quality. Study quality is further considered when we interpret the results and grade SOE (ROB is one of the criteria for downgrading SOE according to GRADE).</p> <p>As state above, for the purposes of this report and consistent with the scope of the prior report, short term was defined as follow-up 1-8 weeks <i>post-treatment</i>, intermediate term &gt;8 to &lt;12 weeks <i>post-treatment</i>, and long term ≥12 weeks <i>post-treatment</i>. Given that these are chronic headaches, our focus was on intermediate and long-term outcomes <i>posttreatment</i> (as stated in our Methods and in our PICOTS table (Table 4) under timing) to assess the lasting effects of acupuncture once treatment had ended. Trials reported short- and long-term data as defined above, but no/very little intermediate term data.</p> <p>Thank you. We have clarified this under the population exclusion criteria in the PICOTS table/Table 4.</p>
<p>Methods Page 26 Table 4 Footer</p>	<p>Evidence for sham acupuncture as an inert comparator is conflicting. Use of non-channel acupuncture points, particularly in pain and chronic conditions, is a part of acupuncture.</p>	<p>Thank you. The report compared all interventions to sham/placebo as a comparator where literature is available. Treatments were also compared to no treatment, waitlist treatment and usual care treatments to the extent that comparative literature is available. Characteristics of treatments and controls were abstracted and</p>

Page	Comment	Response
		<p>described. All studies (and comparators) have inherent strengths and limitations. Across the report, the comparators are delineated.</p> <p>Studies comparing treatments to sham treatments (even those which may be considered “active”) as one type of comparator provide valuable information regarding treatment efficacy for pain conditions. Subjective improvement in patients may result from factors other than a given procedure, whether that treatment is an “active” sham or a specified intervention. Some of these factors include the natural course of the condition, the effects of placebo, and measurement error. A placebo effect does not require a placebo and reflects a change in a patient’s condition attributable to the symbolic importance of a treatment versus specific physiologic or pharmacologic properties. For many interventions, it is common to evaluate treatment effectiveness against a placebo control to account for such effects. (Turner and Meissner references below). For many research purposes, having a sham/placebo control is of more value than having no treatment comparison.</p> <p>There are examples of validated sham controls for acupuncture including the one described by Sherman, et. al. (Referenced below):                      Turner JA, et. al (JAMA. 1994;271:1609-1614)                      Sherman, et. al. ( THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE Volume 8, Number 1, 2002, pp. 11–19)</p>

Page	Comment	Response
		Meissner K, et. al. JAMA Intern Med. 2013;173(21):1941-1951.
Methods Page 28, Section 3.1.5	Data extraction method is absent from the report. For clarity, the authors are encouraged to indicate this process, including the number of reviewers involved.	This information is detailed in section 3.1.5 per our standard process. Number of reviewers was clarified.
Methods Page 30, Section 3.1.7	APS/ACP should be defined and if appropriate cited.	This has been edited.
Results	Overall, the amount of detail presented in the results section is appropriate. However, many sections need some edits for clarity. The information appears to be present for each key question, figure/table, and findings. The gaps in the literature are addressed only to the extent the identified articles could address these gaps. General themes identified in the results section that require clarity include (1) the terms "statistically" and "significantly" need a further explanation when they appear, and (2) a paragraph early in the results section for the identified studies is needed to highlight how each identified article maps to the references, as there are more references than the stated number of identified articles. These themes and other comments are specifically detailed below.	We have reviewed the sections and edited for clarity as appropriate.
Results Page 31-32, Section 4.1	<p>Paragraph 1. Clarity is needed to explain why there were six trials across nine publications (i.e., were some of the trials published more than one time, or were different data from single studies reported in multiple publications, or were there only nine publications for full-text review and only six trials were included).</p> <p>Table 6. As with the last comment, it is unclear what "across X publications" means when reporting the number of identified studies</p> <p>Paragraph 2. Readers would benefit from in-text citations for the relevant studies when reporting types of sources for bias.</p> <p>Paragraph 6. See previous comment about a sham control related to acupuncture. This sentence also provides information more suited for the methods section, rather than the results section.</p>	We have reviewed the sections and edited for clarity as appropriate.
Results Page 32, Section 4.2.1	Paragraph 1. Readers would benefit from in-text citations for the relevant studies when reporting types of comparators and sources for bias.	Agreed. We have added the references.
Results	The bullet points for outcomes for both Treatment Responders and for Reduction in Headache Frequency- For	The bullet was kept as originally written.

