Washington State Health Care Authority

Treatment of
Chronic migraine and chronic tension-type headache

Draft key questions: Comment and response

December 9, 2016

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Treatment of Chronic Migraine and Chronic Tension-type Headache

Provided by:

Spectrum Research, Inc.

Draft Key Questions

Public Comment and Response

December 9, 2016

Responses to public comment on draft key questions

Spectrum Research is an independent vendor contracted to produce evidence assessment reports for the Washington HTA program. For transparency, all comments received during the public comment periods are included in this response document. Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only.

Draft KQ document comments received:

- **Washington East Asian Medicine Association**

Specific responses pertaining to comments are included in **Table 1.**

Table 1. Treatment of Chronic migraine and chronic tension-type headache

Comment		Response
Commenter: **Washington East Asian Medicine Association Board Of Directors**		
	Specific comments:	
Background Section	Editorial suggestions regarding definitions of acupuncture and trigger point injections were made	Thank you for your comments. Suggested edits have been included in the final KQ document.
Key Questions	Suggested the following-footnote be added to the KQs related to sham treatment. ***Note:** The National Center for Complementary and Integrative Health (NCCIH) strongly discourages researchers from submitting research proposals in areas of low programmatic priority, including research comparing clinical outcomes of verum and sham acupuncture. (https://nccih.nih.gov/grants/acupuncture/priorities)*	Thank you for your suggestion. This information is most appropriate in the report background or methods and not as a footnote to key questions. Some discussion of verum verus sham acupuncture can be incorporated in the report for context. The report will compare all interventions to sham/placebo as a comparator as literature is available. Please also see below.
PICOTS: Comparators	There are a number of issues inherent in verum v. sham acupuncture comparisons and so we suggest such measures not be applied to acupuncture for the purposes of the assessment. To put it simply, sham acupuncture is not an inert control, i.e. it is not analogous to a placebo. The difference between acupuncture and sham is *not* the difference between acupuncture and placebo or between specific effects and general effects, which is how it's most often interpreted. We are happy to discuss further with your team the subject of verum v. sham, including issues of active vs. inert control, false negatives, and the preference for comparative effectiveness trials over sham-controlled trials when it comes to evaluating acupuncture. Relatedly, the National Center for Complementary and Integrative Health (NCCIH) "strongly discourages researchers from submitting research proposals in areas of low programmatic priority, including research comparing clinical outcomes of verum and sham acupuncture." (https://nccih.nih.gov/grants/acupuncture/priorities)	Thank you for your comments. The report will compare all interventions to sham/placebo as a comparator where literature is available. Treatments will also be compared to no treatment, waitlist treatment and usual care treatments to the extent that comparative literature is available. Characteristics of treatments and controls will be abstracted and described. All studies (and comparators) have inherent strengths and limitations. 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. (Turner and Meissner references below)

	Comment	Response
		There are examples of validated sham controls for acupuncture including the one described by Sherman, et. al. (Referenced below) References: 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 We cannot speak to NCCIH's reasons for a focus on studies using different control group strategies for future research.
PICOTS: Outcomes	**Suggested Edit:** *Economic outcomes are cost-effectiveness…*	Edit made.

Preserving Our Heritage

Ensuring Our Future

November 3, 2016

To: Washington State Health Care Authority Assessment Program

From: Washington East Asian Medicine Association

Re: Commentary on Draft Key Questions and Background/chronic migraine and tension-type headache

Washington East Asian Medicine Association wishes to provide commentary on the Draft Key Questions and Background regarding the treatment of chronic migraine and chronic tension-type headache. We greatly appreciate the inclusion of acupuncture in this Health Technology Review and recommendations to come.

WEAMA has made some suggestions about the language on the following items:

- the definition of acupuncture;
- the definition of trigger point injection (the injection of trigger points with substances consistent with the practice of East Asian Medicine is within our scope); and
- the requirement of including sham acupuncture studies.

There are a number of issues inherent in verum v. sham acupuncture comparisons and so we suggest such measures not be applied to acupuncture for the purposes of the assessment. To put it simply, sham acupuncture is not an inert control, i.e. it is not analogous to a placebo. The difference between acupuncture and sham is *not* the difference between acupuncture and placebo or between specific effects and general effects, which is how it's most often interpreted. We are happy to discuss further with your team the subject of verum v. sham, including issues of active vs. inert control, false negatives, and the preference for comparative effectiveness trials over sham-controlled trials when it comes to evaluating acupuncture.

