Washington State Health Care Authority

Tinnitus: non-invasive, non-pharmacologic treatments

Clinical Expert

Jay T. Rubinstein, MD

Virginia Merrill Bloedel Professor and Director,
Virginia Merrill Bloedel Hearing Research Center, University of Washington School of Medicine

Professor of Otolaryngology – Head and Neck Surgery,
University of Washington School of Medicine

Professor of Bioengineering, University of Washington School of Medicine

Applicant Name	Jay T Rubinstein, MD, PhD
Address	715 2nd Ave #1802
	Seattle, WA 98104
	Click here to enter text.

1. Business Activities

(a) If you or a member of your household was ***an officer or director of a business*** during the immediately preceding calendar year and the current year to date, provide the following:

Title	Business Name & Address	Business Type
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

(b) If you or a member of your household ***did business under an assumed business name*** during the immediately preceding calendar year or the current year to date, provide the following information:

Business Name	Business Address	Business Type
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

2. Honorarium

If you ***received an honorarium of more than $100*** during the immediately preceding calendar year and the current year to date, list all such honoraria:

Received From	Organization Address	Service Performed
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

3. Sources of Income

(a) Identify ***income source(s) that contributed 10% or more of the combined total gross household income*** received by you or a member of your household during the immediately preceding calendar year and the current year to date.

Source Name & Address	Received By	Source Type
University of Washington	me	salary
WA Dept of Corrections	spouse	salary
Vacation rental condo	both of us	rent
Click here to enter text.	Click here to enter text.	Click here to enter text.

(b) Does any income source listed above relate to, or could it reasonably be expected to relate to, business that has, or may, come before the Committee?

☐ Yes x No

If "yes", describe: Click here to enter text.
Click here to enter text.
Click here to enter text.

(c) Does an income source listed above have a legislative or administrative interest in the business of the Committee?

☐ Yes x No

If "yes", describe: Click here to enter text.
Click here to enter text.
Click here to enter text.

4. Business Shared With a Lobbyist

If you or a member of your household ***shared a partnership, joint venture, or similar substantial economic relationship with a paid lobbyist***, were employed by, or employed, a paid lobbyist during please list the following:

(Owning stock in a publicly traded company in which the lobbyist also owns stock is not a relationship which requires disclosure.)

Lobbyist Name	Business Name	Type Business Shared
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

Provide the information requested in items 5, 6, and 7 below only if:
(a) Your response involves an individual or business if you or a member of your household did business with, or reasonably could be expected to relate to business that has or may come before the Health Technology Clinical Committee.
(b) The information requested involves an individual or business with a legislative or administrative interest in the Committee.

5. Income of More Than $1,000

List each source (***not amounts***) of income over $1,000, other than a source listed under question 3 above, which you or a member of your household received during the immediately preceding calendar year and the current year to date:

Income Source	Address	Description of Income Source
Fidelity investments	Click here to enter text.	Investment Income
Bioengineering & medicolegal consulting	715 2nd Ave #1802	Consulting Fees

Click here to enter text.	Click here to enter text.	Click here to enter text.

6. Business Investments of More Than $1,000

(Do not list the amount of the investment or include individual items held in a mutual fund or blind trust, a time or demand deposit in a financial institution, shares in a credit union, or the cash surrender value of life insurance.)

If you or a member of your household had a personal, beneficial interest or investment in a business during the immediate preceding calendar year of more than $1,000, list the following:

Business Name	Business Address	Description of Business
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

7. Service Fee of More Than $1,000

(Do not list fees if you are prohibited from doing so by law or professional ethics.)

List each ***person for whom you performed a service for a fee of more than $1,000*** in the immediate preceding calendar year or the current year to date.

Name	Description of Service
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.

I certify that I have read and understand this Conflict of Interest Form and the information I have provided is true and correct as of this date.

Print Name Jay T Rubinstein, MD, PhD

Check One: ☐ Committee Member ☐ Subgroup Member ☐ Contractor

[redacted] 5/7/20

Signature Date

COLLEGE OF MEDICINE CURRICULUM VITAE

Jay T. Rubinstein, M.D., Ph.D.

January 25, 2020

I. EDUCATION AND PROFESSIONAL HISTORY

Education

1981	Sc.B. with Honors	Brown University	(Engineering)
1983	Sc.M.	Brown University	(Engineering)
1987	M.D. with Honors	University of Washington	
1988	Ph.D.	University of Washington	(Bioengineering)

Internships and Residencies

1988-89 Intern (Surgery), Beth Israel Hospital, Boston MA
1990-94 Resident (Otolaryngology), Massachusetts Eye & Ear Infirmary, Boston, MA

Clinical and Research Fellowships

1988 Research Fellow, Department of Physiology and Biophysics, University of Washington, Seattle WA
1989-90 Research Fellow, Department of Otology and Laryngology, Harvard Medical School
1994-95 Clinical Fellow in Otology/Neurotology, Department of Otolaryngology, The University of Iowa Hospitals and Clinics, Iowa City IA

Academic Appointments

1989-95 Research Affiliate, Research Laboratory of Electronics, Massachusetts Institute of Technology
1994-95 Fellow Associate, The University of Iowa Hospitals and Clinics, Iowa City IA
1995-00 Assistant Professor, Department of Otolaryngology-Head and Neck Surgery, The University of Iowa Hospitals and Clinics
1997-04 Faculty Appointment, Interdisciplinary Neuroscience PhD Program, The University of Iowa
1996-00 Assistant Professor, Department of Physiology & Biophysics, The University of Iowa
2000-04 Associate Professor with Tenure, Department of Otolaryngology-Head and Neck Surgery, The University of Iowa
2000-04 Associate Professor, Department of Physiology & Biophysics, The University of Iowa
2000-04 Associate Professor, Department of Biomedical Engineering, The University of Iowa
2003-04 Boerhaave Professor, Leiden University, The Netherlands
2004- Virginia Merrill Bloedel Professor and Director, Virginia Merrill Bloedel Hearing Research Center, University of Washington

2004- Professor of Otolaryngology–Head and Neck Surgery, University of Washington
2004-05 Adjunct Professor of Bioengineering, University of Washington
2005- Professor of Bioengineering, University of Washington
2012- Research Affiliate, Washington National Primate Research Center

Other Employment Pertaining to Current Professional Appointments

1975-77 Software Developer, Telmar Communications Corp., New York NY
1979 Research Assistant, Geoelectromagnetics Laboratory, Department of Geological Sciences, Brown University, Providence RI
1980-81 Research Assistant, Visual Physiology Laboratory, Division of Engineering and Center for Neural Science, Brown University, Providence RI
1980-82 Teaching Assistant, Digital Electronics Laboratory, Division of Engineering, Brown University, Providence RI
1981-82 Research Assistant, Laboratory for Engineering Man/Machine Systems, Division of Engineering, Brown University, Providence RI
1996-04 Attending Surgeon, VA Medical Center, Iowa City, Iowa
2005- Board of Trustees, Listen & Talk School, Seattle, WA
2006-08 Board of Trustees, Executive Committee, Northwest Lions Foundation for Sight and Hearing, Seattle, WA
2006-12 Chairman, Board of Trustees, Audient, LLC, Seattle, WA
2008-12 Board of Directors, SightLife, LLC, Seattle, WA
2010- Medical Advisory Board, National Organization for Hearing Research

Certification and Licensure

Certification

1995 Diplomate, American Board of Otolaryngology--Head and Neck Surgery
2005 Neurotology Certificate of Added Qualifications
2013 Neurotology Certificate renewal

Licensure

1994	Iowa License #29758	(expired)
1994	California License	(expired)
1994	Massachusetts License	(expired)
2004	Washington License MD00044088	(active)

Honors and Awards

1981 Honorary Undergraduate Teaching Assistantship
1981 Sigma Xi
1984-86 Poncin Scholarship Award
1987 Alpha Omega Alpha
1992 American Academy of Otolaryngology Resident Research Grant

2003-04 Boerhaave Professor, Leiden University, the Netherlands
2005-06 Best Doctors in America
2006 Elected Senior Member of the IEEE
2006 Elected to the Collegium Oto-Rhino-Laryngologicum Amicitae Sacrum
2007-08 President-elect, American Auditory Society
2007-08 Best Doctors in America
2009 Presidential Citation, American Otologic Society
2009-10 President, American Auditory Society
2009 Honor Award, American Academy of Otolaryngology – HNS
2009-10 Best Doctors in America
2010-11 Best Doctors in America
2012-13 President-elect, Association for Research in Otolaryngology
2012 Seattle Top Doctors
2013-14 President, Association for Research in Otolaryngology
2014-15 Past-President, Association for Research in Otolaryngology
2015 Americas Top Doctors
2016 Seattle Top Doctors
2017 Seattle Top Doctors
2018-21 President-Elect, The Politzer Society
2018 America's Top Doctors 5 years
2019 Elected Fellow, American Institute of Medical and Biological Engineering

II. TEACHING

Classroom, Seminar, or Teaching Laboratory

1980-82 Teaching Assistant, Digital Electronics Laboratory, Brown University
1994-03 Weekly Neurotology Conference - lectures to otolaryngology residents and supervision of temporal bone dissection.
1994-03 Otolaryngology Basic Science Course
1995-03 Lectures to first & third year medical students on physiology & pathophysiology of the ear.
1997-03 Lectures to neuroscience graduate students on auditory physiology
2000-03 Lectures to primary care physicians on management of tinnitus, dizziness and hearing loss

Clinical Teaching (in ward, clinic, or operating room)

Otolaryngology Residents, Fellows and Medical Students

Teaching Activities Other Than Classroom or Clinical

1991-92 Assisted in undergraduate thesis supervision for Konstantina M. Trbovic, "Modeling of Auditory Nerve Responses to Electrical Stimulation," Department of Physics, Massachusetts Institute of Technology

1994 External thesis reader for Johan Frijns, MD, PhD. "Cochlear Implants, A Modeling Approach", Department of ENT, Leiden, Netherlands.
2000 PhD Committee for Leonid Litvak, Harvard/MIT Speech & Hearing Science Program.
2000 PhD Committee for Karen Chi, Department of Speech Pathology and Audiology, University of Iowa
2001 PhD Committee for Christina Runge, Department of Speech Pathology and Audiology, University of Iowa
2001-03 Mentor, Doris Duke Clinical Research Fellowship Program, University of Iowa
2003 PhD Committee for Tiffany Johnson, Department of Speech Pathology and Audiology, University of Iowa
2005-07 Research mentor Chad Ruffin, visiting Howard Hughes Fellow.
2005-06 Research mentor Grace Liu, MD visiting medical student.
2005-06 PhD Committee for Lendra Friesen, Department of Speech and Hearing Sciences, University of Washington
2007 PhD Committee for Olivier Macherey, University of Leuven, Belgium, "Effects of Stimulus Waveform on Hearing with Cochlear Implants"
2007 External Thesis Reader for JE Smit, University of Pretoria, "Modeled Response of the Electrically Stimulated Nerve Fiber"
2008- PhD Committee for Katie Faulkner, Department of Speech and Hearing Sciences, University of Washington

Clinical Activities

A.Inpatient

Surgery performed 1.5 day per week in operating rooms of UW Medical Center and Seattle Childrens

B.Outpatient

Patient appointments 1.5 days per week

Master's and Ph.D. Theses Directed and Postdoctoral Fellows Supervised

1992-93 Committee Member and Thesis Reader for Masters Degree Candidate Eric R. Stutman, Thesis Titled "A Model for Temporal Sensitivity of Neurons in the Auditory Brainstem: The Role of a Slow, Low-Threshold Potassium Conductance," Department of Biomedical Engineering, Boston University
1995-96 Charles Miller, PhD - Postdoctoral Fellow. Physiology of electrically stimulated spiral ganglion cells, University of Iowa.
1995-96 Akihiro Matsuoka, MD, PhD. Response of auditory nerve to pulse trains. Dept of Speech Pathology & Audiology, University of Iowa.
1999-02 Nahla Hussein, MD. Doctoral Thesis, Suez Canal University, Egypt
2001-03 Gang Chen, MSE student, Dept. of Electrical Engineering, U. of I.

2001-03 Haiming Chen, MSE thesis, Dept. of Electrical Engineering, Radial-longitudinal impedance model for human cochlear implants.
2002-03 Ron Andreatta, MSE student, Dept of Biomedical Engineering, U. of I.
2002-03 Robert Hong, MD, Doris Duke Fellow, University of Iowa.
2005-07 Jeff Longnion, MD/PhD student in bioengineering, UW
2005-11 Jong Ho Won, PhD student in bioengineering, UW
2005-09 Vasant Dasika, PhD. Postdoctoral fellow, UW.
2005-06 Steven Bierer, PhD. Postdoctoral fellow, UW.
2005-06 Robert Kang, MD, Otolaryngology-HNS resident, UW.
2007-08 Seeyoun Kwon, Visiting bioengineering graduate student, Hanyang University, Seoul.
2007-11 Nikita Imennov, PhD student in bioengineering, UW.
2009-10 Kyu Hwan Jung, MD, Visiting Fellow, Samsung Medical Center, Seoul.
2010-11 Minhyun Park, MD, Seoul National University, Seoul.
2010-11 Akinori Kashio, MD, Tokyo University, Tokyo
2011-12 Hyun-Joon Shim, MD, Seoul National University
2012-14 Il-Joon Moon, MD, Samsung Medical Center, Seoul
2009-12 Gary Jones, PhD, Postdoctoral fellow, UW
2014-16 Elle O'Brien, PhD student in neurobiology, UW
2016-19 Jesse Resnick, MD, PhD student in neurobiology, UW

Clinical Fellows Supervised

1996-98 Paul Gidley, MD. Currently Professor, Department of Head and Neck Surgery, University of Texas MD Anderson Cancer Center,
1998-00 Brian Perry, MD. Currently in private practice, San Antonio, TX
2000-02 Ravi Samy, MD. Currently Associate Professor, Department of Otolaryngology, University of Cincinnati
2002-04 Ted Meyer, MD, PhD. Currently Associate Professor, Medical University of South Carolina
2011-12 Michal Preis, MD. Currently an otolaryngologist at Maimonides Medical Center, Brooklyn, NY
2014-15 Kavita Dedhia, MD. Currently Assistant Professor, Department of Otolaryngology, Emory University, Atlanta GA

III. SCHOLARSHIP

Papers Published

1. **Rubinstein J.T.** and Silverman, H.F. Some Comments on the Design and Implementation of FIR Filterbanks for Speech Recognition. In: Proceedings of the IEEE International Conference on Acoustics, Speech and Signal Processing. IEEE Speech and Signal Processing Society 812-815, 1983.

2. Soma, M., Spelman, F.A. and **Rubinstein, J.T.** Fields Produced by the Cochlear Prosthesis: The Ear as a Multilayered Medium. In: Frontiers of Engineering and Computing in Health Care. Boston: IEEE Engineering in Medicine and Biology Society 401-405, 1984.

3. **Rubinstein, J.T.**, Spelman, FA and Soma, M. Mixed Boundary Value Problems in the Implanted Cochlea. In: Frontiers of Engineering and Computing in Health Care. IEEE Engineering in Medicine and Biology Society 1120-1123, 1985.

4. **Rubinstein, J.T.**, Suesserman, M.F. and Spelman, F.A. Measurements and Models of Recessed Electrodes. Proceedings of the Ninth Annual Conference of the IEEE Engineering in Medicine and Biology Society. Boston: IEEE Engineering in Medicine and Biology Society 913-914, 1987.

5. **Rubinstein, J.T.**, Spelman, F.A., Soma, M. and Suesserman, M.F. Current Density Profiles of Surface Mounted and Recessed Electrodes for Neural Prostheses. IEEE Transactions Biomedical Engineering BME 34:864-874, 1987.

