

Tinnitus: non-invasive, non-pharmacologic treatments

Draft key questions: public comment and response

November 7, 2019

Health Technology Assessment Program (HTA)

Washington State Health Care Authority

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Public Comments Submitted

The State of Washington's Health Technology Assessment Program posted for public comment the draft key questions and proposed scope for a health technology assessment (HTA) on the topic of "Non-Invasive, Non-Pharmacologic Treatments for Tinnitus" between October 9, 2019 and October 23, 2019. **Table 1** lists the comments received and submitting organization.

Table 1. Number of Comments Received on Draft Key Questions on Non-Invasive, Non-PharmacologicTreatments for Tinnitus

Number	Organization	Location	
1	American Academy of Audiology	Reston, VA	

Summary of Comments and Response

The comments provided did not suggest any changes to the key questions or scope of the review. The comments are summarized in **Table 2**. In addition to the comments submitted, the commenter attached references to several studies mentioned in the comments. These references will be considered against the inclusion and exclusion criteria established for this review.

Table 2. Summary of Comments Received on Draft Key Questions on Non-Invasive, Non Pharmacologic Treatments for Tinnitus

Comment Number	Summary of comment	Response
1	Efficacy Question: Tinnitus Retraining Therapy, Progressive Tinnitus Management, and Tinnitus Feedback Therapy should be considered.	These treatments are included in the scope of the review.
	Safety Question: counseling therapies should be provided by appropriately licensed individuals.	Thank you for this comment.
	Cost Question: cost effectiveness will depend on the therapy or combination of therapies involved.	Thank you for this comment.



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October 23, 2019

Regarding Public Comment on Tinnitus: Non-invasive, Non-pharmacologic Treatments

Washington State Health Care Authority 626 8th Avenue SE Olympia, WA 98501

Dear Colleagues,

The American Academy of Audiology appreciates the opportunity to comment on the questions posed by the State of Washington Health Care Authority regarding non-invasive, non-pharmacologic treatments for tinnitus. The Academy is the world's largest professional organization of, by, and for audiologists, representing over 12,000 members. The Academy promotes quality hearing and balance care by advancing the profession of audiology through leadership, advocacy, education, public awareness, and support of research.

The Academy represents clinicians who are distinctly qualified to diagnose, treat, and manage those with hearing and balance disorders across the lifespan. We hope that our comments and supporting materials are helpful in evaluating these treatment strategies to promote appropriate care for members of the public who are affected by tinnitus.

If you have questions or require additional information, please contact Kathryn Werner, Vice President of Public Affairs, at 703-226-1044; or <u>kwerner@audiology.org</u>.

Sincerely,



Catherine V. Palmer, PhD President, American Academy of Audiology

Enclosures (12)



Question 1 (EQ 1). What is the effectiveness of non-invasive, non-pharmacologic therapies for the treatment of bothersome, subjective tinnitus?

The prevalence of tinnitus is extremely common affecting one in 10 American adults (Bhatt et al, 2018). It should be noted that pharmacologic or invasive intervention has not consistently been proven to be successful in tinnitus treatment (Hesse, 2016), which is why clinicians primarily rely on non-pharmacologic or non-invasive treatments. Moreover, the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) Clinical Practice Guideline: Tinnitus has stated a recommendation against medical therapy for the treatment of tinnitus (Tunkel et al, 2014).

First it is important to distinguish the 1) causes from the 2) reactions to the tinnitus. Causes of tinnitus can vary widely and would merit various treatment pathways, while the non-pharmacologic treatments to the reactions are less numerous and can be categorized as counseling/education, hearing aids, and sound therapy. All three of these treatments have been found to be effective at reducing the reactions to the tinnitus (e.g., Aazh et al, 2016; Henry et al, 2016). Recent literature suggests that counseling was perceived as the most favorable followed by education (Aazh et al, 2016) and that hearing aids and combination (hearing aid plus tinnitus masking) devices are clinically-effective as non-invasive treatment options for tinnitus (Henry et al 2017). AAO-HNS Guidelines provided a systematic review and synthesis of the literature and recommend prompt audiologic evaluation, education, counseling, and hearing aid evaluation (Tunkel et al, 2014). Under these guidelines, sound therapies are considered an option without a recommendation for or against (Tunkel et al, 2014).