Page	Comment	Response
Page 33, Section 4.2.1.1	<p>clarity, please consider making separate sentences to address each outcome of interest (one for headache days and one for moderate to severe headache days).</p> <p>The bullet point for Reduction in Headache Frequency. The 4 weeks for auricular acupuncture seems as if it should be included with the first bullet point- the draft sets up a cadence where we are presented the results by short term and then by long term. This also goes with the last bullet point in this list as it reports on 24 weeks and appears to be better suited to list under the long-term section.</p>	<p>Thank you. The first 2 bullets represent one outcome, and the last 2 bullets represent a different outcome. For clarity we added subheadings of “headache days per month” and “headache episodes/attacks per month”; under each heading the results remain organized by short term first followed by long term.</p>
Results  Page 34-39, Section 4.2.1.2	<p>All references to trials need in-text citations.</p> <p>For clarity, the authors are encouraged to change the word "sites" to either "acupuncture point locations" or "acupuncture points," depending on the context of the sentence.</p> <p>"...or needles used" should be clarified to indicate if this means the number of needles used, or the type of needles used, or both.</p> <p>Paragraph 1- this is a dense paragraph. Consider creating multiple paragraphs for clarity.</p> <p>Paragraph 2- last sentence. For clarity, provide information on what the study should have accounted for. Is this referencing the reasons for drop-outs?</p> <p>Table 7 and Table 8. "Population" row points to the number of people in each study (N). This might create confusion as the term population commonly references the defined population under study.</p>	<p>We have added in-text citations to trials for clarity where we felt it was needed/appropriate.</p> <p>We have made edits to the report per suggestions.</p>
Results  Page 40, Section 4.2.1.3.1	<p><b>Treatment Responders-</b> For clarity here and elsewhere where something is described as "statistically," please consider re-wording these sentences to indicate whether something reached statistical significance or failed to reach statistical significance and what the significance level was.</p>	<p>We have revised the text for clarity as appropriate.</p>
Results  Page 42-44, Section 4.2.1.3.2	<p><b>Reduction in Frequency of Moderate or Severe Headache Days, Reduction in Frequency of Mild Headache Days. Please see previous comments about the number of studies across multiple publications.</b> Please clarify when the pooled treatment effects indicate a number of trials that do not equal the number of references cited.</p>	<p>We made edits as appropriate.</p>

Page	Comment	Response
Results Page 46-51, Section 4.2.1.3.5	<p><b>Secondary Outcomes, Reduction in VAS pain scores</b> Longer-term (12–24 weeks): "...in one small trial (N=69) at moderately high low risk of bias." Please clarify if this was a high or low risk of bias.</p> <p><b>Secondary Outcomes, Depression and Anxiety</b> Short-term (1 week): what was the risk of bias assessment for this study?</p> <p><b>Secondary Outcomes, Frequency of Analgesic Use Long-term</b> (36 weeks): "In an unplanned analysis, a third trial (moderately high risk of bias) summed and scaled..." needs a reference. Two references are provided at the end of the last sentence, and it is unclear how these map to the three studies presented.</p>	<p>Thank you for catching this error; it has been changed to "moderately low risk of bias".</p> <p>We have added this information.</p> <p>We have edited the in-text citations for clarity.</p>
Results Page 51 Line Section 4.2.2	The word "differences" might lead a reader to expect the reporting of differences in measured effects. The authors are encouraged to use another word.	Thank you for your comment.
Results Page 51, Line Section 4.2.2.1	<p><b>Reduction in Headache Frequency:</b> The sentence "There were no differences between acupuncture and sham based on the pooled mean..." and the sentence in the second bullet point are unclear. If there were no differences, then this indicates the means were identical. For clarity, please indicate if this is the case, or if the differences were not meaningful, or failed to reach statistical significance.</p> <p><b>Function:</b> the word "significantly" is not clear. Please indicate if this references statistical significance, or meaningful improvements, or both.</p>	We have edited for clarity.
Results Page 52, Section 4.2.2.2	<b>Description of Study Populations for Chronic Tension-Type Headache:</b> Clarity is needed as the cited references indicate two studies when the text says there is one study for active comparisons for physical therapy/exercise. This refers to earlier comments on the number of studies across the number of publications.	We have edited for clarity where appropriate.
Results Page 52, Section 4.2.2.2.1	<b>4.2.2.2.1 Acupuncture versus Sham Acupuncture:</b> See previous comments on sham acupuncture. The authors are encouraged to indicate where the sham acupuncture occurred for the study by Karst et al. (2000). I.e., was the sham device placed over the location of the acupuncture point, or only nearby, or in a completely different area?	We have made edits to the text for clarification.
Results Page 53, Section 4.2.2.2.2	<b>Acupuncture versus Active Controls:</b> Here, we are told a single study is across two publications. Please see previous comments about clarifying this information.	We have edited the sentence for clarification.