6. **Rubinstein, J.T.** and Spelman, F.A. Analytical Theory for Extracellular Electrical Stimulation of Nerve with Focal Electrodes 1: Passive Unmyelinated Axon. Biophysical Journal 54:975-981, 1988.

7. Suesserman, M.F., Spelman, F.A. and **Rubinstein, J.T**. In-Vitro Measurement and Characterization of Current Density Profiles Produced by Nonrecessed, Simple Recessed, and Radially Varying Recessed Stimulating Electrodes. IEEE Transactions on Biomedical Engineering 38(5):401-408, 1991.

8. **Rubinstein, J.T**. Analytical Theory for Extracellular Electrical Stimulation of Nerve with Focal Electrodes 2: Passive Myelinated Axon. Biophysical Journal 60: 538-555, 1991.

9. **Rubinstein, J.T**. Axon Termination Conditions for Electrical Stimulation. IEEE Transactions on Biomedical Engineering 40(7):654-663, 1993.

10. **Rubinstein, J.T**. Threshold Fluctuations in an N Sodium Channel Model of the Node of Ranvier. Biophysical Journal 68:779-785, 1995.

11. Zbar RIS, Megerian CA, Khan A, **Rubinstein JT**. Invisible Culprit: Intralabyrinthine Schwannomas that do not appear on Enhanced Magnetic Resonance Imaging. Annals of Otology, Rhinology & Laryngology, 106(9):739-742, September 1997.

12. Arcuri MR and **Rubinstein JT**. Facial Implants. Dental Clinics of North America, Vol 42, Number 1, January 1998

13. Miller CA, Abbas PJ, **Rubinstein JT**, Robinson BK, Matsuoka AJ, Woodworth G. Electrically evoked compound action potentials of Guinea pig and cat: responses to monopolar, monophasic stimulation. Hear. Research 119(1-2):142-154, 1998.

14. **Rubinstein JT**, Parkinson WS, Lowder MW, Gantz BJ, Tyler RS. Single-channel to multichannel conversions in adult cochlear implant subjects. American Journal of Otology, 19 (4): 461-466, July, 1998.

15. **Rubinstein JT**, Gantz BJ, Parkinson WS. Management of cochlear implant infections. American Journal of Otology, 20 (1) 46-49, 1999.

16. **Rubinstein JT**, Wilson BS, Finley CC, Abbas PJ. Pseudospontaneous activity: stochastic independence with electrical stimulation of the auditory nerve. Hearing Research, 127, 108-118, 1999.

17. Miller CA, Abbas PJ, Robinson BK, **Rubinstein JT**, Matsuoka AJ. Electrically evoked single-fiber action potentials from cat: responses to monopolar, monophasic stimulation. Hearing Research, 130 (1-2) 197-218, 1999.

18. **Rubinstein JT,** Parkinson WS, Tyler RS, Gantz BJ. Residual speech recognition and cochlear implant performance: effects of implantation criteria. American Journal of Otology, 20 (3)445-452, 1999.

19. Gantz, BJ, **Rubinstein JT**, Gidley P, Woodworth G. Surgical management of Bell's Palsy. Laryngoscope 109:1177-1188,1999

20. **Rubinstein JT**, Miller CA. How do cochlear prostheses work? Current Opinion in Neurobiology 9:399-404,1999.

21. Miller CA, Abbas PJ, **Rubinstein JT.** An empirically based model of the electrically evoked compound action potential. Hearing Research, 135 (1-2)1-18,1999.

22. Gidley PW, Gantz BJ, **Rubinstein JT**. Facial nerve grafts - from cerebellopontine angle and beyond. American Journal of Otology 20:781-788, 1999.

23. **Rubinstein JT**, Bauman NM. Management of Meniere's Disease in Children. Meniere's Disease 1999--Update, 409-418, 1999.

24. Vannier MW, Wang G, Skinner MW, **Rubinstein JT**. New X-ray imaging strategies – Implications for cochlear implantation. Review of Progress in Qualitative Nondestructive Evaluation 18(B): 1569-1574, 1999.

25. Ali T, **Rubinstein, JT**. Rheumatoid arthritis of the temporomandibular joint with herniation into the external auditory canal. Annals of Otology, Rhinology, and Laryngology 109 (2) 177-179, 2000.

26. White JA, **Rubinstein JT,** Kay AR. Intrinsic noise in neurons. Trends in Neuroscience 23:131-137, 2000.

27. Tyler RS, **Rubinstein JT**, Teagle H, Kelsay D, Gantz BJ. Pre-lingually deaf children can perform as well as post-lingually deaf adults using cochlear implants. Cochlear Implants International 1 (1), 39-44, 2000.

28. Yoo SK, Wang G, **Rubinstein JT**, Skinner M, Vannier M. Three-dimensional modeling and visualization of the cochlea on the internet. IEEE Transactions on Information Technology in Biomedicine 412, 144-151, 2000.

29. Yang S, Wang G, Skinner MW, **Rubinstein JT**, Vannier MW. Localization of dense markers in radiographs. Medical Physics 27 (4), 775-777, 2000.

30. Wang G, Skinner MW, **Rubinstein JT**, Howard MA, Vannier MW: Digital X-ray stereophotogrammetry for cochlear implantation. IEEE Transactions on Biomedical Engineering, 47 (8) 1120-1130, 2000.

31. Matsuoka AJ, Abbas PJ, **Rubinstein JT**, Miller CA. The neuronal response to electrical constant-amplitude pulse train stimulation: evoked compound action potential recordings. Hearing Research, 149, 115-128, 2000.

32. Matsuoka AJ, Abbas PJ, Miller CA, **Rubinstein JT**. The neuronal response to electrical constant-amplitude pulse train stimulation: additive Gaussian noise. Hearing Research, 149 , 129-137, 2000.

33. Gantz B, **Rubinstein J**, Tyler R, Teagle HFB, Cohen N, Waltzman S.Miyamoto R, Kirk K. Long-term results of cochlear implants in children with residual hearing. Ann Otol Rhinol Laryngol, 109 (12), 33-36, 2000.

34. Tyler RS, Kelsay DMR, Teagle HFB, **Rubinstein JT**, Gantz BJ, Christ AM. Seven year speech perception results and the effects of age, residual hearing and preimplant speech perception in prelingually deaf children using the nucleus and clarion cochlear implants. Adv Oto-Rhino-Laryngology 57, 305-310, 2000.

35. Tyler RS, Parkinson A, Wilson B, Parkinson W, Lowder M, Witt S, **Rubinstein J**, Gantz B. Evaluation of different choices of *n* in an *n*-of-*m* processor for cochlear implants. Adv Oto-Rhino- Laryn 57, 311-315, 2000.

36. Yoo SK, Wang G, **Rubinstein JT,** Vannier MW. Three-dimensional geometric modeling of the cochlea using helico-spiral approximation. IEEE Transactions on Biomedical Engineering 47 (10) 1392-1402, 2000

37. Perry BP, **Rubinstein JT.** Imaging case study of the month: meningitis due to acute otitis media and arachnoid granulations. Annals of Otology, Rhinology & Laryngology, 109, 877-879, 2000

38. Miller CA, Robinson BK, **Rubinstein JT**, Abbas PJ, Samuelson CR Auditory nerve response to monophasic and biphasic electric stimuli. Hearing Research 151, 79-94, 2001.

39. Matsuoka AJ, **Rubinstein JT**, Abbas PJ, Miller CA. The effects of interpulse interval on stochastic properties of electrical stimulation models and measurements. IEEE Transactions on Biomedical Engineering, Vol 48, No 4, 416-424, April 2001.

40. Perry BP, Gantz BJ, **Rubinstein JT**. Acoustic neuromas in the elderly. Otology & Neurotology Vol 22, No 3, 389-391, May, 2001.

41. Lustig, LR, Arts HA, Brackmann DE, Francis HF, Molony T, Megerian CA, Moore GF, Moore KM, Morrow T, Postic W, **Rubinstein JT**, Srireddy S, Syms III, CA, Takahashi G, Vernick D, Wackym PA, Niparko JK. Hearing rehabilitation using the BAHA bone anchored hearing aid: results in 40 patients. Otology & Neurotology Vol 22, No 3, 328-334, May 2001.

42. **Rubinstein JT**, Miller CA, Mino H, Abbas PJ. Analysis of monophasic and biphasic electrical stimulation. IEEE Transactions on Biomedical Engineering 48(10): 1065-1070, 2001.

43. Gantz, BJ, **Rubinstein JT**, Gidley P, Woodworth G. Results of Surgical Decompression for Bell's Palsy. Update on Facial Nerve Disorders, AAOHNS Monograph, Alexandria, VA, pp. 181-193, 2001.

44. Yoo SK, Wang G, **Rubinstein JT**, Vannier MW. Semi-automatic segmentation of the cochlea using real-time volume rendering and regional adaptive snake modeling. Journal of Digital Imaging 14(4): 173-181, 2001

45. Tyler RS, Gantz GJ, **Rubinstein JT**, Wilson BS, Parkinson AJ, Wolaver A, Preece JP, Witt S, Lowder MW. Three-month results with bilateral cochlear implants. Ear & Hearing 23 (supplement): 80-89, 2002.

46. Gantz BJ, Tyler RS, **Rubinstein JT**, Wolaver A, Lowder M, Abbas P, Brown C, Hughes M, Preece JP. Binaural cochlear implants: results of subjects implanted bilaterally during the same operation. Otology & Neurotology 23(2): 169-180, 2002.

47. Jiang M, Wang G, Skinner MW, **Rubinstein JT**, Vannier MW. Blind deblurring of spiral CT image: comparative studies on edge to noise ratios. Medical Physics 29(5): 821-829, 2002.

48. Tyler RS, Preece JP, Wilson BS, **Rubinstein JT**, Parkinson AJ, Wolaver AA, Gantz BJ. Distance, localization and speech perception pilot studies with bilateral cochlear implants. Cochlear Implants – An Update, 517-522, 2002.

49. Mino H, **Rubinstein JT**, White JA. Comparison of algorithms for the simulation of action potentials with stochastic sodium channels. Annals of Biomedical Engineering 30(4): 578-587, 2002.

50. **Rubinstein JT.** Pediatric cochlear implants: prosthetic hearing and language development. by invitation to The Lancet 360: 483-85, 2002.

51. **Rubinstein JT** and Turner CW. A novel acoustic simulation of cochlear implant hearing: effects of temporal fine structure. First International IEEE EMBS Conference on Neural Engineering, IEEE press, 142-145, 2003.

52. Chen AF, Samy RF, Kirby P, Gantz BJ and **Rubinstein JT**. Neuroepithelial Cysts of the Middle Ear. Annals of Otology, Rhinology and Laryngology 112: 356-360, 2003.

53. **Rubinstein JT,** Tyler RS, Wolaver A and Brown CJ. Electrical suppression of tinnitus with high-rate pulse trains. Otology & Neurotology, 24: 478-485, 2003.

54. Hong RS, **Rubinstein JT,** Wehner D, Horn D. Dynamic range enhancement for cochlear implants. Otology & Neurotology, 24: 590-595, 2003.

55. **Rubinstein JT** and Della Santina CC**.** Analysis of a biophysical model for vestibular prosthesis research. Journal of Vestibular Research 12(2-3): 69-76, 2003.

56. Jiang M, Wang G, Skinner MW, **Rubinstein JT**, Vannier MW. Blind deblurring of spiral CT images. IEEE Transactions on Medical Imaging 22(7): 837-845, 2003.

57. **Rubinstein JT**, Hong RS. Signal coding in cochlear implants: Exploiting stochastic effects of electrical stimulation. Annals of Otology, Rhinology and Laryngology 112(suppl 191): 14-19, 2003.

58. Gomaa NA, **Rubinstein JT,** Lowder MW, Tyler RS, Gantz BJ. Residual speech perception and cochlear implant performance in postlingually deafened adults. Ear & Hearing 24(6): 539-544, 2003.

59. Hong RS and **Rubinstein JT.** High-rate conditioning pulse trains in cochlear implants: Dynamic range measures with sinusoidal stimuli. Journal of the Acoustical Society of America 114(6): 3327-3342, 2003.

60. Christensen GE, He J, Dill JA,. **Rubinstein JT**, Vannier M, and Wang G. Automatic Measurement of the Labyrinth Using Image Registration and a Deformable Inner Ear Atlas**.** Academic Radiology 10(9): 988-99, 2003.

61. Mino H, **Rubinstein JT,** Miller CA, Abbas PJ. Effects of electrode-to-fiber distance on temporal jitter with electrical stimulation. IEEE Transactions on Biomedical Engineering 51(1): 13-20, 2004.

62. Yoo SK, Wang G, Collison F, **Rubinstein JT,** Vannier MW, Kim HJ, Kim NH. Three-dimensional localization of cochlear implant electrodes using epipolar stereophotogrammetry. IEEE Transactions on Biomedical Engineering 51(5): 838-846, 2004.

63. **Rubinstein JT.** How cochlear implants encode speech. Currrent Opinion in Otolaryngology **12**(5): 444-448, 2004.

64. Runge-Samuelson CL, Abbas PJ, **Rubinstein JT**, Miller CA, Robinson BK. Response of the auditory nerve to sinusoidal electrical stimulation: effects of high-rate pulse trains. Hearing Research **194**(1-2):1-13, 2004.

65. **Rubinstein, JT.** An introduction to the biophysics of the eCAP. International Journal of Audiology, 43: suppl 1: S3-9, 2004.

66. Wang G, Zhao S, Yu H, Miller CA, Abbas PJ, Gantz BJ, Lee SW, **Rubinstein JT**. Design, analysis and simulation for development of the first clinical micro-CT scanner. Acad Radiol. Apr;12(4):511-25, 2005.

67. Hong RS and **Rubinstein JT.** Conditioning pulse trains in cochlear implants: Effects on loudness growth. Otology & Neurotology 27(1):50-6, 2006.

68. Meyer, TA, Canty, PA, Wilkinson, EP, Hansen, MR, **Rubinstein, JT,** Gantz, BJ**.** Small Acoustic Neuromas: Watch and Wait versus Surgical Excision. Otology & Neurotology 27(3):380-392, 2006.

69. Mino H, **Rubinstein JT.** Effects of neural refractoriness on spatio-temporal variability in neural spike initiations with electrical stimulation. IEEE Transactions on Neural Systems and Rehabilitation Engineering 14(3): 273-80, 2006.

70. White JA, **Rubinstein JT** and Mino H. Implementation Issues in Approximate Methods for Stochastic Hodgkin-Huxley models. Ann Biomed Eng. 35(2):319, 2007.

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C.A. Miller, P.J. Abbas**, J.T. Rubinstein,** C.J. Brown. First Quarterly Progress Report N01-DC-9-2107. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 2000.

P.J. Abbas, C.A. Miller**, J.T. Rubinstein**, B.K. Robinson, B.A. Abkes, C. Runge-Samuelson. Third Quarterly Progress Report N01-DC-9-2106. The Effects of Remaining Hair Cells on Cochlear Implant Function, 2000.

C.A. Miller, P.J. Abbas**, J.T. Rubinstein,** C. Runge-Samuelson. Second Quarterly Progress Report N01-DC-9-2107. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 2000.

H. Mino**, J.T. Rubinstein,** C.A. Miller, P.J. Abbas. Fourth Quarterly Progress Report N01-DC-9-2106. The Effects of Remaining Hair Cells on Cochlear Implant Function, 2000.

J.T. Rubinstein, C.A. Miller, H. Mino, P.J. Abbas. Third Quarterly Progress Report N01-DC-9-2107. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 2000.