Relatedly, the National Center for Complementary and Integrative Health (NCCIH) "strongly discourages researchers from submitting research proposals in areas of low programmatic priority, including research comparing clinical outcomes of verum and sham acupuncture." (https://nccih.nih.gov/grants/acupuncture/priorities)

Thank you again for the opportunity to comment on this important process.

Sincerely,

WEAMA Board of Directors

DRAFT key questions and background
Treatment of chronic migraine and chronic tension-type headache

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. The two major subtypes are common migraine (without aura) and classic migraine (with aura or neurological symptoms). Chronic tension-type headache and chronic migraine will be evaluated in this report. 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. 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. A variety of interventions may be used to treat or prevent chronic migraine and chronic tension-type headache. Interventions to be evaluated in this report include botulinum toxin injections, trigger point injections, transcranial magnetic stimulations, manipulation/manual therapy, acupuncture and massage.

OnabotulinumtoxinA (onaBoNT-A, Botox) is a type of botulinum toxin that is FDA approved for the prophylaxis of headaches in adults with chronic migraine (≥ 15 days per months with headache lasting ≥4 hours a day). It has been associated with reduction in the number chronic migraine headaches attacks.

Trigger point injections involve the injection of local anesthetic or other injectate ~~insertion of a small needle~~ into trigger points which are muscle areas that are very irritable, show a band of tightness in the area of muscle itself, and, when pressed, produce a twitch within the affected muscle. Pain may not be confined to the affected muscle and may affect distant areas such as the head and neck, which is called referred pain. ~~Usually local anesthetic is injected into the painful muscle and soft tissues.~~ Trigger point injections may be done in conjunction with peripheral nerve blocks which involves injection of medication on or near nerves. Peripheral nerve blocks are not included in this review.

Transcranial magnetic stimulation involves use of a portable device that is held to the scalp and sends a series of brief magnetic pulses through the skin. FDA approval has been received for the Cerena Transcranial Magnetic Stimulator (TMS). Manual therapies, including manipulation, involve passive movement of joints and soft tissues by hands or equipment to treat musculoskeletal and disability including headache and may be used by physiotherapists, chiropractors, osteoapths and others. Massage is often classified as a manual therapy and involves systematic and methodical manipulation of body tissues, including trigger points, usually with the hands.

Acupuncture ~~involves~~ is the ~~placement~~ insertion of ~~thin~~ 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 ~~for therapeutic benefit~~ to promote health and treat organic or functional disorders. ~~along specific pathways, meridians, trigger points or pain points based on the condition being treated.~~

…

Policy context:

Interventions for treatment of headaches include botulinum toxin injections, trigger point injections, transcranial magnetic stimulations, acupuncture, manipulation, manual therapy and massage. The topic is proposed to determine the safety, efficacy and value of interventions for treatment of migraines and other headache types. The topic was selected based on medium/high concerns for safety, efficacy and cost.

Draft 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 botulinum toxin injection, trigger point injection, acupuncture, transcranial magnetic stimulation, manipulation/manual therapy and massage compared with standard alternative treatment options, placebo, sham*, or no treatment?
2. What is the evidence regarding short- and long-term harms and complications of botulinum toxin injection, trigger point injection, acupuncture, transcranial magnetic stimulation, manipulation/manual therapy and massage compared with standard alternative treatment options, placebo, sham*, or no treatment?
3. Is there evidence of differential efficacy, effectiveness, or safety of botulinum toxin injection, trigger point injection, acupuncture, transcranial magnetic stimulation, manipulation/manual therapy and massage compared with standard alternative treatment options, placebo, sham,* 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 botulinum toxin injection, trigger point injection, acupuncture, transcranial magnetic stimulation, manipulation/manual therapy and massage compared with standard alternative treatment options, placebo, sham,* or no treatment?

*Note: The National Center for Complementary and Integrative Health (NCCIH) strongly discourages researchers from submitting research proposals in areas of low programmatic priority, including research comparing clinical outcomes of verum and sham acupuncture. (https://nccih.nih.gov/grants/acupuncture/priorities)

Proposed 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.

Interventions: Botulinum toxin injection, trigger point injection, acupuncture, transcranial magnetic stimulation (TMS), manipulation/manual therapy, massage Comparators: Standard alternative treatment(s), sham, placebo 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 and randomized controlled trials and full economic studies.