Page	Comment	Response
<p>Results Page 60 – 61, Section 4.2.2.3.2</p>	<p><b>Reduction in Frequency of Headache Attacks:</b> see prior comment about the word "differences."</p> <p><b>Reduction in Frequency of Headache Attacks, Acupuncture versus physiotherapy, physical training, or relaxation training, Short- to Intermediate-Term (4 to 9 weeks):</b> please specify which response goes with which numeric rating, does 1 = almost never?</p> <p><b>Reduction in Frequency of Headache Attacks, Acupuncture versus physiotherapy, physical training, or relaxation training:</b> when the word "significantly" is used here and throughout the document, the authors are encouraged to indicate if this means statistical significance, or meaningful differences, or both.</p> <p><b>Reduction in Frequency of Headache Attacks, Acupuncture versus physiotherapy, physical training, or relaxation training, Longer-term (26 weeks):</b> as with the previous comment, the authors are encouraged to rephrase "statistical differences" to indicate if the estimated reports were considered statistically significant.</p>	<p>We have edited for clarity where appropriate.</p>
<p>Results Page 62-65, Section 4.2.2.3.5</p>	<p><b>Secondary Outcomes Patient perception of improvement:</b> what was the comparison group?</p> <p><b>Secondary Outcomes Acupuncture versus active comparators Quality of Life:</b> "In the trial comparing acupuncture with physical training/exercise and acupuncture with relaxation training<sup>91,93</sup>" There is one trial showing two references. See prior comments about the number of studies across the number of publications</p> <p><b>Secondary Outcomes Acupuncture versus active comparators Headache intensity:</b> "One trial reported less improvement..." needs a reference</p> <p><b>Secondary Outcomes Acupuncture versus active comparators Headache intensity:</b> the 5-point scale- how does it map to the categorical responses?</p>	<p>There is data provided by acupuncture vs. sham for this outcome and it is clearly delineated as such.</p>
<p>Results Page 65-67, Section 4.3.1.1</p>	<p><b>Summary of Results for all Headache Types Chronic Migraine, Headache:</b> it might be beneficial to point out that headache in this regard expressly references an adverse event and not an outcome from objective 1.</p>	<p>Thank you. We edited the sentence to say "treatment-related headache."</p>
<p>General Page 79-96, Strength of</p>	<p>As mentioned in previous comments, it is important to establish why short terms are being considered when the primary outcome is for chronic headaches early in the manuscript.</p>	<p>As state above, for the purposes of this report and consistent with the scope of the prior report, short term was defined as follow-up 1-8 weeks <i>post-treatment</i>,</p>



Page	Comment	Response
Evidence Tables		intermediate term >8 to <12 weeks <i>post-treatment</i> , and long term ≥12 weeks <i>post-treatment</i> . Given that these are chronic headaches, our focus was on intermediate and long-term outcomes <i>posttreatment</i> (as stated in our Methods and in our PICOTS table (Table 4) under timing) to assess the lasting effects of acupuncture once treatment had ended. Trials reported short- and long-term data as defined above, but no/very little intermediate term data.
General Page 79-84, Section 5.1	<p>Here, for clarity, please indicate in the table the number of times the overall strength is downgraded for all categories. For example, in the first row, <b>Responders: Proportion with ≥50% reduction in <u>any</u> headache days from baseline.</b> Strength of Evidence (SOE) was downgraded two times for the Short-term and one time for the Long term. In both cases, the Unknown rating for Serious Inconsistency does not affect the overall SOE. But in the row for <b>Proportion with ≥50% reduction in mild headache days from baseline</b>, the SOE downgraded one time, but Quality is rated as Low, and it appears that perhaps the <i>Unknown</i> rating for <i>Serious Inconsistency</i> may have downgraded the overall SOE. The footnote on inconsistency indicates when a downgrade may result. Specifically, pointing out the downgrade in the table (e.g., Yes (-1) ) is needed for all areas where downgrades were made.</p> <p>Other areas where the indicated downgrades appear incongruent with the reported SOE and clarification is needed in the table:</p> <p><b>Proportion with ≥50% reduction in moderate/severe headache days from baseline</b>, Both Short and Long-term categories are rated as a Low SOE, although there is only a single reduction indicated from Serious Risk of Bias and Serious Imprecision only for the Short-Term.</p> <p><b>Proportion with ≥50% reduction in moderate/ severe headache days from baseline.</b> SOE downgraded one time for Long Term, yet the Quality is rated for Long Term as Low.</p> <p><b>Proportion with ≥35% improvement in headache score* from baseline.</b> SOE downgraded one time, but Quality is rated as Low</p>	<p>We have reviewed the SOE evaluations and have re-affirmed our final judgements regarding them. For comparison we looked at Cochrane reviews on this topic (Linde 2016, Linde 2016) and AHRQ reviews involving acupuncture. We believe that our final ratings are reasonably consistent, keeping in mind different evidence bases, outcomes, approaches to evaluating the domains and objectives for the various reviews. For example, one Cochrane review (on chronic TTH) typically downgraded for ROB (lack of blinding) and limited precision of the effect estimate, as well as variable effect size (inconsistency) at times. In this report we typically downgraded – across routine care/sham – for ROB and imprecision, as well as unknown consistency when applicable. We have attempted to be transparent and consistent in evaluation of the domains and downgrading; to that end we do footnote the SOE tables and point out specific aspects of the evidence. We have also included rationale for risk of bias and SOE application throughout the report and described specific issues with studies and outcomes. Because</p>