C.A. Miller, P.J. Abbas**, J.T. Rubinstein,** C. Runge-Samuelson**,** B.K. Robinson, Fifth Quarterly Progress Report N01-DC-9-2106. The Effects of Remaining Hair Cells on Cochlear Implant Function, 2000.

C. Runge-Samuelson, **J.T. Rubinstein,** P.J. Abbas, C.A. Miller, G.J. Smith, B.K. Robinson, B.A. Abkes. Fourth Quarterly Progress Report N01-DC-9-2107. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 2000.

J.T. Rubinstein, C.A. Miller, P.J. Abbas, H. Mino. Sixth Quarterly Progress Report N01-DC-9-2106. The Effects of Remaining Hair Cells on Cochlear Implant Function, 2001.

C.A. Miller, P.J. Abbas**, J.T. Rubinstein,** B.K. Robinson. Fifth Quarterly Progress Report N01-DC-9-2107. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 2001.

P.J. Abbas, C.A. Miller**, J.T. Rubinstein**, B.K. Robinson. Seventh Quarterly Progress Report N01-DC-9-2106. The Effects of Remaining Hair Cells on Cochlear Implant Function, 2001.

C.A. Miller, P.J. Abbas**, J.T. Rubinstein,** J.F. Hetke. Sixth Quarterly Progress Report N01-DC-9-2107. The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation, 2001.

Other Special Presentations

Theses

1. **Rubinstein, J.T.** A Microprocessor-Based Bone Mineral Analyzer [Undergraduate Thesis]. Providence RI: Brown University, 1981.
2. **Rubinstein, J.T.** Some Analysis and a Program for the Design of FIR Digital Filterbanks for Speech Recognition [Masters Thesis]. Providence RI: Brown University, 1982.
3. **Rubinstein, J.T.** Quasi-static Analytical Models for Electrical Stimulation of the Auditory Nervous System [Dissertation]. Seattle WA: University of Washington, 1988.

Invited Presentations

1991 Invited Speaker; Asilomar Conference on Implantable Auditory Prostheses
1993 Invited Speaker; Bryant College Conference on Cochlear Implants
1995 Invited Speaker; Asilomar Conference on Implantable Auditory Prostheses
1995 Chairman, Neural Modeling Session, Biomedical Engineering Society
1996 Moderator, Cochlear Implant Session, Association for Research in Otolaryngology
1996 Invited speaker, Bloedel Hearing Research Center, University of Washington
1997 Invited speaker, 5th International Cochlear Implant Conference, New York, NY
1997 Invited speaker, Asilomar Conference on Implantable Auditory Prostheses, Pacific Grove, CA
1998 International Faculty, First International Symposium & Workshop on Objective Measures in Cochlear Implants, Nottingham, U.K.
1999 Invited speaker, Asilomar Conference on Implantable Auditory Prostheses, Pacific Grove, CA
2000 Invited speaker, CI 2000, 6th International Cochlear Implant Conference, Miami Beach, Florida
2000 Invited speaker, 5th European Symposium on Paediatric Cochlear Implantation, Antwerp, Belgium
2000 Invited speaker, World Congress on Medical Physics & Biomedical Engineering, Chicago, IL
2000 Invited Speaker, 45th Japan Audiological Society Meeting, Nagoya, Japan
2001 Moderator, 8th Symposium on Cochlear Implants in Children, Los Angeles, CA

2001 Moderator, Second International Symposium & Workshop on Objective Measures in Cochlear Implants, Lyon, France
2001 Visiting Professor, Hospital of the University of Geneva, Geneva Switzerland
2001 Co-Chair, Asilomar Conference on Implantable Auditory Prostheses, Pacific Grove, CA
2001 Visiting Professor, Department of Otolaryngology, Johns Hopkins School of Medicine, Baltimore, MD
2002 Outreach Faculty, Wireless Integrated MicroSystems Engineering Research Center, University of Michigan, Ann Arbor, MI
2002 Visiting Professor, First International Temporal Bone Dissection Course, Samsung Medical Center, Sungkyunkwan School of Medicine, Seoul, Korea
2002 Panel on the Future of Cochlear Implants in Children. Triological Society Annual Meeting, Boca Raton, FL
2002 Invited Speaker, Prentice Bloedel Day, Department of Otolaryngology, University of Washington, Seattle, WA
2002 Visiting Professor, Department of Otolaryngology, Mount Sinai School of Medicine, New York, NY
2002 Invited Speaker, Symposium on frontiers of organ and tissue replacement, American Society for Artificial Internal Organs, New York, NY
2002 International Advisory Member, 7th International CochlearImplant Conference, Manchester, UK
2002 Visiting Professor, Department of Otolaryngology, University of Cincinnati, Cincinnati, OH
2002 Featured Speaker, Research Study Club, Los Angeles County Otolaryngology Society
2003 Keynote Speaker, NYU Cochlear Implant Course, Department of Otolaryngology, New York University, NY
2002 Invited panel on artificial organs, Third Annual Conference on Regenerative Medicine & DNA Therapies, Washington, D.C.
2003 Faculty Board, 4th International Symposium on Electronic Implants in Otology & Conventional Hearing Aids, Toulouse, France
2003 Guest speaker, American Auditory Society, Scottsdale, AZ
2003 Visiting Professor, Second International Temporal Bone Dissection Course, Samsung Medical Center, Sungkyunkwan School of Medicine, Seoul.
2003 Invited speaker, Asilomar Conference on Implantable Auditory Prostheses, Pacific Grove, CA
2003 Invited speaker, Research Plenary Session, Annual meeting of Self-Help for Hard of Hearing People, Atlanta, GA
2003 Invited Faculty, 9th Symposium on Cochlear Implants in Children, Washington, DC
2003 Invited speaker, Workshop on Cochlear Implants: Perception, Physiology, Models, Association for Research in Otolaryngology, Daytona Beach, FL

2003 Invited speaker, Symposium on Tinnitus: Mechanisms, Models, Therapy, Association for Research in Otolaryngology, Daytona Beach, FL
2003 Visiting Professor, Saint Louis University / Washington University combined grand rounds, Saint Louis, MO.
2003 Visiting Professor, Department of Otolaryngology, University of Texas, Houston, Guest Speaker, Houston Society of Otolaryngology.
2003 Guest Faculty, Third International Symposium on Objective Measures in Cochlear Implantation, Department of Otolaryngology, University of Michigan, Ann Arbor, MI.
2003 Invited Lecturer, Department of Phonetics and Linguistics, University College London, UK.
2003 Twilight Lecture, The Ear Foundation, University of Nottingham, UK.
2003 Keynote Speaker, Asia-Pacific Symposium on Cochlear Implants, Taipei, Taiwan.
2004 International Advisory Panel, VIII International Cochlear Implant Conference, Indianapolis, IN.
2004 International Faculty, 7th European Symposium on Paediatric Cochlear Implantation, Geneva, Switzerland
2004 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
2004 Invited Lecturer, MRC Cognition and Brain Sciences Unit, University of Cambridge, UK
2004 Visiting Professor, Laboratory of Experimental ORL, University of Leuven, Belgium
2004 Guest Speaker, 204th General Meeting of the Netherlands Union of Otolaryngology, Nieuwegein, Netherlands
2004 Moderator, Research Forum, American Academy of Otolaryngology – Head and Neck Surgery, New York, NY
2004 Visiting Professor, Third International Temporal Bone Dissection Course, Samsung Medical Center, Sungkyunkwan School of Medicine, Seoul
2004 Guest Speaker, 2nd International Symposium on Advanced Technology for Recovery of Human Sensibility, Kyungpook University, Daegu, Korea.
2004 Guest Professor, University of Michigan Temporal Bone Dissection Course, Ann Arbor, MI
2004 Guest Speaker, Hearing, Balance and Chemical Senses Seminar, Kresge Hearing Research Institute, Ann Arbor, MI
2005 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
2005 Keynote Speaker, Frontiers in Hearing, Breckenridge, CO
2005 Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
2005 International Faculty, 5th Asia Pacific Symposium on Cochlear Implant and Related Sciences, Hong Kong.
2006 Visiting Professor, Department of Otolaryngology, University of Florida, Gainesville.
2006 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO

2006 Visiting Professor, Department of Otolaryngology, University of Pennsylvania, Philadelphia.
2006 Guest Speaker, Neuroengineering Now, Department of Bioengineering, University of Texas, Dallas, TX
2006 Visiting Professor, Osaka University Department of Otolaryngology, Osaka, Japan
2006 Guest Speaker, Second Annual Cochlear Implant Centres Group Education Day, Sunnybrook Health Sciences Centre, Toronto, Canada
2007 Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
2007 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
2007 Howard P House Memorial Lecture, Pacific Coast Oto-Ophthalmologic Society, Oahu, HI
2007 Visiting Professor, Fourth International Temporal Bone Dissection Course, Samsung Medical Center, Sungkyunkwan School of Medicine, Seoul
2007 Guest Professor, Updates in Otology & Neurotology, Cesme, Turkey
2007 International Faculty, Asia Pacific Symposium on Cochlear Implant and Related Sciences, Sydney, Australia
2008 Keynote Speaker, 2nd International Music and Cochlear Implant Symposium, University Hospital of Zurich, Switzerland
2008 Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
2008 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
2008 Visiting Professor, Fifth International Temporal Bone Dissection Course, Samsung Medical Center, Sungkyunkwan School of Medicine, Seoul, Korea
2008 Keynote Speaker, 6th Inner Ear Disease and Cochlear Implant Symposium, Izmir Teaching and Research Hospital, Kusadasi, Turkey
2009 Guest Translational Research Lecture, American Auditory Society, Scottsdale, AZ
2009 Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
2009 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
2009 Invited Speaker, Nemours Cochlear Implant Symposium, AI duPont Hospital for Children, Wilmington, DE
2009 Invited Speaker, Conference on Implanted Auditory Prostheses, Lake Tahoe, CA
2009 International Faculty, Asia Pacific Symposium on Cochlear Implant and Related Sciences, Singapore
2010 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
2010 International Otologist, Frontiers of Otolaryngology, University of Melbourne, Australia
2010 Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
2010 Distinguished speaker, House Ear Institute, Los Angeles
2010 Consulting speaker, IESLab, Ltd, Jinan, China
2010 Guest Professor, Dept of Otolaryngology, Miyazaki University, Japan
2010 Invited Speaker, Sixth International Symposium on Meniere's disease, Kyoto, Japan

2010 International Faculty, 7th Inner Ear and Cochlear Implantation Symposium, Bodrum, Turkey
2011 Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
2011 Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
2011 Holy Hour Speaker, Dept ExpORL, Katholieke Universiteit Leuven, Belgium
2011 Willard Fee Lecture, Dept of Otolaryngology, Stanford University, Stanford, CA
2011 Keynote speaker, Korean Otological Society, Jeong-Sun, Korea
2011 Plenary speaker, 8th Asia-Pacific Symposium on Cochlear Implant, Daegu, Korea
2011 Visiting professor, Samsung Medical Center, Seoul, Korea
2012 Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
2012 Guest surgeon, Xijing Hospital, Xi'an, China
2012 Keynote address, 7th International Symposium on Objective Measures in Auditory Implants, Amsterdam, Netherlands
2012 International Faculty, 8th Inner Ear and Cochlear Implantation Symposium, Cappadoccia, Turkey
2012 Guest speaker, 16th International Symposium on Audiological Medicine, Beijing
2012 Seminar speaker, Weldon School of Biomedical Engineering, Purdue University, West Lafayette, IN
2013 Visiting Professor, Department of Otolaryngology, Bnai Zion Medical Center, Technion, Haifa, Israel
2013 Keynote speaker, Leiden University Cochlear Implant Course, The Netherlands.
2013 Schindler Lecture, UC San Francisco Department of Otolaryngology-HNS.
2014 Visiting Surgeon, Global Foundation for Children with Hearing Loss, Childrens' Hospital #1, Ho Chi Minh City, Hanoi Nat'l Childrens' Hospital, Vietnam
2014 Keynote speaker, Leiden University Cochlear Implant Course, The Netherlands.
2014 Guest Faculty, Cochlear Colloquium, Mumbai, India
2015 Keynote speaker, Asia Pacific Symposium on Cochlear Implants, Beijing, China
2015 Invited speaker, Acoustical Society of America, Pittsburgh, PA
2016 Wilson TS Wang Visiting Professor, Department of Otolaryngology, Chinese University of Hong Kong
2016 Invited Speaker, Barany Society, Seoul, Korea
2016 Visiting Professor, Department of Otolaryngology, UT Southwestern, Dallas, TX.
2017 Robert H Mathog MD Memorial Lectureship, Department of Otolaryngology - HNS, Wayne State University, Detroit
2017 Schuknecht Lecture, Massachusetts Eye & Ear, Harvard Medical School, Boston
2017 John Niparko Lecture, Department of Otolaryngology, University of Southern California, Los Angeles
2018 Invited speaker, Crossroads of Music and Technology, Berklee School of Music, Boston, MA
2018 Guest speaker, The Politzer Society, Las Palmas de Gran Canaria, Spain
2018 Guest faculty, Cochlear China surgeons advisory board, Beijing, China
2019 John Daly Lecture, Department of Otolaryngology, New York University

2019 Guest Faculty, Ibero-American Conference on Cochlear Implants, Pamplona
2019 Keynote speaker, Asia-Pacific Conference on Cochlear Implants, Tokyo

Patents Received

1. **Jay T Rubinstein**. Pseudospontaneous Neural Stimulation System and Method. U.S. Patent No. 6,078,838. 6/20/00.
2. **Jay T Rubinstein**, Carolyn J Brown, Richard S Tyler, Paul J Abbas. System and Method for Application of Pseudospontaneous Neural Stimulation. U.S. Patent No. 6,295,472, 9/25/01.
3. **Jay T Rubinstein,** Carolyn J Brown, Richard S Tyler. System and Method for Diagnosing and/or Reducing Tinnitus. U.S. Patent No. 6,631,295, 10/7/03.
4. **Jay T Rubinstein**, Blake S Wilson. Speech Processing System and Method using Pseudospontaneous Stimulation. U.S. Patent No. 6,907,130, 6/14/05.
5. Kaibao Nie, Les Atlas, J**ay Rubinstein,** Xing Li, Charles Clark. Enhanced Signal Processing for Cochlear Implants. U.S. Patent No. 8.019,431, 9/13/11
6. Frank Risi, Colin Irwin, **Jay T Rubinstein**, Felipe Santos and James O Phillips. Vestibular stimulation Device. U.S. Patent No. 9,089,692, 7/28/15

Patents Applied For

1. **Jay Rubinstein**, Kaibao Nie, Steven Bierer, James Phillips, Leo Ling Electrically-evoked Vestibular Compound Action Potentials to Guide Placement and Programming of a Vestibular Neural Stimulator, 2009

2. **Jay Rubinstein**, James Phillips, Albert Fuchs, Leo Ling, Kaibao Nie, Steven Bierer, Vestibular Implant Stimuli for the Treatment of Meniere's Disease, 2009

3. **Jay Rubinstein,** William Harrison. Electrodes for the Treatment of Tinnitus, 2008

4. **Jay Rubinstein**, William Harrison. Systems and Methods for the Treatment of Tinnitus, 2008

Areas of Research

Functional electrical stimulation of the inner ear
Treatment of hearing loss, tinnitus and vestibular dysfunction
High performance computing for neural modeling

Grants and Contracts

1995-97 San Diego Supercomputer Center.
Biophysical Model of Spiral Ganglion Cell and Auditory Nerve
Principal Investigator 200 Cray hours quarterly

1996-99 The Whitaker Foundation.
Biophysical Model of Type - I Spiral Ganglion Cells
Principal Investigator $210,000

1996-98 NIH, Shannon Award, NO1-R55 DC/ODO2948-01.
Comparative Biophysical Model of Spiral Ganglion Cells
Principal Investigator $100,000