For specific treatment regimens such as Tinnitus Retraining Therapy (TRT), Progressive Tinnitus Management (PTM), and Tinnitus Feedback Therapy (TFT) we would like to present the following evidence on their respective effectiveness. For TRT, a randomized controlled clinical trial evaluated the effectiveness of TRT compared to standard of care for patients with chronic tinnitus. Their findings suggested that patients treated with TRT demonstrated significant improvements and larger treatment effects than the comparator group, and that effects were sustained as long as 18 months (Bauer et al, 2017). However, a study by Tyler and colleagues (2012) found that some of the premises for TRT (i.e., mixing point) did not seem to be necessary in producing favorable outcomes. Another randomized controlled trial found that PTM significantly improved functional impacts seen from chronic tinnitus (Henry et al, 2017). Tinnitus Activities Treatment (TAT) is another option for tinnitus management which focuses on counseling, changing reactions to tinnitus, environmental controls, and treatment for hearing loss when appropriate (Tyler et al, 2007).

The effectiveness of each therapy will depend on the training and skills of the clinician, and the distress of the patient. Thus, there is a wide variety of outcomes across patients, which undoubtedly necessitates a broader spectrum of treatments to be available to those who suffer from bothersome tinnitus. This constellation of available treatment options should include all of the following discussed above.

Safety Question 2 (SQ 1). What are the harms associated with non-invasive, non-pharmacologic therapies for the treatment of bothersome, subjective tinnitus?

Because these interventions (i.e., counseling, education, hearing aids, and sound therapy) are considered to be non-invasive and non-pharmacologic, there is no direct harm to these therapies. However, there is a potential for emotional harm if certain types of counseling are poorly delivered. As such, this and similar therapies or counseling should only be performed by a qualified professional in accordance with state

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licensure and scope of practice. It should be noted that tinnitus can sometimes be categorized as catastrophic, whereby suicidal thoughts and ideation may merit additional therapies outside of those discussed here. This fact reiterates the importance of access to appropriate, effective, and timely treatment of and management for tinnitus, which can be life-saving in some instances.

Cost Question (CQ 1). What are the costs and cost-effectiveness of non-invasive, non-pharmacologic therapies for the treatment of bothersome, subjective tinnitus?

The cost-effectiveness will depend on the therapy or combination of therapies involved, and their effectiveness. Positive effects from treatment or management strategies also depend on one's understanding of the stress and consequences of bothersome tinnitus. Moreover, cost-effectiveness will depend on the individual. The detrimental effects of tinnitus on health-related quality of life are well-documented in the literature and affect domains such as mobility, self-care, activities of daily living, pain/discomfort, and anxiety and depression (e.g., Joo et al, 2015). Four areas affected by tinnitus also can be categorized from a functional standpoint: 1) thoughts and emotions, 2) hearing, 3) sleep and 4) concentration. Successful therapies for tinnitus can keep some employed, keep some in a spousal relationship (it is difficult for those who do not have tinnitus to appreciate its effects), and can maintain an individual's quality of life and contributions to society.

Research on the cost-effectiveness of tinnitus treatment and management indicate that habituation to tinnitus by any means of intervention is cost-effective compared to no treatment at all or self-management (Stockdale et al, 2017). Individuals with greater problems at baseline often demonstrate higher levels of effectiveness from treatment; intuitively, those with lesser problems demonstrate smaller gains because of a lower baseline measurement.

In terms of cost these are the expected ranges for the treatment options discussed earlier:

- Counseling/Education: The costs will vary depending on the individual counselor and the time involved. (~\$100-300 per session)
- Hearing aids: The costs will vary depending on the device recommendations. (Range: \$500 to \$6,000)
- Sound therapy: The costs will vary depending on the sound therapy chosen for treatment. (Range: \$100 to \$10,000)

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