Page	Comment	Response
	<p><b>Reduction in moderate/ severe headache days per month.</b> SOE downgraded one time for Long Term, yet the Quality is rated for Long Term as Low.</p> <p><b>Reduction in mild headache days per month (adjusted for baseline)</b> SOE downgraded one time, but Quality is rated as Low</p> <p><b>Reduction in headache episodes/attacks per month.</b> SOE downgraded three times, Quality is rated as Insufficient, but indicators show the SOE was downgraded only one time.</p>	<p>the consistency of the evidence from a single study cannot be known, the SOE is usually downgraded. Decisions regarding final SOE can be complex and require considering the interaction among the domains being graded, the specific outcome (and often the risk of bias and/or measurement associated with that outcome need to be considered as well as any MCID) and unique concerns about the body of evidence to arrive at a confidence in the effect for a given outcome. We also attempt to formulate final SOE in consideration of what the best quality evidence may be and may focus on the higher quality RCTs for a given outcome to the extent possible. The SOE may thus vary between outcomes. As pointed out in many publications regarding determination of SOE, its determination should not be solely a reductive, single grade of the evidence for describing the findings and implications of them and some level of judgement is required. Again, we have attempted to be transparent and provide context around these judgments via foot notes as well as descriptions of study limitations, areas where there is lack of precision and/or unclear consistency/heterogeneity in the narrative portions of the report. This is important so that readers may consider the influence of various study limitations on effect estimates for a given outcome together with other factors such as impression and inconsistency.</p>
<p>General Page 85-89, Section 5.2</p>	<p>As with above, these areas are where the indicated downgrades appear incongruent with the reported SOE and clarification is needed in the table:</p>	<p>Please see comment above regarding the complexities of grading SOE and our approach.</p>

Page	Comment	Response
	<p>Responders Proportion with &gt;33% and &gt;50% improvement from baseline on the HI*. SOE downgraded two times for 4 weeks and 52 weeks, but Quality is rated as insufficient.</p> <p>Reduction in headache episodes per month. SOE downgraded two times for 26-52 weeks, but Quality is rated as insufficient.</p>	
<p>General Page 90-94, Section 5.3</p>	<p>As with the previous two sections, these areas are where the indicated downgrades appear incongruent with the reported SOE, and clarification is needed in the table:</p> <p>Safety Results for Chronic Migraine, Hematoma, facial hematoma. SOE downgraded two times for 4 weeks to 12 weeks, but Quality is rated as insufficient.</p> <p>Safety Results for Chronic Migraine, headache. SOE downgraded one time, but Quality is rated as Low.</p>	<p>Please see comment above regarding the complexities of grading SOE and our approach.</p>
<p>General Page 79-94, Section 5 in general</p>	<p>In addition to all previous comments on this section, although the limitations of individual studies are mentioned throughout the report, a dedicated section should be included in the summary section and should include possible limitations from both the individual studies and from the review level as well (discussion of the search strategy, heterogeneity of the included studies as it relates to data synthesis, etc.).</p> <p>Additionally, although AAI does not suggest implications for policy, the authors are encouraged to provide a conclusion paragraph summarizing the overall findings. Currently, any conclusions are presented in the strength of evidence tables, but these conclusions do not indicate if the quality of evidence is being considered.</p>	<p>Thank you for your comments. Per the standard format of these HTAs there is no formal discussion or conclusion section. Any limitations have been pointed out at the beginning of the results section and throughout the results to give context to their interpretation.</p> <p>Please see comment above regarding the complexities of grading SOE and our approach.</p>
<p>Report Presentation</p>	<p>Overall, the review is structured and organized logically. The sections flow conventionally from the introduction, background, and methods to results and synthesis. The main points about key questions are clearly presented, but the methods used and synthesis of the results for these main points require clarity, as noted in the comments. Non-pharmacologic options for treating headache pain is necessary, and the topic of acupuncture as an option for treating chronic headache is important for consideration for health insurance coverage.</p>	<p>Thank you.</p>
<p>Quality of report</p>	<p>Good - with recommendations addressed and clarity provided*</p> <p>*Several areas require clarification and some additional information. Provided the clarity is provided and comments are addressed, the quality of the report would be selected as "Good"</p>	<p>Thank you.</p>