1996-99 National Institutes of Health, Contract No. N01-DC-6-2111.
The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation
Co-Principal Investigator $852,000

1997 National Institutes of Health, SBIR R43DC03505
Cochlear Electrode with High Channel Selectivity
Subcontract PI $99,550

1998 National Institutes of Health
Cochlear Implant Conference
Co-Investigator (Shannon, PI) $25,000

1999-00 Braintronics, Inc.
Tinnitus Suppression with Electrical Stimulation
Principal Investigator $150,000

1999-04 National Institutes of Health 1 R01 DC03590
Spiral CT for Cochlear Implantation
Investigator (Wang, PI) $1,159,301

1999-02 National Institutes of Health Contract No. NIH-DC-98-14
The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation
Co-Principal Investigator $1,116,095

1999-02 National Institutes of Health Contract No. NIH-DC-98-11
Effects of Remaining Hair Cells on Cochlear Implant Function
Co-Investigator (Abbas, PI) $879,110

2000-03 Tinnitus Research Consortium
Electrical Suppression of Tinnitus
Principal Investigator $300,000

2001 National Institutes of Health 1 R13 DC005041-01
2001 Conference on Implantable Auditory Prostheses
Conference Co-Chair (Shannon, PI) $30,000

2001-06 National Institutes of Health P50
Iowa Cochlear Implant Center IV
Co-Director (Gantz, PI) $10,823,000

2002-06 National Institutes of Health Contract No. NIH-DC-98-11

	Effects of Remaining Hair Cells on Cochlear Implant Function	
	Co-Investigator (Abbas, PI)	$1,522,412
2002-03	Braintronics, Inc	
	Ear Implant for Tinnitus Suppression	
	Principal Investigator	$250,000
2002	Advanced Bionics Inc.	
	Dynamic range with high-rate conditioning stimuli	
	Principal Investigator	$30,000
2003	Advanced Bionics Inc.	
	Frequency discrimination with high-rate conditioning stimuli	
	Principal Investigator	$30,000
2004-08	National Institutes of Health R01 DC05972	
	Randomized Trial of Tinnitus Retraining Therapy	
	Investigator (Tyler, PI)	$1,768,575
2006	National Organization for Hearing Research Foundation	
	Measuring and improving hearing in infants with cochlear implants	
	Role: Mentor (Dasika, PI)	$20,000
2005-10	National Institutes of Health R01 DC007525	
	Optimized Conditioned Processing for Cochlear Implants	
	Principal Investigator	$1,905,126
2006-11	National Institutes of Health R13 DC006616	
	Building the Next Generation of Clinical Researchers - American Auditory Society	
	Role: Co-Investigator (Gorga, PI)	$133,579
2006-11	National Institutes of Health DC-05-0011 (Phillips, PI)	
	Neurophysiological Studies of Electrical Stimulation for the Vestibular Nerve	
	Investigator	$2,831,646
2006-07	Cochlear Corporation	
	Validation of the UW CAMP music test for cochlear implant recipients.	
	Role: PI	$30,000
2007-08	Advanced Bionics Corporation	
	Validation of the UW CAMP music test for cochlear implant recipients	
	Role: PI	$15,000
2006-08	Cochlear Corporation	
	Clinical Trial of the Nucleus Hybrid Cochlear Implant	
	Role: PI	$7,500
2008	National Institutes of Health F32 DC008238 (Dasika, PI)	
	The development of sensitivity to electrical stimulation with cochlear implants.	
	Role: Mentor	$58,898
2009-11	National Institutes of Health F31 DC009755 (Won, PI)	
	Psychophysics of speech processor modifications in cochlear implants.	
	Role: Mentor	$68,836

2008-09 Cochlear Corporation
Clinical Trial of the Nucleus Hybrid S12 Cochlear Implant
Role: PI $7,500

2009-11 Wallace Coulter Foundation
Clinical Feasibility of a Vestibular Neurostimulator
Role: PI $212,000

2009-11 National Institutes of Health F31 DC010306
A model-based approach for optimizing cochlear implant stimulation
Role: Co-mentor (Goldwyn, PI) $68,836

2010 University of Washington Technology Gap Innovation Fund
Improving speech and music perception with cochlear implants
Role: Investigator (Nie, PI) $50,000

2009-11 National Institutes of Health F31 DC010309 (Faulkner, PI)
Auditory Training to Improve Spectral Resolution in Cochlear Implant Listeners
Role: Co-mentor $41,000

2010-12 National Institutes of Health F32 DC011431 (Jones, PI)
Modeling spectral-ripple discrimination by cochlear implant users
Role: Mentor $80,000

2010-15 National Institutes of Health R01 DC010148 (Drennan, PI)
Improved analysis of cochlear implant sound processing
Role: Investigator $1,875,000

2011 ITHS/National Primate Research Center (Phillips, PI)
Vestibular Prosthesis for Bilateral and Uncompensated Unilateral Loss
Role: Co-investigator $75,000

2011-14 Kranwinkle Family
Clinical Feasibility of a Vestibular Implant for Meniere's disease
Role: PI $1,004,000

2013-14 American Otologic Society (Horn, PI)
Spectral and Temporal Resolution in Children with Cochlear Implants
Role: Co-mentor $80,000

2014-15 Wallace Coulter Foundation (Atlas, PI)
Tonality in Cochlear Implants
Role: Investigator $100,000

2014-19 National Institutes of Health R01 DC014002
Optimization of a human vestibular implant
Role: PI $2,961,610

2014-19 National Institutes of Health K23 DC013055 (Horn, PI)
Spectral and Temporal Resolution in Children with Cochlear Implants
Role: Co-Mentor $1,151,530

2014 Anderson Family
Operating support for the Bloedel Center

	Role: PI	$100,000
2014-	Bill and Melinda Gates Foundation Bloedel Minigrant Endowment Role: PI	$500,000
2015-16	Wallace Coulter Foundation (Atlas, PI) Tonality in Cochlear Implants Role: Investigator	$100,000
2018-19	NIDCD F31DC017349-01 (Resnick, PI) Peripheral Limitations in Cochlear Implant Performance: Computational Exploration of how Demyelination and Degeneration Impact Neural Electrophysiology and Coding Role: Mentor	$77,000
2018-21	Department of Defense DM170556OD (Drennan, PI) Early Detection of Noise-induced Hearing Loss Role: Investigator	$1,568,560
2018-19	Cheney Foundation (Horn, PI) Psychophysics of infants with cochlear implants Role: Mentor	$10,000
2019-20	Cheney Foundation (Carlson, PI) Genetics of pediatric hearing loss Role: Mentor	$5,000

IV. SERVICE

Professional Affiliations

1980-	IEEE Engineering in Medicine and Biology Society
1986-	Association for Research in Otolaryngology
1990-	American Academy of Otolaryngology-Head and Neck Surgery
1992-94	Triological Society Resident Fellow
1996-	American Neurotology Society - Associate Member
1999-	American Auditory Society
2002-	American Otological Society
2006-	IEEE Senior Member
2006-	Collegium ORLAS
2007-09	President-elect and Program Chair, American Auditory Society
2008-11	Council, Association for Research in Otolaryngology
2009-10	President, American Auditory Society
2009-16	Vice-President, CORLAS-US group
2012-13	President-elect, Association for Research in Otolaryngology
2013-14	President, Association for Research in Otolaryngology
2014-15	Past-President, Association for Research in Otolaryngology

2016- Treasurer, CORLAS-US group
2019- College of Fellows, American Institute of Medical and Biological Engineering
2018-22 President-Elect, The Politzer Society

Collegiate, University and National Committees

1992-94 Graduate Medical Education Committee, Massachusetts Eye and Ear Infirmary
1994-00 Committee on Implantable Hearing Devices, American Academy of Otolaryngology--Head and Neck Surgery
1995- Scientific Advisory Council, NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry
1996 Steering Committee, 1997 Asilomar Conference on Implantable Auditory Prostheses
1996 Ad Hoc NIH Site Visitor
1997 IAIMS Task Force, The University of Iowa
1997- American Neurotology Society Research Committee
1997- College of Medicine Research Committee
1997 Ad Hoc member NIH Hearing Research Study Section
1997 Ad Hoc member NIH Sensory Disorders SBIR Study Section
1998 Ad Hoc member NIH Hearing SBIR Study Section
1999 Ad Hoc member NIH IFCN Study Section
2000 Ad Hoc Member, NIH IFCN6 SBIR Study Section
2000 Peer reviewer, Conference of Rectors of the Austrian Universities
2000 NIH NINDS Special Emphasis Panel ZNS1 SRB-H(04)
2001 NIH NIDCD Special Emphasis Panel ZDC1 SRB-O
2001 Conference co-chair, Asilomar Conference on Implantable Auditory Prostheses
2001 Steering Committee, NIH/VA International Hearing Aid Conference
2001 Task Force on New Materials, American Board of Otolaryngology
2001 Nominating Committee, Association for Research in Otolaryngology
2001 Peer Reviewer, Hearing Loss Guideline Panel, New York State Department of Health
2002 Steering Committee, 2003 Asilomar Conference on Implantable Auditory Prostheses
2002 Outreach Faculty, Wireless Integrated MicroSystems Engineering Research Center, University of Michigan, Ann Arbor, MI
2002 NIH NIDCD Special Emphasis Panel, ZRG1 IFCN-4(06)
2002 Prosthetic Clinical Management National Workgroup on Cochlear Implants, Department of Veteran Affairs
2002 Ad Hoc Reviewer, Swiss National Science Foundation
2003 NIH NIDCD Special Emphasis Panel ZDC1 SRB-O

2003 Ad Hoc Reviewer, Royal National Institute for the Deaf, UK
2003 NIH NIDCD Special Emphasis Panel ZDC1 SRB-R (42)
2004 Ad hoc member, NIH AUD study section
2005 Ad hoc member, NIH R03 study section
2005-09 Permanent member NIH AUD study section
2005-08 Government Relations Committee, ARO
2006 Guest examiner, American Board of Otolaryngology
2006-07 Program Advisory Committee, American Otologic Society
2007 Guest examiner, American Board of Otolaryngology
2007 Steering committee, Conference on Implantable Auditory Prostheses
2007 Ad Hoc Reviewer, US Department of Energy Retinal Prosthesis Program
2008 Neurotology Examiner, American Board of Otolaryngology
2008-09 Scientific Advisory Panel, NIH Roadmap Nanomedicine Initiative
2009 Guest Examiner, American Board of Otolaryngology
2010 Neurotology Examiner, American Board of Otolaryngology
2010 Chair, nominating committee, American Otologic Society
2010 Program Committee, American Otologic Society
2012 Program Committee, American Otologic Society
2012-13 President-elect, Association for Research in Otolaryngology
2013-14 President, Association for Research in Otolaryngology
2014-15 Past President, Association for Research in Otolaryngology
2018-22 President-Elect, The Politzer Society
2018 Chair, NIDCD Special Emphasis Panel
2019 Chair, NIDCD Special Emphasis Panel
2019 Guest Examiner, American Board of Otolaryngology

Board Memberships

2001- Scientific Advisory Board, American Tinnitus Association
2002- Surgical Advisory Board, Cochlear Corporation
2003- Editorial Board, Otology and Neurotology
2003- Editorial Board, Hearing Research
2005-08 Associate Editor, Journal of the Association for Research in Otolaryngology
2004-08 Executive Board, American Auditory Society
2005- Board of Trustees, Listen & Talk School, Seattle, WA
2005- Surgical Advisory Board, Advanced Bionics Corporation
2006-08 Board of Trustees, Executive Committee, Northwest Lions Foundation for Sight and Hearing, Seattle, WA
2006-12 Chairman, Board of Trustees, Audient, LLC, Seattle, WA
2008-11 Council-at-large, Association for Research in Otolaryngology
2008-13 Board of Directors, SightLife, LLC, Seattle, WA
2010-13 Board of Directors, Otology & Neurotology
2010-18 Research Advisory Board, American Otologic Society

2012-17 Board of Scientific Counselors, NIDCD
2015 2017-21 NIDCD Strategic Plan Working Group
2017 Chair, Scientific Advisory Board, American Otologic Society

Ad Hoc Reviewer
Annals of Biomedical Engineering
Annals of Neurology
Annals of Otology, Rhinology & Laryngology
American Journal of Otology
Archives of Otolaryngology
Audiology and Neuro-otology
Ear and Hearing
Hearing Research
Hospital Physician
IEEE Transactions on Biomedical Engineering
Journal of Biomechanics
Journal of Neurophysiology
Journal of Neuroscience
Journal of the Acoustical Society of America
Journal of the Association for Research in Otolaryngology
Laryngoscope
Medical & Biological Engineering & Computing
Nature Medicine
Otology and Neurotology
Science Translational Medicine
The Lancet

Washington State Health Care Authority

Tinnitus: non-invasive, non-pharmacologic treatments

Judy Zerzan, MD, MPH
Chief Medical Officer
Health Care Authority

Friday May 15, 2020

Washington State Health Care Authority

Introduction

- Clinical questions
- Current policies and utilization
- Evidence summary
- Rationale and recommendations

2

Washington State Health Care Authority

Tinnitus

- Tinnitus = auditory experience of ringing, buzzing, roaring, hissing in the ears
  - Subjective or objective
  - Constant or intermittent
  - Pulsatile or rhythmical
  - One or both ears
- NHANES 7.1-14.6% of the population
- Comorbidities include depression, anxiety, hearing and concentration difficulties, sleep disturbance

3

Washington State Health Care Authority

Clinical Questions

- What is the effectiveness of non-invasive, non-pharmacologic therapies for the treatment of bothersome, subjective tinnitus?
- What are the harms associated with non-invasive, non-pharmacologic therapies for the treatment of tinnitus?
- What are the costs and cost-effectiveness of non-invasive, non-pharmacologic treatment of tinnitus?