Page	Comment	Response
<b>Diane Behall, DAOM, LAc</b>		
<p>Background</p> <p>Page 14, Line 2.3.1</p>	<p>Acupuncture is a holistic system of medicine with roots in Taoist philosophy. We look at the whole body when creating a treatment plan. Ultimately it is a system that tries to prevent illness and stimulate the body’s innate capacity for healing. Qi is part of it but not the entire part. I would want to change the first paragraph into something along these lines.</p> <p>“Acupuncture has been used for thousands of years and is part of a larger system of holistic medicine with roots in Eastern philosophy. This system takes the health of the whole body into consideration and focuses on activating or correcting qi, the believed vital energy source in humans.”</p>	<p>Thank you for your comments. We have taken your verbiage into consideration and made the necessary changes.</p>
<p>Background</p> <p>Page 15, Line 2.3.1.1</p>	<p>There has been more research into the mechanism of action for acupuncture; though not specifically about the relationship between acupuncture and migraine/headache.</p> <ol style="list-style-type: none"> <li>1) Acupuncture stimulates the discharge of endogenous (internally-sourced) opioids, e.g. endorphins (substances that suppress the sensation of pain).</li> <li>2) Acupuncture increases endomorphin-1, beta endorphin, enkephalin, and serotonin levels in plasma and brain tissue.</li> <li>3) Analgesic effects of acupuncture are mediated by the release of adenosine binding to receptor.</li> <li>4) Acupuncture modulates the pain pathway; can suppress the conduction of pain signals to the brain; can regulate balance between PNS and SNS</li> </ol> <p>Bauer M, McDonald J. Acupuncture in Pain Management: Strengths and Weaknesses of a Promising Non-Pharmacologic Therapy in the Age of the Opioid Epidemic. Accessed: February 13, 2022. <a href="https://www.acunow.org/uploads/1/1/8/6/118615065/anf-fda-20170712.pdf">https://www.acunow.org/uploads/1/1/8/6/118615065/anf-fda-20170712.pdf</a></p> <p>Cheng KJ. Neurobiological mechanisms of acupuncture for some common illnesses: a clinician's perspective. J Acupunct Meridian Stud. 2014 Jun;7(3):105-14.</p> <p>Pomeranz B. (2001) Acupuncture Analgesia — Basic Research. In: Stux G., Hammerschlag R. (eds) Clinical Acupuncture. Springer, Berlin, Heidelberg. pp1-28.</p> <p>Goldman N, Chen M, Fujita T, Xu Q, Peng W, Liu W, Jensen TK, Pei Y, Wang F, Han X, Chen JF. Adenosine A1 Receptors Mediate Local Anti-Nociceptive Effects of Acupuncture.</p>	<p>Thank you. The background has been edited as appropriate.</p>

Page	Comment	Response
	<p>Nature Neuroscience. 2010 Jul 1;13(7):883-8.</p> <p>Takano T, Chen X, Luo F, Fujita T, Ren Z, Goldman N, Zhao Y, Markman JD, Nedergaard M. Traditional Acupuncture Triggers a Local Increase in Adenosine in Human Subjects. The Journal of Pain. 2012 Dec 31;13(12):1215-23.</p> <p>Zhao ZQ. Neural Mechanism Underlying Acupuncture Analgesia. Progress in Neurobiology. 2008;85(4):355- 75.</p> <p>Han JS. Acupuncture Analgesia: Areas of Consensus and Controversy. Pain. 2011;152(3 Suppl):S41-8.</p> <p>Han JS. Acupuncture and Endorphins. Neuroscience Letters. 2004;361(1-3):258-61.</p>	
Objectives and Key Questions	All clearly stated.	Thank you for your comments.
Methods, general	<p>Regarding risk of bias assessment. Initial acupuncture studies tried to emulate the RCT gold standard of double blind placebo studies. The field has been moving away from these types of studies after a 2009 study from Harris on mu opioid binding potential in sham versus verum acupuncture. Verum acupuncture increased the mu opioid binding potential in most of the pain processing areas of the brain and provided longer pain relief. Sham acupuncture has a more immediate and short-term increase in endogenous opioids but pain reduction does not last. This paper led the NIH to declare that they didn't want sham comparisons. They also declared that they didn't want studies on comparative acupuncture point prescriptions. Studies now focus more on acupuncture versus usual care versus waitlist; or acupuncture + usual care versus usual care alone versus acupuncture alone.</p> <p>Harris RE, Zubieta JK, Scott DJ, Napadow V, Gracely RH, Clauw DJ. Traditional Chinese acupuncture and placebo (sham) acupuncture are differentiated by their effects on mu-opioid receptors (MORs). Neuroimage. 2009 Sep;47(3):1077-85. doi: 10.1016/j.neuroimage.2009.05.083. Epub 2009 Jun 6. PMID: 19501658; PMCID: PMC2757074.</p>	<p>Thank you. While the field may be moving away from these things, we are restricted to the evidence that is currently available.</p> <p>Thank you. The report compared all interventions to sham/placebo as a comparator where literature is available. Treatments were also compared to no treatment, waitlist treatment and usual care treatments to the extent that comparative literature is available. Characteristics of treatments and controls were abstracted and described. All studies (and comparators) have inherent strengths and limitations. Across the report, the comparators are delineated.</p> <p>Studies comparing treatments to sham treatments (even those which may be considered "active") as one type of comparator provide valuable information regarding treatment efficacy for pain conditions. Subjective improvement in patients may result from factors other than a given procedure, whether that treatment is an "active" sham or a specified intervention. Some of</p>