4

Agency Medical Directors' Concerns

- Safety: medium
- Efficacy: high
- Cost: high

5

Non-invasive and Non-pharmacologic Treatments

- **Sound Therapies**
  - Sound generators, sound maskers, altered auditory stimuli, hearing aids that include sound masking or generating
- **Repetitive Transcranial Magnetic Stimulation (rTMS)**
  - Delivery of multiple electromagnetic pulses to the scalp
- **Cognitive Behavioral Therapy**
  - Psychotherapy approach to reduce the distress associated with tinnitus
- **Tinnitus Specific Therapies**
  - Tinnitus retraining, tinnitus masking plus counseling

6

Washington State Health Care Authority

Current State Agency Policy

- **Sound Therapies**
  - L&I covers sound masking
- **Repetitive Transcranial Magnetic Stimulation (rTMS)**
  - Not covered for this indication
- **Cognitive Behavioral Therapy**
  - Covered
- **Tinnitus Specific Therapies**
  - No policy or not covered

7

Washington State Health Care Authority

Coverage Overview

	Sound Therapies	rTEMS	CBT	Tinnitus Specific Therapies	No Policy
Medicare					X
Aetna	NC	NC		NC	
Cigna			Cover		
Humana	NC	NC	NC	NC	
Kaiser	NC				
Premera					X
Regence		NC			
Tricare	NC				
United	NC	NC			

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Washington State Health Care Authority

WA Utilization Medicaid

State health program	State fiscal year			Overall (3 years)
	2017	2018	2019	Unique individuals
Medicaid, fee-for-service population	139,173	111,414	111,222	120,603
Individuals with at least one procedure/service	139	126	118	359
Number of procedure-days	256	226	192	674
Average procedure-days per individual	1.8	1.8	1.6	1.9
Max procedure days per individual	7	10	5	12
Paid amount total	$23,966	$24,454	$27,144	$75,564
Average payments per individual	$172	$194	$230	$210
Medicaid, managed care population	1,579,124	1,570,142	1,532,692	1,560,653
Individuals with at least one procedure/service	2296	2480	2414	6799
Number of procedure-days	4168	4320	4295	12783
Average procedure-days per individual	1.8	1.7	1.8	1.9
Max procedure days per individual	16	17	20	25
Paid amount total	$271,369	$243,488	$263,892	$778,748
Average payments per individual	$118	$98	$109	$115

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Washington State Health Care Authority

WA Utilization: L&I and UMP

State health program	State fiscal year			Overall (3 years)
Washington State Department of Labor and Industries (L&I)	2017	2018	2019	Unique individuals
Workers' compensation claims by year	126,524	124,081	124,959	125,188
Individuals with at least one procedure/service	1171	878	831	2645
Number of procedure-days	1779	1310	1277	4366
Average procedure-days per individual	1.5	1.5	1.5	1.7
Max procedure days per individual	36	54	27	78
Paid amount total	$684,271	$544,929	$527,036	$1,756,236
Average payments per individual	$584	$621	$634	$664
Public Employees Benefit Board Uniform Medical Plan (PEBB/UMP)	2017	2018	2019	Unique individuals
Annual members	187,673	196,020	198,347	194,013
Individuals with at least one procedure/service	662	730	734	1973
Number of procedure-days	920	1064	1073	3057
Average procedure-days per individual	1.4	1.5	1.5	1.5
Max procedure days per individual	35	15	17	35
Paid amount total	$148,095	$182,116	$182,185	$512,396
Average payments per individual	$224	$249	$248	$260

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Washington State Health Care Authority

Clinical Practice Guidelines

	Sound Maskers	rTEMS	CBT	Tinnitus Specific Therapies
Multidisciplinary European guideline (2019)	n/a	Against	Strong recommend	n/a
Assoc. of Scientific Medical Societies – Germany (2015)	n/a	n/a	Recommend	Against
American Acad. Of Otolaryngology (2014)	Option	Against	Recommend	
International Federation of Clinical Neurophysiology (2014)		Possible, but partial and transient benefit		

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Washington State Health Care Authority

Evidence Summary

- 59 studies reported in 69 articles 1996-2019
- All low or very low quality
- Effectiveness
  - Tinnitus distress and disability (14 instruments, 5 with defined clinical meaningful difference)
  - Psychological measures (18 instruments, 5 with defined clinical meaningful difference)
  - Quality of life (6 instruments, 2 with defined clinically meaningful difference)

12

Evidence on Sound Therapies

- All very low quality
- Effectiveness
  - Tinnitus distress and disability: no benefit or unable to determine
  - Psychological measures: no benefit or unable to determine
- Harms: no harms
- Cost: not reported

13

Evidence on rTEMS

- Low or very low quality
- Effectiveness
  - Tinnitus distress and disability: no benefit
  - Psychological measures: no benefit
  - Quality of life: no benefit
- Harms: unable to determine
- Cost: not reported

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Evidence on CBT Therapist led and Internet/book led

- All low quality evidence except very low on QOL
- Effectiveness
  - Tinnitus distress and disability: benefit
  - Psychological measures: benefit
  - Quality of life: no benefit (book led)
- Harms: no harms
- Cost: not reported

15

Evidence on Tinnitus Specific Therapies

- Mostly very low quality and a few low quality
- Effectiveness
  - Tinnitus distress and disability: benefit in studies that also used CBT principles
  - Psychological measures : unable to determine
  - Quality of life: unable to determine
- Harms: unable to determine
- Cost: unable to determine

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Washington State Health Care Authority

AMD Recommendations

- **Sound Therapies**
  - Non coverage (would cover hearing aids if hearing loss is present)
- **Repetitive Transcranial Magnetic Stimulation (rTMS)**
  - Non coverage
- **Cognitive Behavioral Therapy**
  - Cover
- **Tinnitus Specific Therapies**
  - Non coverage

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Washington State Health Care Authority

Questions?

More Information:

www.hca.wa.gov/about-hca/health-technology-assessment/tinnitus-non-invasive-non-pharmacologic-treatments

18

Order of scheduled presentations:

Tinnitus: non-invasive, non-pharmacologic treatments

	Name
1	
2	
3	

No requests were received to provide public comment on this technology assessment.

Non-Invasive, Non-Pharmacologic Treatments for Tinnitus

RTI INTERNATIONAL

UNC THE CECIL G. SHEPS CENTER FOR HEALTH SERVICES RESEARCH

RTI-University of North Carolina Evidence-based Practice Center

Health Technology Assessment
State of Washington Health Care Authority

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Presented by:
Leila Kahwati, MD, MPH

May 15, 2020
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www.rti.org

Overview of Presentation

- Background and policy context
- Methods and search results
- Summary findings and conclusions
- Questions
- Detailed results, as requested by the Committee

2

Background

3

Background: Condition

Tinnitus refers to the experience of hearing ringing, buzzing, roaring, or hissing in the ears.

- Prevalence ranges from 7.1% to 14.6%.
- Treatment is aimed at reducing the perception of and/or reaction to the tinnitus noise.
- Due to the heterogeneity of the condition, no one treatment may be universally effective.

Source: https://www.123rf.com/stock-photo/ear.html?sti=oaerstckydhvvg8a61|&mediapopup=43279008

4 Page in report: 1

Background: Therapies & Technologies-Sound Therapies

Source: http://bradentonsertoma.org/speech-hearing

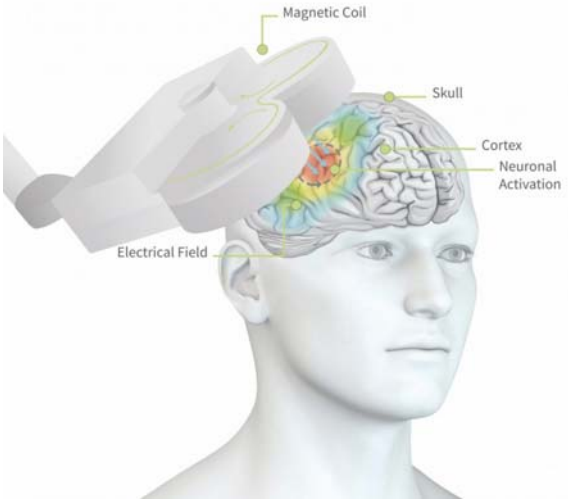
- **Sound maskers**
  - Introduce sound using ambient or ear-level devices to mask tinnitus sounds, distract user, or both
- **Altered auditory stimuli**
  - Music or other sounds that is altered to emit noise at specific frequencies, often matched to an individual's tinnitus frequency
- **Hearing aids with sound generating or masking**
  - For individuals with hearing loss and tinnitus.

5 Page in report: 2

Background: Therapies & Technologies-rTMS

Repetitive transcranial magnetic stimulation (rTMS)

- Non-invasive neuromodulation intervention
- Multiple electromagnetic pulses targeted to specific brain regions
- Delivered over multiple sessions over the course of days to weeks



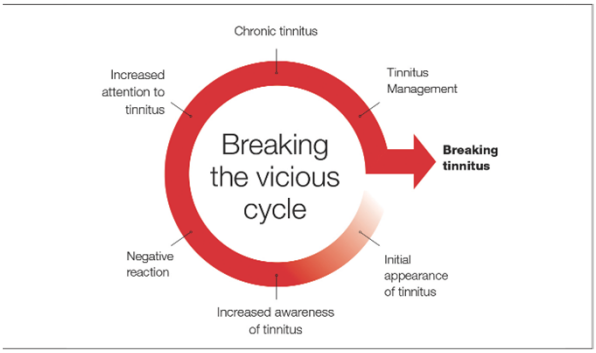
Source: https://brainclinics.com/rtms/

6 Page in report: 2

Background: Therapies & Technologies-CBT

Cognitive Behavioral Therapy (CBT)

- Cognitive restructuring and behavior modification
- CBT principals are used to promote changes to reduce the distress associated with tinnitus



Source: https://a360-wp-uploads.s3.amazonaws.com/wp-content/uploads/hearingr/2013/05/Tinnitus_fig1.png

7 Page in report: 2

Background: Therapies & Technologies-Tinnitus-specific Therapy

Tinnitus-specific therapies describe interventions that use components of sound and psychological therapy in combination to treat tinnitus. These include, among others:

- Tinnitus retraining therapy (TRT)
- Neuromonics tinnitus treatment (NTT)
- Tinnitus activities treatment (TAT)
- Tinnitus-masking counseling

8 Page in report: 2

Regulatory Status and Policy Context

- Some of the technologies evaluated in the scope of this HTA are devices regulated by the U.S. Food and Drug Administration
  - 72 FDA-cleared sound devices as of late 2019
  - rTMS approved for treatment-resistant depression, acute migraine headache, obsessive-compulsive disorder
- The State of Washington Health Care Authority selected non-invasive, non-pharmacologic treatments for tinnitus for an HTA because of medium concerns of safety and high concerns for efficacy and cost.

9 Page in report: 4

Methods

10

Key Questions

- **Key Question 1: Effectiveness (Health Outcomes)**
  - What is the effectiveness of non-invasive, non-pharmacologic therapies for the treatment of bothersome, subjective tinnitus?
- **Key Question 2: Safety**
  - What are the harms associated with non-invasive, non-pharmacologic therapies for tinnitus?
- **Key Question 3: Cost**
  - What are the costs and cost-effectiveness of non-invasive, non-pharmacologic therapies for the treatment of tinnitus?

11 Page in report: 5

Scope

Population	Adults with subjective, idiopathic tinnitus without underlying anatomical conditions
Interventions	Sound therapies; rTMS; Cognitive behavioral therapy; Tinnitus-specific therapies
Comparators	No treatment, usual care, waitlist or delayed treatment, sham treatment
Outcomes	• KQ 1 (Effectiveness): validated measures o Tinnitus symptom, severity, distress, disability, or handicap o Psychological measures (e.g., depression, anxiety), o Sleep impact o Health-related quality of life o Functional status • KQ 2 (Safety): adverse events, serious adverse events, side effects • KQ 3 (Cost): Cost, cost-effectiveness
Setting	Any primary or specialty care setting in countries categorized as *very high* on the United Nations' Human Development Index
Study Designs	Randomized controlled trials, controlled trials (all KQ) Cohort studies with a concurrent comparator group (KQ2) Cost-studies (KQ3)

12 Page 6, Table 1

Abbreviations: KQ=key question; NTT=neuromonics tinnitus treatment; rTMS=repetitive transcranial magnetic stimulation; TAT=tinnitus activities treatment; TRT=tinnitus retraining therapy. *only if at least 3 low or some risk of bias RCTs not available

Search and Assessment Methods

- PubMed MEDLINE, Embase, Cochrane Library, PsycInfo, Relevant web sites
  Dates: Database inception through September 9, 2019
- ClinicalTrials.gov search for ongoing studies
- Individual study risk of bias assessment
- OpenEpi for ARD, IRR, RR, and CI calculations when not provided
- Modified Grading of Recommendations, Assessments, Development and Evaluation (GRADE) approach for overall certainty of evidence

13 Page in report: 6

GRADE

Certainty Level

Outcomes assessed: tinnitus distress & disability, psychological measures (including sleep), quality of life, adverse events, cost outcomes

Certainty Level	
High	•Very confident that the estimate of effect of intervention on outcome lies close to the true effect.
Moderate	•Moderately confident in estimate of effect of intervention on outcome. True effect is likely close to estimate, but possibly different.
Low	•Little confidence in estimate of effect of intervention on outcome. True effect may be substantially different from estimate.
Very low	•No confidence in estimate of effect of intervention on outcome. True effect is likely substantially different from estimate.

RCTs

Cohorts

14 Page 11, Table 2

Measures of Tinnitus Distress and Disability

Most commonly used

Instrument Name	Abbreviation
Tinnitus Handicap Inventory	THI
Tinnitus Questionnaire	TQ and mini-TQ
Tinnitus Handicap Questionnaire	THQ
Tinnitus Reaction Questionnaire	TRQ
Tinnitus Functional Index	TFI
Visual Analog Scale	VAS
Tinnitus Experience Questionnaire	TExQ
Tinnitus Effects Questionnaire	TEfQ
Tinnitus Cognitions Questionnaire	TCQ
Tinnitus Disability Questionnaire	TD
Tinnitus Coping Style Questionnaire	TCSQ
Tinnitus Severity Index	TSI
Tinnitus Acceptance Questionnaire	TAQ
Tinnitus Severity Scale	TSS

15 Page in Report: 14, Table 3

Summary of Findings

16

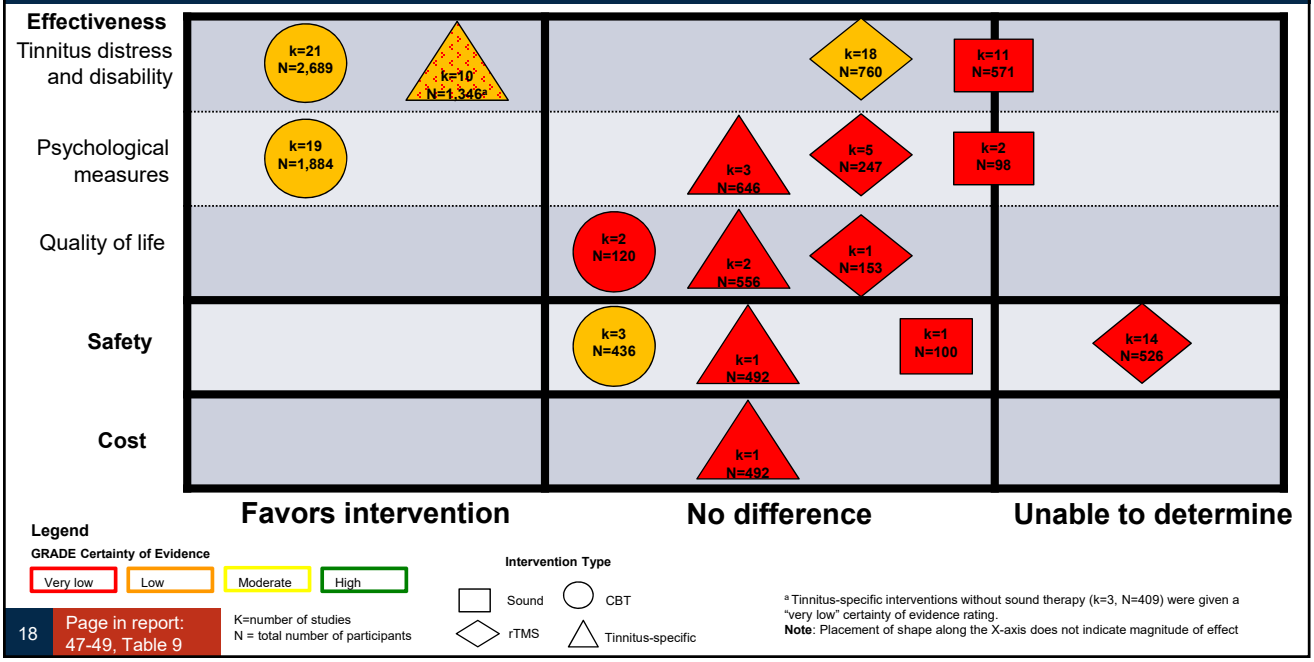
Summary of Search Yield

- 3,310 records identified through database searches
- 177 full-text articles assessed for eligibility
- 59 RCTs* eligible for this review
  - 11 sound therapy
  - 19 rTMS
  - 21 CBT
  - 10 Tinnitus-specific

17 Page in report: 11

* Some studies reported on multiple interventions across categories

Evidence Map and Topline Summary



K=number of studies
N = total number of participants

[a] Tinnitus-specific interventions without sound therapy (k=3, N=409) were given a "very low" certainty of evidence rating.
Note: Placement of shape along the X-axis does not indicate magnitude of effect

18 Page in report: 47-49, Table 9

Findings: Cognitive Behavioral Therapy

19

Study Characteristics: Cognitive Behavioral Therapy

21 RCTs

- 1996 to 2018
- N range 20-304
- Duration: NR- 6 months

4 U.S.	17 in other countries	
8 some risk of bias	13 high risk of bias	
3 industry support	15 no industry support	3 NR
12 therapist-led	8 self-directed	1 Both
3 KQ1	18 KQ1 & KQ2	
14 wait list control	7 attention control	

20 Page in report: 33, Table 7

Abbreviations: KQ = key question; NR = not reported; RCT = randomized controlled trial

Cognitive Behavioral Therapy-GRADE Table

Intervention (Comparison)	Outcome	No. Studies (No. Participants)	GRADE Certainty of Evidence[a]	Direction
Therapist-led individual or group CBT interventions (delayed treatment or attention control)	Tinnitus distress and disability	13 RCTs (1,743)	⊕⊕◯◯	Benefit
	Psychological measures	11 RCTs (1,100)	⊕⊕◯◯	Benefit
	Safety	3 RCTs (436)	⊕⊕◯◯	No harms
Internet or book-guided CBT interventions (wait list or attention control)	Tinnitus distress and disability	9 RCTs (946)	⊕⊕◯◯	Benefit
	Psychological measures	8 RCTs (784)	⊕⊕◯◯	Benefit
	Quality of life	2 RCTs (120)	⊕◯◯◯	No benefit

Notes: [a]Certainty ratings: ⊕◯◯◯ Very low, ⊕⊕◯◯ Low, ⊕⊕◯◯ Moderate. ⊕⊕⊕⊕ High
Abbreviations: CBT = cognitive behavioral therapy; RCT = randomized controlled trial

21 Page in report: 47, Tables 9, H6, H7

Additional Detail on Effectiveness of CBT interventions

- Therapist-led interventions
  - Tinnitus distress and disability
    - 7 studies reporting using TQ; primary study outcome in 4 studies
      - Effect sizes(ES) 0.81 to 0.95 based on 3 studies
      - All but 1 also reported other measures (VAS, TDQ, TRQ)
    - 3 studies reported using THI; primary study outcome in 1 study
      - ES 0.38 and 0.98, based on 2 studies
      - All also reported other measures (TFI, TAQ)
    - 3 studies reported measures other than the TQ and THI
      - TRQ: 7.8 to 10.3 larger point improvement for intervention vs. control (statistically significant in 1 study, significance NR by other 2 studies)
      - Other measures reported by 2 of the 3 studies, larger numerical improvements for intervention but no statistical significance testing

Effect Size
1.2 very large
0.8 large
0.5 medium
0.2 small

22 Page in Report: 35

Additional Detail on Effectiveness of CBT interventions

- Self-directed interventions
  - Tinnitus distress and disability
    - 4 studies reported using THI, primary study aim for 2 studies
      - Effect sizes ranged from 0.56* to 0.70* across the 4 studies
      - Three of the 4 also reported larger improvements on other measures (mini-TQ, TAQ, TRQ, VAS for loudness, VAS for distress)
    - 3 studies reported using TRQ, primary study aim for 2 studies
      - 1 study: ES 0.28 at 6 weeks
      - 1 study: 12.5-point larger improvement*; % achieving meaningful reduction (13% vs. 3%)
      - 1 study: No significant difference at 6 weeks (actual values NR)
    - 1 study reported using TFI, primary study aim
      - ES 0.7 at post-intervention (8 weeks)
    - 1 study reported using TQ, primary study aim
      - Internet-delivered: ES 1.0* at 3 months, 0.66* at 9 months
      - Book-delivered: ES 0.24 at 3 months, 0.39* at 9 months

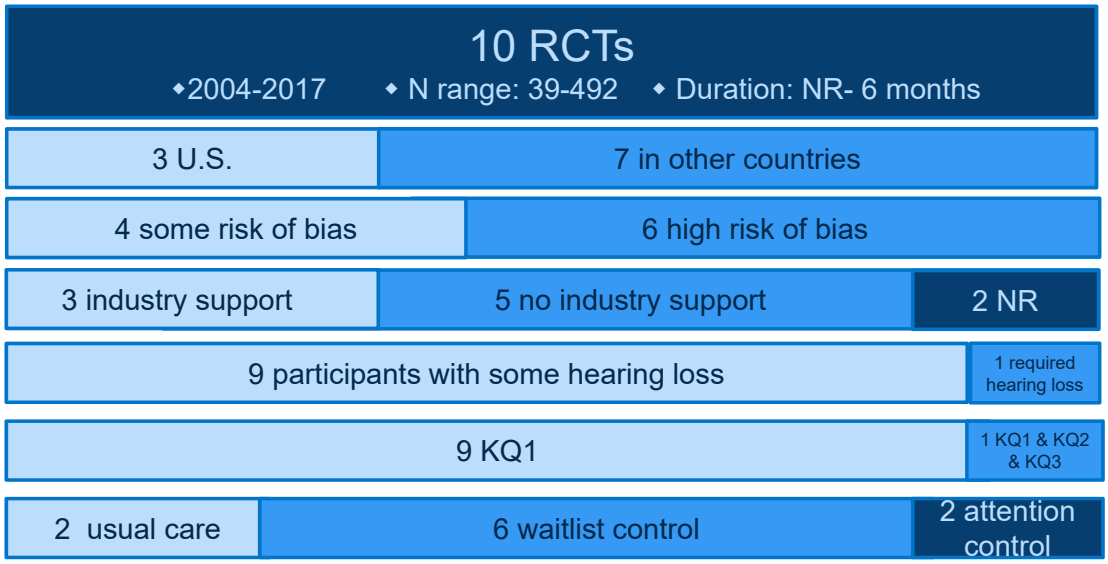
23 Page in Report: 36

* Indicates a statistically significant result

Findings: Tinnitus Specific Therapies

24

Study Characteristics: Tinnitus-specific Therapies



25 Page in report: 42, Table 8

Abbreviations: KQ = key question; NR = not reported; RCT = randomized controlled trial

Tinnitus-specific therapy-GRADE Table

Intervention (Comparison)	Outcome	No. Studies (No. Participants)	GRADE Certainty of Evidence[a]	Direction
Tinnitus-specific-interventions with sound therapy (delayed treatment or attention control)	Tinnitus distress and disability	7 RCTs (937)	●●○○	Benefit
	Psychological measures	2 RCTs (556)	●○○○	Unable to determine
	Quality of life	2 RCTs (556)	●○○○	Unable to determine
	Safety	1 RCT (492)	●○○○	Unable to determine
	Cost	1 RCT (492)	●○○○	Unable to determine
Tinnitus-specific interventions without sound therapy (delayed treatment or attention control)	Tinnitus distress and disability	3 RCTs (409)	●○○○	Benefit
	Psychological measures	1 RCT (90)	●○○○	Unable to determine

26 Page in report: 47, Tables 9, H8, H9

Notes: [a]Certainty ratings: ●○○○ Very low, ●●○○ Low, ●●○○ Moderate. ●●●● High
Abbreviations: RCT = randomized controlled trial

Findings: Sound Therapy

27

Study Characteristics: Sound Therapy

11 RCTs

- 1999 to 2018
- N range 30-136
- Duration : NR to 1 year

3 U.S.	8 other countries		
5 some risk of bias	6 high risk of bias		
5 industry funding	6 No industry funding		
7 participants with hearing loss	3 excluded hearing loss	1 NR	
10 KQ 1		1 KQ1 & KQ2	
3 HA + SG vs. HA alone	4 Altered auditory stimulus vs. placebo stimulus	3 SG + intervention vs. intervention alone	1 game

28 Page in report: 19, Table 5

Abbreviations: HA = hearing aid; KQ = key question; NR = not reported; SG= sound generator

Sound therapy interventions -GRADE Table

Intervention (Comparison)	Outcome	No. Studies (No. Participants)	GRADE Certainty of Evidence[a]	Direction
Hearing aids with sound-generating features (regular hearing aids)	Tinnitus distress and disability	3 RCTs (87)	⊕◯◯◯	No benefit
Altered auditory stimulus (control stimulus)	Tinnitus distress and disability	4 RCTs (219)	⊕◯◯◯	Unable to determine
	Psychological measures	1 RCT (50)	⊕◯◯◯	No benefit
	Safety	1 RCT (100)	⊕◯◯◯	No harms
Sound generators with information, education, counseling (information, education, counseling alone)	Tinnitus distress and disability	3 RCTs (234)	⊕◯◯◯	No benefit
	Psychological measures	1 RCT (48)	⊕◯◯◯	Unable to determine
Auditory Attention Training Game (control game)	Tinnitus distress and disability	1 RCT (31)	⊕◯◯◯	Unable to determine

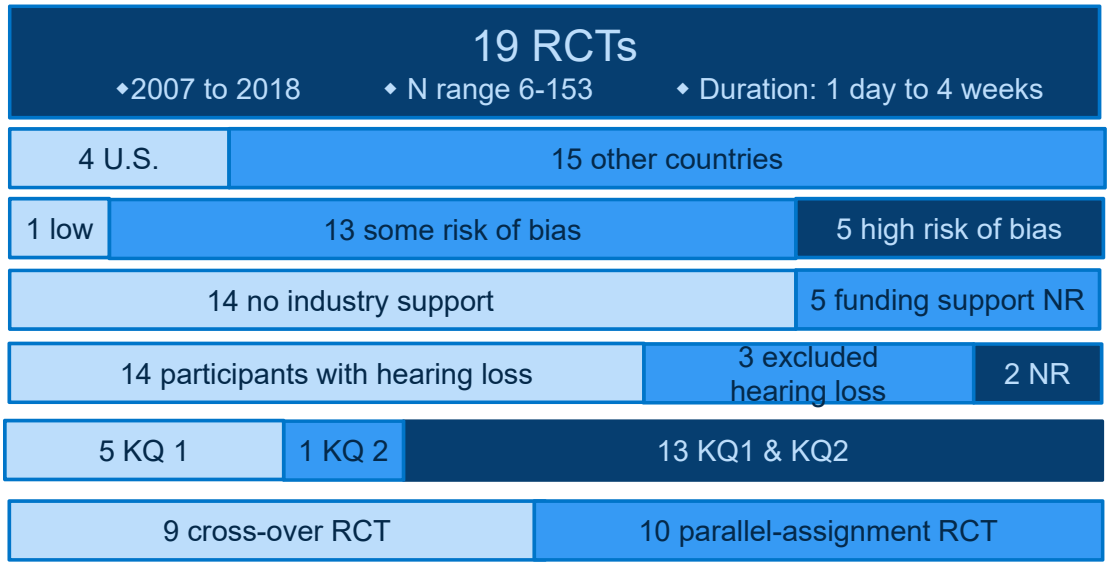
29 Page in report: 47, Tables 9, H1, H2, H3, H4

Notes: [a]Certainty ratings: ⊕◯◯◯ Very low, ⊕⊕◯◯ Low, ⊕⊕◯◯ Moderate. ⊕⊕⊕⊕ High
Abbreviations: RCT = randomized controlled trial

Findings: rTMS

30

Study Characteristics: active rTMS vs. sham rTMS



31 Page in report: 27, Table 6

Abbreviations: KQ = key question; NR = not reported; RCT = randomized controlled trial; rTMS = repetitive transcranial magnetic stimulation

rTMS intervention-GRADE Table

Intervention (Comparison)	Outcome	No. Studies (No. Participants)	GRADE Certainty of Evidence[a]	Direction
Active rTMS (sham rTMS)	Tinnitus distress and disability	18 RCTs (760)	⨁⨁◯◯	No benefit
	Psychological measures	5 RCTs (247)	⨁◯◯◯	No benefit
	Quality of life	1 RCT (153)	⨁◯◯◯	No benefit
	Safety	14 RCTs (526)	⨁◯◯◯	Unable to determine

32 Page in report: 46, Tables 9, H5

Notes: [a]Certainty ratings: ⨁◯◯◯ Very low, ⨁⨁◯◯ Low, ⨁⨁◯◯ Moderate. ⨁⨁⨁⨁ High
Abbreviations: RCT = randomized controlled trial; rTMS = repetitive transcranial magnetic stimulation.

Discussion

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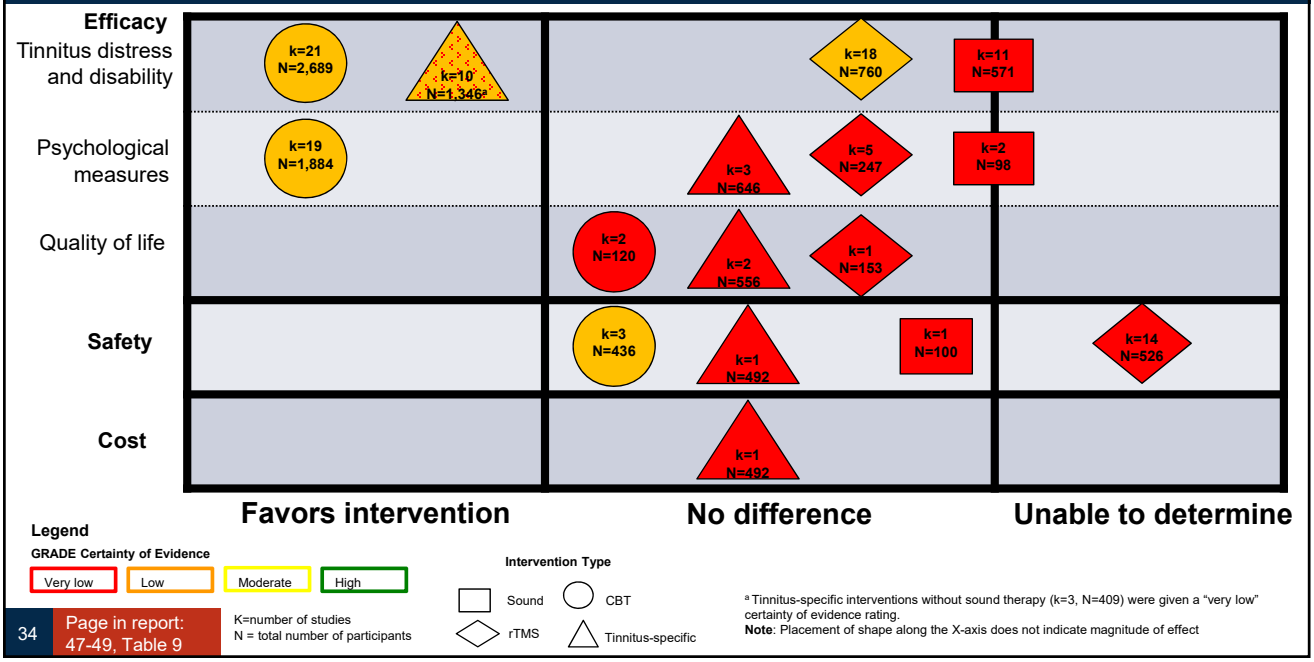
Evidence Map -Reprise



34

Page in report: 47-49, Table 9

K=number of studies
N = total number of participants

Limitations of the Evidence

- Many high risk of bias studies
- Small sample sizes leading to imprecise effect estimates
- Harms not consistently ascertained
- Heterogeneity of interventions
- Limited evidence for subgroups of interest
  - e.g., Occupational noise exposure
- Only 1 study reporting cost outcomes

35 Page in Report: 49

Ongoing Studies

- We identified 35 relevant ongoing studies registered in clinicaltrials.gov
  - Most trials were interventional and had less than 100 subjects
  - Ongoing studies fell into the following broad intervention categories
    - 18 neuromodulation studies many but not all are on rTMS
    - 7 sound therapy studies
    - 4 psychological or behavioral studies
    - 4 studies with ≥2 types of therapy
    - 2 studies that address the etiology, diagnosis, and experience of tinnitus

36 Page in report: 54

Clinical Practice Guidelines and Payor Coverage Policies

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Clinical Practice Guidelines

CPG, Year	AGREE-II Quality Rating	CBT	Sound Therapy	rTMS	Tinnitus-Specific Therapies
NICE, 2020	7	✓	?	?	?
European consensus, 2019	6	✓	?	⊘	?
German Medical Society, 2015	5	✓	?	?	⊘
AAOHNS, 2014	5	✓	✓--?	⊘	--

✓ Recommend for ⊘ Recommend against ? No recommendations for or against, more research needed

38 Page in report: 50, Table 10

Agree-II: 1=worst possible quality, 7 = best possible quality

Payor Policies

- CMS
  - National Coverage Determination (NCD) prior to 2014 stated that tinnitus masking was considered experimental and was therefore not covered, however, that NCD was removed effective December 18, 2014
- Other Payors

Treatment Type	Medicare	Aetna	Cigna	Humana	Kaiser Permanente	Premera Blue Cross	Regence BlueShield	TRICARE	UnitedHealth
CBT	—	—	—	X	—	—	—	—	—
rTMS	—	X	X	X	—	X	X	—	X
Sound Therapy	—	X	—	X	X	—	—	X	X
Tinnitus-Specific Interventions	—	X	—	X	—	—	—	—	—

Notes: X = not covered; — = no policy identified.