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		<p>these factors include the natural course of the condition, the effects of placebo, and measurement error. A placebo effect does not require a placebo and reflects a change in a patient’s condition attributable to the symbolic importance of a treatment versus specific physiologic or pharmacologic properties. For many interventions, it is common to evaluate treatment effectiveness against a placebo control to account for such effects. (Turner and Meissner references below). For many research purposes, having a sham/placebo control is of more value than having no treatment comparison.</p> <p>There are examples of validated sham controls for acupuncture including the one described by Sherman, et. al. (Referenced below):                      Turner JA, et. al (JAMA. 1994;271:1609-1614)                      Sherman, et. al. ( THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE Volume 8, Number 1, 2002, pp. 11–19)                      Meissner K, et. al. JAMA Intern Med. 2013;173(21):1941-1951.</p>
<p>Methods, general</p>	<p>A concern that exclusion criteria might be too narrow. A large meta analyses was completed in 2017, entitled the Acupuncture Evidence Project. It was commissioned by the Australian Acupuncture and Chinese Medicine Association. Migraine prophylaxis and headache (chronic tension-type and chronic episodic) were both found to have evidence of positive effect. I’ve provided the section on migraine and headache below as well as the link to the full report. Plus a list of the studies they referenced.</p> <p>“2.1 Migraine prophylaxis [Positive effect]</p> <p>For migraine prophylaxis, acupuncture was rated as ‘effective’ in the Australian DVA review (2010) and ‘evidence of positive effect’ in the USVA Evidence map of acupuncture (2014) (5, 6). Since March 2013 a narrative review of high</p>	<p>We have reviewed this publication and the citations referenced below. The studies are not specific to chronic headache (migraine or TTH or chronic daily headache) and most are in episodic migraine. Some also include trials of headache types that are not included in this HTA such as menstrual headache. Several of the individual articles cited are in Chinese from Chinese journals that do not seem to be indexed in the peer reviewed literature (PubMed, EMBASE) (specifically in Yang 2016,</p>

Page	Comment	Response
	<p>quality randomised controlled trials and two systematic reviews including a Cochrane systematic review update, have confirmed that acupuncture is superior to sham acupuncture and seems to be at least as effective as conventional preventative medication in reducing migraine frequency (40-42). Moreover, acupuncture is described as ‘safe, long-lasting and cost effective’ (40). Subgroup analysis in the Cochrane systematic review found that 16 or more treatment sessions showed a larger effect size (Z=4.06) than 12 treatments or fewer (Z=2.32). Evidence levels in these three reviews was moderate to high quality.</p> <p>2.2 Headache (chronic tension-type and chronic episodic) [Positive effect]</p> <p>Chronic tension-type headaches and chronic episodic headaches were not reviewed in the Australian DVA review (2010) and rated as ‘evidence of positive effect’ in the USVA Evidence map of acupuncture (2014) (5, 6). The most recent Cochrane systematic review update confirmed that acupuncture is effective for frequent episodic and chronic tension-type headaches with moderate to low quality evidence (43). A brief review of systematic reviews and meta-analyses described acupuncture as having a ‘potentially important role as part of a treatment plan for migraine, tension-type headache, and several different types of chronic headache disorders’ (44). Studies in Germany and the UK found acupuncture for chronic headaches to be cost-effective (44).”</p> <p>McDonald J, Janz S. The Acupuncture Evidence Project: A Comparative Literature Review (Revised Edition). Brisbane: Australian Acupuncture and Chinese Medicine Association Ltd; 2017. <a href="http://www.acupuncture.org.au/">http://www.acupuncture.org.au/</a> p.7</p> <p>(<a href="https://www.acupuncture.org.au/resources/publications/the-acupuncture-evidence-project">https://www.acupuncture.org.au/resources/publications/the-acupuncture-evidence-project</a>)</p> <p>References from that article cited above:</p> <p>5. Biotext. Alternative therapies and Department of Veterans' Affairs Gold and White Card arrangements. In: Australian Government Department of Veterans' Affairs, editor: Australian Government Department of Veterans' Affairs; 2010.</p> <p>6. Hempel S, Taylor SL, Solloway MR, Miake-Lye IM, Beroes JM, Shanman R, et al. VA Evidence-based Synthesis Program Reports. Evidence Map of Acupuncture. Washington (DC): Department of Veterans Affairs; 2014.</p>	<p>REF 42). Coeytaux 2016 SR (REF 44) is more of a narrative review and relies solely on the 2 Cochrane SR published in 2016 (REFS 41, 43) as the evidence for migraine and TTH which do not meet are inclusion criteria (REF 41 is solely episodic migraine and REF 43 is a mixed of episodic and chronic TTH and is not stratified by chronicity; the reference list of the latter article was reviewed for relevance previously).</p> <p>Section 2.2 is based solely off the Cochrane review by Linde et al. 2016 (REF 43), “Acupuncture for the prevention of tension-type headache. Cochrane Database Syst Rev. 2016;4:Cd007587” which included both episodic and chronic TTH and did stratify by or do sensitivity analyses around chronicity. This SR was included in the prior (2017) report for completeness, even though it does not address the question of chronic TTH specifically and its reference list was reviewed for relevant individual trials previously.</p>

Page	Comment	Response
	<p>40. Da Silva AN. Acupuncture for migraine prevention. Headache. 2015 Mar;55(3):470-3.</p> <p>41. Linde K, Allais G, Brinkhaus B, Fei Y, Mehring M, Vertosick EA, et al. Acupuncture for the prevention of episodic migraine. Cochrane Database Syst Rev. 2016(6):Cd001218.</p> <p>42. Yang Y, Que Q, Ye X, Zheng G. Verum versus sham manual acupuncture for migraine: a systematic review of randomised controlled trials. Acupunct Med. 2016 Apr;34(2):76-83.</p> <p>43. Linde K, Allais G, Brinkhaus B, Fei Y, Mehring M, Shin BC, et al. Acupuncture for the prevention of tension-type headache. Cochrane Database Syst Rev. 2016;4:Cd007587.</p> <p>44. Coeytaux RR, Befus D. Role of Acupuncture in the Treatment or Prevention of Migraine, Tension-Type Headache, or Chronic Headache Disorders. Headache. 2016 Jul;56(7):1238-40.</p>	
Results	<p>Figures and tables are clear and easy to understand. Results are primarily positive and clearly stated. My only concern is that most of the studies chosen are described as having some level of bias, which may lead some to think the studies have less merit. Given my statement before about the trend of acupuncture research away from double blind RCTs, I think the word “bias” can be misleading and potentially detrimental.</p>	Thank you for your comments.
General	<p>My only concern, as stated above, is that the number of high bias studies will imply that the data isn’t valid.</p>	Thank you for your comments.
Report Presentation	<ul style="list-style-type: none"> <li>• Is the review well-structured and organized?</li> <li>• Are the main points clearly presented?</li> <li>• Is it relevant to clinical medicine?</li> <li>• Is it important for public policy or public health?</li> </ul> <p>Yes to all of the above.</p>	Thank you for your comments.



**Responses to public comment on draft report**

This second section responds to comments received during the public comment period from the following:

- Dr. John Zheng, Greenlake Acupuncture
- Dr. Nick Spurlock, Bastyr University
- Dr. Jianfeng Yang, Acupuncture and Eastern Medicine Center
- Dr. Brenda Loew, Japanese Acupuncture Center
- Dr. Liz Artola, Seattle Children’s Hospital

**Table 2. Responses to public comments**

Page	Comment	Response
<b>Dr. John Zheng, Greenlake Acupuncture</b>		
General	Our clinic has been very successful in treating chronic migraine and chronic tension-type headache.	Thank you for your comments.
<b>Dr. Nick Spurlock, Bastyr University</b>		
General	I am writing to express my support for acupuncture in the treatment of migraines and tension-type headaches. As a licensed acupuncture and eastern medicine provider, I have seen effective, fast relief for patients who suffer from various types of headaches, including migraines and tension-type.	Thank you for your comments.
General	Acupuncture is a safe, cost-effective, non-pharmacological treatment option for people suffering from these conditions. Americans deserve access to acupuncture to help manage pain from chronic migraines and tension-type headaches so they can be productive at work, reduce their dependence on addictive substances, and cultivate thriving communities!	Thank you for your comments.
<b>Dr. Jianfeng Yang, Acupuncture and Eastern Medicine Center</b>		
General	I am Jianfeng Yang and I have been practicing acupuncture and Chinese Medicine since 1970. In the past 52 years of practice both in China and the USA, I have treated thousands of migraine headache patients with acupuncture and combined with Chinese herbal medicine in some cases. The clinical results are very successful. Many patients can get migraine headaches relieved after 5-10, or even 3-5 treatments and they can sleep and concentrate better and very soon many of them go back to normal function status. Acupuncture is a very effective therapeutic method and it should be covered by insurance.	Thank you for your comments.
<b>Dr. Brenda Loew, Japanese Acupuncture Center</b>		
General	<i>The Journal of Integrative Medicine</i> is about to publish (currently in article preview) a report on	Thank you. This article does not appear to include MAs solely