39 Page in report: 52, Tables 11, 12

Limitations of the HTA

- Only included peer-reviewed journal publications in English
- Did not evaluate comparative effectiveness of interventions
- Did not evaluate neuromodulation interventions other than rTMS
- Did not evaluate psychological interventions other than CBT unless part of a multicomponent intervention (e.g. tinnitus retraining therapy)
  - Poor study reporting means it's possible we misclassified some interventions, or excluded some interventions
- HTA not scoped to evaluated medications, lifestyle modifications, alternative and complementary therapies, or invasive interventions

40 Page in Report: 54

Conclusions

***LOW* certainty**	• CBT, or tinnitus specific interventions that combine psychological counseling with sound therapy, offer some benefit for reducing tinnitus related distress and disability
***VERY LOW* to *LOW* certainty**	• Sound therapy alone and rTMS (as used in studies) may not be effective
***VERY LOW* certainty**	• Across the body of evidence, harms were poorly ascertained and reported. o May be few to no harms from CBT or sound therapy o Insufficient evidence to determine harms from rTMS and tinnitus-specific therapies

41 Page in Report: 55

Questions?

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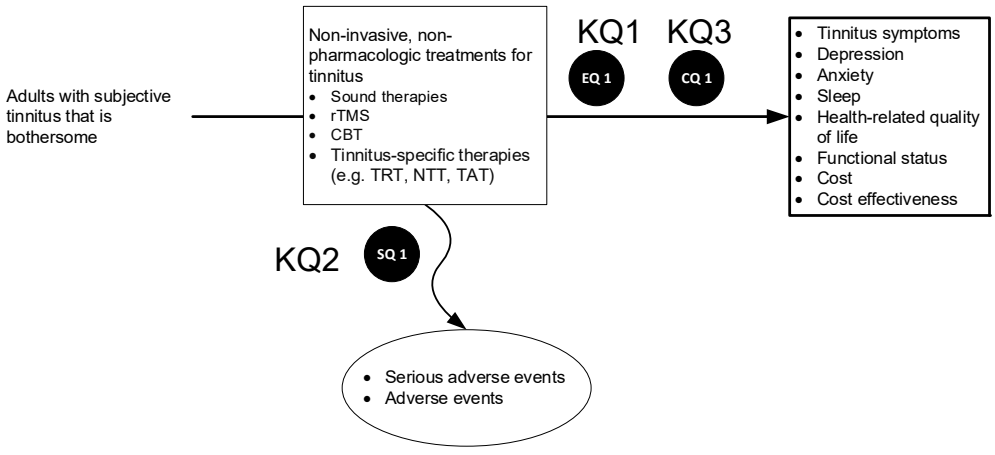
Additional Slides

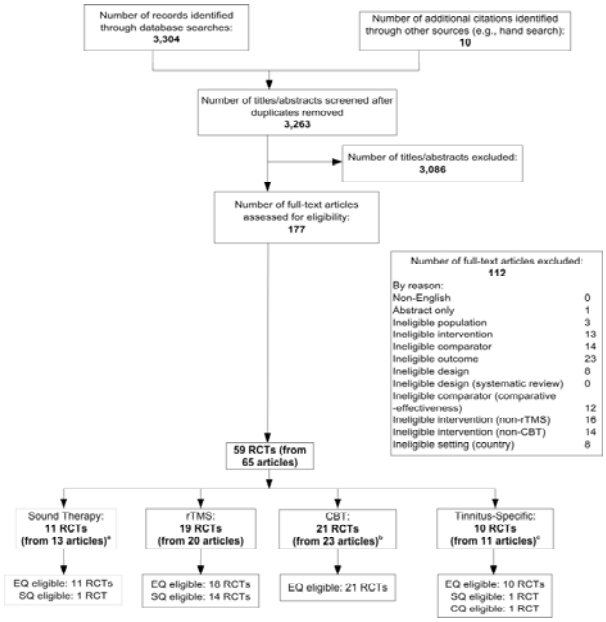
43

Analytic Framework



44 Page in Report: 5, Figure 1

Literature Flow Diagram



45 Page in report: 12, Figure 2

Table 5. Sound therapy studies (k=11)

Author (Year)	Country	Risk of Bias	Eligible Interventions & Comparators (N randomized)	Total Sample Size[a]	Treatment Duration	Mean Age (SD)	N (%) Female	Outcomes Reported
Davis (2008)	Australia	High	Counseling only (13) Acoustic stimulus plus counseling (15)	28	1 year	49.8 (15.8)	24 (48.0˚)	Tinnitus distress
Dineen (1999) Dineen (1997) Dineen (1997)	Australia	High	Information only (28) Information with sound device (20)	48	NR	53.6 (15.0)#	28# (58.3˚)	• Tinnitus distress • Psychological
Henry (2015)	U.S.	Some	Hearing aid only (15) Hearing aid with sound generator (15)	30	3-4 months	67.2 (9.2)	10˚ (33)	Tinnitus distress
Henry (2017)	U.S.	Some	Hearing aid only (18) Hearing aid with sound generator (19)	37	4-5 months	Mean (Range) Hearing aid: 61 (48-75) Hearing aid+sound: 64 (54-75)	Hearing aid: 4 (22) Hearing aid+sound: 4 (21)	Tinnitus distress
Hiller (2005)	Germany	Some	Tinnitus education without sound generator (36) CBT without sound generator (33) Tinnitus education + sound generator (34) CBT plus sound generator (33)	136	Education: 4 weeks Education or CBT+ sound: 10 weeks	Education: 45.2 (14.1) Education+sound: 52.5 (15.3) CBT+sound: 51.0 (13.2)	Education: 13˚ (39) Education+sound: 15˚ (48) CBT+sound: 10* (32)	Tinnitus distress
Li (2016)	Canada	High	Placebo music (25) Altered music (25)	50	1 year	Placebo: 55.8 (8.5) Altered: 55.2 (13.9)	Control: 10* (40)˚ Altered: 6˚ (24)˚	• Tinnitus distress • Psychological
Okamoto (2010)	Germany	High	Placebo music (13) Notched music (13)	26	1 year	40.5 (10.8)	NR	Tinnitus distress
Schad (2018)	U.S.	High	Placebo noise (10) Notched noise (10) Matched noise (10)	30	2 weeks	58 (NR)	10 (33˚)	Tinnitus distress
Stein (2016)	Germany	Some	Placebo music (50) Notched music (50)	100	3 months	47.5 (10.8)	33˚ (33)	• Tinnitus distress • Safety
Strauss (2015)	Germany	Some	Hearing aid (10) Hearing aid plus sound generator (10)	20	3 weeks	Hearing aid: 53.5 (4.8) Hearing aid+sound: 52.7 (5.9)	Hearing aid: 1 (10˚) Hearing aid+sound: 2 (20˚)	Tinnitus distress
Wise (2016)	New Zealand	High	Control computer game (16) Attention training computer game (15)	31	20 days	Control: 62.3 (4.6)# Attention training: 52.3 (10.6)#	10 (32.3*)#	Tinnitus distress

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Table 6- rTMS studies Part I (k=19)

Author (Year)	Country	Risk of Bias	Eligible Interventions & Comparators (N randomized)	Total Sample Size	Treatment Duration	Mean Age (SD)	N (%) Female	Outcomes Reported
Anders (2010)	Czech Republic	High	Sham rTMS (26) rTMS (26)	52	2 weeks	Sham: 50.1 (14.0) rTMS: 48.1 (14.9)	13 (31)	• Tinnitus distress • Safety
Barwood (2013)	Australia	High	Sham rTMS (4) rTMS (4)	8	10 days	42.4 (8.8*)	4 (50)	Tinnitus distress
Chung (2012)	Taiwan	Some	Sham rTMS (10) rTMS (12)	22	10 days	53.0 (16.8)	2 (9)	•Tinnitus distress •Safety
Folmer (2015)	U.S.	Some	Sham rTMS (35) rTMS (35)	70	2 weeks	Sham: 62.8 (8.3) rTMS: 58.3 (9.5)	13 (20)	• Tinnitus distress Safety
Formanek (2018)	Czech Republic	Some	Sham rTMS (12) rTMS (20)	22	5 days	Sham: 51.8 (10.3) rTMS: 47.9 (14.3)	9 (28)	• Tinnitus distress • Psychological • Safety
Hoekstra (2013)	The Nether-lands	Some	Sham rTMS (24) rTMS (26)	52	5 days	52 (12)	9 (18)	• Tinnitus distress Safety
Kleinjung (2005) Langguth (2007)	Germany	Some	Sham rTMS (10) rTMS (10)	10	5 days	47.6 (13.4)	2 (20)	• Tinnitus distress • Safety
Landgrebe (2017)	Germany	Low	Sham rTMS (75) rTMS (71)	153	2 weeks	Sham: 49.9 (13.2) rTMS: 48.1 (12.5)	41 (28)	• Tinnitus distress • Psychological • QoL • Safety
Mennemeier (2011)	U.S.	Some	Sham rTMS (21) rTMS (21)	21	1 week	NR	NR	• Tinnitus distress • Psychological • Safety
Piccirillo (2013)	U.S.	High	Sham rTMS (20) rTMS (20)	20	4 weeks	Median 42 (range 22 to 59)	5 (36)	• Tinnitus distress • Safety
Piccirillo (2011)	U.S.	Some	Sham rTMS (14) rTMS (14)	14	2 weeks	Median 52	4 (29)	• Tinnitus distress • Safety
Plewnia (2012)	Germany	Some	Sham rTMS (16) Secondary auditory cortex rTMS (16) Temporoparietal association cortex rTMS (16)	48	4 weeks	Sham rTMS: 45.6 (10.3) Secondary auditory cortex rTMS: 46.4 (13.0) Tempoparietal association cortex rTMS: 55.8 (9.7)	23* (48)*	• Tinnitus distress • Safety

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Table 6- rTMS studies Part 2 (k=19)

Author (Year)	Country	Risk of Bias	Eligible Interventions & Comparators (N randomized)	Total Sample Size	Treatment Duration	Mean Age (SD)	N (%) Female	Outcomes Reported
Plewnia (2007)	Germany	Some	Sham rTMS (6) rTMS (6)	6	2 weeks	57.7* (5.9*)	1 (17*)	• Tinnitus distress • Safety
Rossi (2007)	Italy	Some	Sham rTMS (16) rTMS 1 Hz (16)	16	1 week	52.5 (10.6)	3 (21)	• Tinnitus distress • Psychological • Safety
Sahlsten (2017)	Finland	Some	Sham rTMS (20) rTMS (22)	42	10 days	Sham: 51.5 (10.7) rTMS: 48.9 (13.1)	12 (31)#	•Tinnitus distress •Psychological •Safety
Schecklmann (2016)	Germany	Some	Sham cTBS (11) cTBS (12)	23	10 days	Sham: 46.5 (11.5) cTBS: 48.2 (10.7)	9 (39)	Tinnitus distress
Vanneste (2012)	Belgium	High	Study 1 Sham rTMS (21) Study 1 rTMS 1-Hz (21) Study 2 Sham rTMS-10 Hz (39) Study 2 rTMS 10 Hz (39)	60	1 session	50.1 (11.8)	24 (40*)	Tinnitus distress
Vanneste (2012)	Belgium	Some	Study 1 Sham rTMS (24) Study 1 rTMS 1-Hz (24) Study 1 rTMS 10-Hz (24) Study 2 Sham rTMS (40) Study 2 rTMS 1-Hz (40) Study 2 rTMS 5-Hz (40) Study 2 rTMS 10-Hz (40)	64	1 session	Study 1: 52.2 (9.8) Study 2: 53.7 (7.6)	Study 1: 11 (46)* Study 2: 16 (40)*	Tinnitus distress
Vanneste (2011)	Belgium	High	Sham rTMS (78) rTMS 1-Hz (78) rTMS 3-Hz (78) rTMS 5-Hz (78) rTMS 10-Hz (78 rTMS 20-Hz (78)	78	1 session	53.5 (11.9)	15 (19)*	Tinnitus distress

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Table 7-CBT studies Part I (k=21)

Author (Year)	Country	Risk of Bias	Eligible Interventions & Comparators (N randomized)	Total Sample Size[a]	Treatment Duration	Mean Age (SD)	N (%) Female	Outcomes Reported
Abbott et al. (2009)	Australia	High	Information-only control (24) Internet-based CBT (32)	56	NR	Control: 48.7 (8.6) CBT: 50.5 (9.5)	5 (10*)	• Tinnitus distress • QoL • Psychological
Andersson et al. (2002)	Sweden	High	Waitlist control (64) Group-based CBT (53)	117	NR	Control: 47.2 (15.0) CBT: 48.5 (12.3)	Control: 31*(48) CBT: 24*(46)	• Tinnitus distress • Psychological
Andersson et al. (2005)	Sweden	High	Waitlist control (11) Internet-based CBT (12)	23	NR	70.1 (3.9)	11 (47.8*)	• Tinnitus distress • QoL • Psychological
Beukes et al. (2018) Beukes (2018)	U.K.	Some	Attention-only control (73) Internet-based CBT (73)	146	8 weeks	55.6 (12.9)	63 (43)	• Tinnitus distress • QoL • Psychological
Henry et al. (1996)	Australia	High	Waitlist control (20) Group-based CBT (20)	60	NR	64.6 (NR)	8 (13*)	• Tinnitus distress • Psychological
Henry et al. (1998)	Australia	High	Waitlist control (12) Group-based CBT (12)	24	NR	56.3 (NR)[#]	19 (38*)[#]	• Tinnitus distress • Psychological
Henry et al. (2017)	U.S.	High	Waitlist control (150) Group-based CBT[b] (150)	300	8 weeks	58(13)[#c]	15* (5)	• Tinnitus distress
Henry et al. (2018)	U.S.	Some	Waitlist control (104) Individual, telephone-based CBT[b] (101)	205	8 weeks	59.0 (10.5)	30 (14)	• Tinnitus distress • QoL • Psychological
Hesser et al. (2012)	Sweden	Some	Online discussion forum control (32) Internet-based CBT (32)	64	8 weeks	48.5 (14.7)	43 (43.4)	• Tinnitus distress • QoL • Psychological
Jasper et al. (2014) Conrad et al. (2015)	Germany	Some	Online discussion forum control (44) Group-based CBT (43) Internet-based CBT (41)	128	10 weeks	Control: 52.1 (9.0) Group CBT: 50.2 (13.1) Internet CBT: 51.3 (9.8)	Control:16 (36.4) Group CBT:19 (44.2) Internet CBT:16 (39.0)	• Tinnitus distress • QoL • Psychological
Kaldo et al. (2007)	Sweden	Some	Waitlist control (38) Book-guided CBT (34)	72	NR	Control: 48.5 (15.7) CBT: 45.9 (13)	Control: 18 (47) CBT: 17 (50)	• Tinnitus distress • QoL • Psychological

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Table 7-CBT Studies Part 2 (k=21)

Author (Year)	Country	Risk of Bias	Eligible Interventions & Comparators (N randomized)	Total Sample Size[a]	Treatment Duration	Mean Age (SD)	N (%) Female	Outcomes Reported
Kroner-Herwig et al. (2003)	Germany	High	Waitlist control (20) Group-based CBT (43)	116	NR	Control: 47.3 (7.9) CBT: 44.7 (12.7)	Control: 10*(50) CBT: 24*(55.8)	• Tinnitus distress • Psychological
Malouff et al. (2010)	Australia	High	Waitlist control (78) Book-guided CBT (84)	162	8 weeks	Control: 57.8 (13.3) CBT: 57.3 (13.7)	72* (44*)	• Tinnitus distress • QoL
Martz et al. (2018)	U.S.	High	Waitlist control (10) Group-based CBT (10)	20	NR	57.8 (16.4)[#]	8 (20)[#]	• QoL • Safety
Nyenhuis et al. (2013)	Germany	Some	Information-only control (77) Book-guided CBT (77) Internet-based CBT (79) Group-based CBT (71)	304	Control, book, and internet CBT:12 weeks Group CBT: 4 weeks	48.5 (12.8)	132*(43*)	• Tinnitus distress • Psychological
Robinson et al. (2008)	U.S.	High	Waitlist control (27) Group-based CBT (38)	65	8 weeks	55.0 (11.3)	31 (48)*	• Tinnitus distress • Psychological
Sadlier et al. (2008)	U.K.	High	Waitlist control (11) Individual-based CBT (14)	25	NR	Control: 54.3 (15.3) CBT: 60 (14.6)	Control: 6 (55*) CBT: 11 (79*)	• Tinnitus distress • Psychological
Weise et al. (2008)	Germany	Some	Waitlist control (67) Individual-based CBT (63)	130	3 months	Control: 52.9 (11.9) CBT: 49.5 (11.8)	Control: 26 (44.1) CBT: 23 (44.2)	• Tinnitus distress • Psychological • Safety
Weise et al. (2016)	Germany	Some	Online discussion forum control (62) Internet-based CBT (62)	124	3 months	Control: 47.5 (14.1) CBT: 47.81 (12.3)	74* (60*)	• Tinnitus distress • QoL • Psychological
Zachriat et al. (2004)	Germany	High	Education-only control (23) Group-based CBT (29) Tinnitus Retraining Therapy (31)	77	CBT: 12 weeks TRT: 6 months	Control: 56.1 (10.6) CBT: 53.8 (11.8) TRT: 51.6 (11.0)	Control: 5 (26)* CBT: 11 (41)* TRT: 10 (33)*	• Tinnitus distress
Zenner et al. (2013)	Germany	High	Waitlist control (120) Individual-based CBT (166)	286	NR	Median 49 (Range 14 to 78)	98 (34)	• Tinnitus distress • Safety

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Table 8-Tinnitus-specific studies (k=10)

Author (Year)	Country	Risk of Bias	Eligible Interventions & Comparators (N randomized)	Total Sample Size[a]	Treatment Duration	Mean Age (SD)	N (%) Female	Outcomes Reported
Bauer et al. (2017)	U.S.	Some	Standard care (19) Tinnitus retraining therapy (20)	39	18 months	N (%) in age categories 18 to 50 years: 6 (16)* 51 to 65 years: 25 (66)* 66 to 75 years: 7 (18)*	12 (32)*	Tinnitus distress
Caffier et al. (2006)	Germany	High	Waitlist control (20[b]) Tinnitus retraining therapy (20[b])	48	12 months	51 (NR)	22 (46*)	Tinnitus distress
Cima et al. (2012) Maes (2014)	The Nether-lands	Some	Usual care (247) Tinnitus retraining therapy + CBT (245)	492	8 months	54.2 (11.5)	184 (37)*	• Tinnitus distress • Psychological • Safety • Cost
Davis et al. (2008)	Australia	High	Counseling only (13) Neuromonics (22)	69	12 months	49.8 (15.8)	24 (48.0*)	Tinnitus distress
Henry et al. (2016)	U.S.	Some	Waitlist control (33) Tinnitus education (39) Tinnitus retraining therapy (34) Tinnitus masking (42)	148	18 months	61.7 (9.8)	4 (2.7)*	Tinnitus distress
Henry et al. (2007)	U.S.	High	No treatment (91) Traditional support (84) Tinnitus retraining therapy (94)	269	4 weeks	61.6 (9.9)	9 (3)	Tinnitus distress
Krick et al. (2015)	Germany	High	Waitlist control (25) Tinnitus retraining- based music therapy (25)	50	1 week	Control: 42.6 (11.5) Music therapy: 43.9 (10.4)	Control: 9(41*) Music therapy: 9(45*)	Tinnitus distress
Seydel et al. (2010)	Germany	High	Waitlist control (45) Tinnitus retraining therapy (45)	90	7 days	51 (NR)	119 (50*)	• Tinnitus distress • Psychological
Westin (2011)	Sweden	Some	Waitlist control (22) Tinnitus retraining therapy (20)	64	18 months	Control: 49.6 (11.9) Tinnitus retraining therapy: 49.0 (14.5)	Control: 8 (36) Tinnitus retraining therapy: 8 (40)	• Tinnitus distress • Psychological • QoL
Zachriat (2004)	Germany	High	Education-only (23) Tinnitus retraining therapy (31)	77	24 weeks	Control: 56.1 (10.6) Tinnitus retraining therapy: 51.6 (11.0)	Control: 5 (26)* Tinnitus retraining therapy: 10 (33)*	Tinnitus distress

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Cost Outcome

- One study reported cost outcomes.
- This study comparing TRT to usual care over 8 months duration reported that the mean total health care costs per patient in 2009 USD over the duration of the intervention was $3,875 for usual care and $4,023 for TRT, resulting in a difference of $152 (95% CI, $-333 to $643).
- The cost per quality-adjusted life year (QALY) gained from health care payor perspective was $10,456 (95% CI, NR) for the TRT intervention compared to usual care.
- Given a willingness-to-pay threshold of $45,000, there was a 68% probability that TRT is cost-effective.
- With regard to societal costs, the cost per patient over the duration of the intervention was $7,027 for usual care and $7,380 for TRT, resulting in a difference of $357 (95% CI, -$1,034 to $1,782).
- The cost per QALY gained from societal perspective was $24,580 (95% CI, NR) for the TRT intervention compared to usual care.
- Given a willingness-to-pay threshold of $45,000, there was a 58% probability that TRT is cost-effective.76

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HTCC Coverage and Reimbursement Determination
Analytic Tool

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

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

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

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

Principle One: Determinations are evidence-based

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

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

Principle Two: Determinations result in health benefit

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

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

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

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

Using evidence as the basis for a coverage decision

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

1. Availability of evidence:

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

2. Sufficiency of the evidence:

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

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

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

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

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

3. Factors for Consideration - Importance

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

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

Clinical committee findings and decisions

Efficacy considerations

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

Safety

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

Cost impact

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

Overall

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

Next step: Cover or no cover

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

Next step: Cover with conditions

If covered with conditions, the committee will continue discussion.

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

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

Clinical committee evidence votes

First voting question

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

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

Safety outcomes	Importance of outcome	Safety evidence/ confidence in evidence
Serious adverse events		
adverse events		
side effects including device-related complications		

Efficacy – effectiveness outcomes	Importance of outcome	Efficacy / Effectiveness evidence
Validated tinnitus symptom severity or handicap		
depression		
anxiety		
sleep		
health-related quality of life		
functional status		

Cost outcomes	Importance of outcome	Cost evidence
Cost		
Cost effectiveness		

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

For safety:

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

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

For efficacy/ effectiveness:

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

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

For cost outcomes/ cost-effectiveness:

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

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

Discussion

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

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

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

Second Vote

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

_____Not covered _____ Covered unconditionally _____ Covered under certain conditions

Discussion item

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

Next step: proposed findings and decision and public comment

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

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

Next step: final determination

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

Final vote

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

If yes, the process is concluded.

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

Medicare Coverage and Guidelines

[From page 52 of final evidence report]

Prior to 2014, a CMS National Coverage Determination (NCD) stated that tinnitus masking was considered experimental and was therefore not covered. However, effective December 18, 2014,[96] CMS removed the tinnitus NCD. As a result, there is no stated CMS policy on any of the tinnitus treatments considered within the scope of this HTA

Clinical Practice Guidelines

[From page 50 of final evidence report]

We identified 6 clinical practice guidelines (CPGs) related to tinnitus diagnosis and treatment that evaluated the interventions included within the scope of this HTA;[87,93-95,199,200] these are summarized in ***Table 10***. We rated the quality of each guideline using the Appraisal of Guidelines for Research & Evaluation II (AGREE-II) instrument.[91,92] With this instrument 6 domains are assessed and an overall score of 1 (lowest quality) to 7 (best quality) is assigned. In addition to the interventions included within the scope of the HTA, some of the guidelines we identified also included interventions outside of the scope of this HTA, notably medications, herbal supplements, and invasive treatments. Our summary focuses only on the interventions that were in the scope of this HTA.

Table 10. Summary of Clinical Practice Guidelines for the Treatment of Tinnitus

Title	Year	Summary	AGREE Rating (1-worst quality to 7-best quality)
National Institutes for Health and Care Excellence (NICE) Guideline: Tinnitus assessment and management (NG 155)[200,201]	2020	**Recommendation for:** CBT (individual face-to-face, group-based, or virtual) **No recommendation:** rTMS, sound therapy, combination therapies; more research needed for these therapies.	7
A multidisciplinary European guideline for tinnitus: diagnostics, assessment, and treatment[93]	2019	**Strong recommendation for:** CBT **Weak recommendation for:** Hearing aids for patients with hearing loss; hearing aids should not be offered to patients with tinnitus in the absence of hearing loss. **Recommendation against:** rTMS **No recommendation:** Transcranial electrical stimulation; vagus nerve stimulation; acoustic coordinated reset neuromodulation; tinnitus retraining therapy; invasive nerve stimulation, sound therapy (including masking, music, environmental sound, Neuromonics)[a]	6
Association of the Scientific Medical Societies in Germany Guideline 01 7/064: Chronic Tinnitus[94]	2015	**Recommend for**: tinnitus-specific CBT (carried out using an evidence-supported and structured therapeutic manual) **Recommend against**: Tinnitus retraining therapy **No recommendation**: Sound therapy, music therapy or acoustic neuromodulation, hearing aids (although hearing aids and middle ear implants can be recommended for the treatment of an appropriate accompanying hearing loss), rTMS, other electromagnetic procedures or other electrical stimulation (e.g., transcutaneous electrical stimulation in the ear or cervical spine areas, vagus nerve stimulation)	5
American Academy of Otolaryngology-Head and Neck Surgery Clinical Practice Guideline: Tinnitus[95]	2014	**Recommendation for**: CBT **Recommendation for:** Hearing aid evaluation for patients with hearing loss and persistent, bothersome tinnitus **Option (flexible decision making)**: Sound therapy (including environmental enrichment devices, hearing aids, ear-level sound generators, masking devices, or combination tinnitus instruments) **Recommendation against**: rTMS (for routine[b] treatment)	5

Title	Year	Summary	AGREE Rating (1-worst quality to 7-best quality)
International Federation of Clinical Neurophysiology: Evidence-based guidelines on the therapeutic use of repetitive transcranial magnetic stimulation[87]	2014	Low frequency (1 Hz) rTMS single or repeated sessions has possible therapeutic efficacy (Level C recommendation) but the effects are partial and transient. The best method of targeting is not fully validated and there remain numerous uncertainties about its feasibility and usefulness in clinical practice. No recommendations for high frequency rTMS.	4
VA/DoD Clinical Practice Guidelines: Management of Concussion-mild Traumatic Brain Injury[199]	2016	There is **no evidence to suggest for or against the use of any particular modality** for the treatment of tinnitus after mild traumatic brain injury. The strength of this recommendation was not assessed due to limited evidence.	5

Notes: [a] Authors state, "May be useful for acute relief purposes but is not considered an effective intervention with long-term results."

[b] Authors state, "The words routine and routinely are used to avoid setting a legal precedent and to acknowledge that there may be individual circumstances for which clinicians and patients may wish to deviate from the prescribed action in the statement."

Abbreviations: AAA = American Audiologic Association; AAO-HNSF = American Academy of Otolaryngology—Head and Neck Surgery Foundation; AGREE = Appraisal of Guidelines for Research & Evaluation II instrument; ASMS = Association of the Scientific Medical Societies (Germany); CBT = cognitive behavioral therapy; CR = coordinated reset; DoD = Department of Defense; mTBI = mild traumatic brain injury; NCRAR = National Center for Rehabilitative Auditory Research; NICE = National Institute for Health and Clinical Excellence; rTMS = repetitive transcranial magnetic stimulation; tACS = transcranial alternating current stimulation; tDCS = transcranial direct current stimulation; TRT = Tinnitus retraining therapy; VA = Department of Veterans Affairs; (t)VNS = (transcutaneous) Vagus Nerve Stimulation.

The most recent CPG is from the National Institute for Health and Care Excellence (NICE) in the United Kingdom;[200,201] we rated this guideline as a "7" on the AGREE-II instrument. This CPG was published in March 2020. With respect to psychological therapies, this guideline recommends use of face-to-face individual, virtual, or group-based CBT. Acceptance and commitment therapy (not included in the scope of this HTA) was also recommended. With respect to sound therapy and neuromodulation therapies (including rTMS), this guideline did not make a recommendation for use of these treatments in practice because of limited evidence for effectiveness. For both therapies, the guideline recommended additional research. The guideline also did not make a recommendation for use in practice for combination therapies, including TRT, and also called for more research on this approach.

Other CPGs include similar recommendations as the NICE guideline. A consensus multidisciplinary European guideline from 2019 included a strong recommendation for CBT, a weak recommendation for hearing aids in patients with hearing loss and tinnitus, and a recommendation against rTMS.[93] The guideline panel made no recommendations on sound therapy, Neuromonics, TRT, and neuromodulation therapy other than rTMS. CPGs issued by the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) in 2014and the German Association of the Scientific Medical Societies in 2015 made similar recommendations for CBT.[94,95] The AAO-HNS recommended against rTMS and states that sound therapy is optional,[95] while the German society made no recommendation for or against rTMS or sound therapies but did recommend against TRT.[94] The International Federation of Clinical Neurophysiology issued guidelines in 2014 specific to the use if rTMS across a wide variety of conditions, including tinnitus. They state that low-frequency rTMS may have possible therapeutic efficacy for tinnitus, but results are partial and transient and many uncertainties remain.[87] Lastly, the Department of Veterans Affairs/Department of Defense issued a joint CPG in 2016 for the management of concussion and mild traumatic brain injury in 2016 that included recommendations specific to tinnitus management in this population.[199] This guideline made no recommendation for or against the use of any interventions for tinnitus in this population.