Page	Comment	Response
	<p>acupuncture for patients with migraine. Excerpt from this research:                      “ Acupuncture has been widely used in the prevention and treatment of migraine, in China and Western countries, especially for drug-refractory patients [11], [12]. In recent years, several systematic reviews (SRs) with meta-analyses (MAs) focusing on acupuncture for migraine have been published [13], [14], [15], [16]. ... the present overview is designed to summarize evidence from published MAs concerning acupuncture for patients with migraine, which can provide more highly concentrated evidence to facilitate decision-making. Specifically, the primary aim is to evaluate the reporting and methodological quality of MAs concerning acupuncture for migraine and the secondary aim is to summarize its efficacy and safety.”                      Citation:                      Ting-ting Lu, Cun-cun Lu, Mei-xuan Li, Li-xin Ke, Hui Cai, Ke-hu Yang,  <b>Reporting and methodological quality of meta-analyses of acupuncture for patients with migraine: A methodological investigation with evidence map</b>, Journal of Integrative Medicine, 2022, ISSN 2095-4964,  <a href="https://doi.org/10.1016/j.joim.2022.02.003">https://doi.org/10.1016/j.joim.2022.02.003</a>.                      (<a href="https://www.sciencedirect.com/science/article/pii/S2095496422000127">https://www.sciencedirect.com/science/article/pii/S2095496422000127</a>)  <b>Abstract:</b>                      Background                      Acupuncture has been widely used to relieve migraine-related symptoms. However, the findings of previous systematic reviews (SRs) and meta-analyses (MAs) are still not completely consistent. Their quality is also unknown, so a comprehensive study is needed.                      Objective                      To evaluate the reporting and methodological quality of these MAs concerning acupuncture for migraine, and summarize evidence about the efficacy and safety of acupuncture for migraine.                      Search strategy                      PubMed, Embase, Cochrane Library, China National Knowledge Infrastructure, Chinese Biomedical Databases, Wanfang Data, and VIP databases were searched from inception to September 2020, with a comprehensive search strategy.                      Inclusion criteria                      The pairwise MAs of randomized controlled trials (RCTs) concerning migraine treated by acupuncture or</p>	<p>related to chronic headache and thus would not meet inclusion criteria. Furthermore, MAs are not typically included as primary evidence in these reports, but the bibliographies would be reviewed for possibly relevant individual trials. Also, only published, peer-reviewed literature in includable.</p>

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	<p>acupuncture-based therapies, with a control group that received sham acupuncture, medication, no treatment, or acupuncture at different acupoints were included.</p> <p>Data extraction and analysis Two independent investigators screened studies, extracted relevant data, and assessed reporting and methodological quality using PRISMA 2009 and AMSTAR 2, then all results were cross-checked. Spearman correlation test was used to evaluate the correlation between reporting and methodological quality scores.</p> <p>Results A total of 20 MAs were included in this study. The included MAs indicated that acupuncture was efficacious and safe in preventing and treating migraine when compared with control intervention. There was a high correlation between reporting and methodological quality scores (<math>r_s = 0.87, P &lt; 0.001</math>). The quality of the included SRs needs to be improved mainly with regard to protocol and prospective registration, using a comprehensive search strategy, summarizing the strength of evidence body for key outcomes, a full list of excluded studies with reasons for exclusion, reporting of RCTs’ funding sources, and assessing the potential impact of risk of bias in RCTs on MA results.</p> <p>Conclusion Acupuncture is an effective and safe intervention for preventing and treating migraine, and could be considered as a good option for patients with migraine. However, the reporting and methodological quality of MAs included in this overview is suboptimal. In the future, AMSTAR 2 and PRISMA tools should be followed when making and reporting an SR with MA. Keywords: Migraine; Acupuncture; Systematic review; Meta-analysis; AMSTAR 2; PRISMA Please take into consideration this report in your policy considerations.</p>	
<b>Dr. Liz Artola, Seattle Children’s Hospital</b>		
General	I am a pediatric acupuncturist. My experience over the last 8 years has been mixed as many of the pediatric patients we see in the outpatient setting also had a hx of chronic pain in addition to their chronic migraines/headaches. When patients have done well with acupuncture, they have done really well in terms of reduction in frequency and duration of headaches/migraines as well as decreased pain levels.	Thank you for your comments.
General	However, when they have not done well, their headaches/migraines were variable in duration and pain	Thank you for your comments.

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	<p>level. There are a few issues to consider for those who do not do well with acupuncture in our outpatient clinic:</p> <ol style="list-style-type: none"> <li>1. Unlike treating adults, I am not always able to do all the necessary acupuncture points for headache/migraine that is needed after coming up with my diagnosis and treatment plan due to limitation of the number of needles and/or placement area by the patient. So for example, sometimes I am not able to place acupuncture needles at LI4, LV3, GV20 due to discomfort or fear from the patient. I do adjust my treatment plan to choose other acupuncture points and/or change the gauge of the needle, however sometimes once a patient experiences discomfort with an acupuncture treatment (albeit with me or another provider) it can be difficult to allow you to place acupuncture needles at these locations again.</li> <li>2. The other challenge is that not all patients come in consistently for their acupuncture treatments which affects how well acupuncture can help migraines/headaches.</li> <li>3. A separate issue to also consider is equity. Not all families are referred to acupuncture for migraines/headaches. Not all families have reliable transportation to get to our clinic. Additionally, State insurance (DSHS) does not always provide transportation for acupuncture appointments because acupuncture therapy is not deemed an “essential” medical visit.</li> </ol>	
General	Thank you for allowing me the opportunity to express my viewpoints. Please let me know if you have any questions.	Thank you for your comments.

**APPENDIX: Clinical/peer reviews and public comments received**