

# Current Device-based Clinical Treatments for Tinnitus



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## KEYWORDS

• Sound therapy • Hearing aids • Cochlear implants • Tinnitus treatment devices

## KEY POINTS

- Current medical devices for tinnitus are intended to reduce the functional impact of bothersome tinnitus on sleep, concentration, mood, and hearing.
- Sound therapy devices and hearing aids serve to reduce the perceptual strength of the perceived tinnitus signal by offsetting the internal perception of sound with external sound and also reduce neural hyperactivity associated with tinnitus perception.
- Cochlear implants likely work in a manner similar to more conventional sound-based devices, by augmenting external sound perception and modulating neural activity.
- Devices other than hearing aids and cochlear implants are available and give patients more options to choose a device-based treatment compatible with personal preferences, lifestyle, and financial resources.

## INTRODUCTION

Tinnitus is the perception of sound in the absence of an external sound source. An estimated 10% of the population has tinnitus, but only a subset of that population has tinnitus bothersome enough to disrupt or disturb sleep, concentration, and/or mood.<sup>1,2</sup> Tinnitus perception itself is not a problem; the problem is the reaction to tinnitus that is associated with these disruptions and disturbances. Reaction to tinnitus results in a cascade of events involving the limbic and autonomic nervous systems, such that the stress response is activated continuously, thereby affecting sleep, concentration, and mood. Many patients are told there is nothing that can be done. This

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negative counseling exacerbates the reaction and is counterproductive and incorrect. There are many options to reduce the negative reaction to tinnitus and facilitate habituation so that tinnitus no longer significantly affects quality of life.

Counseling therapies have the best evidence for reducing the impact of tinnitus on quality of life,<sup>3</sup> but there are medical devices available to facilitate a reduction in the perception of tinnitus and thus mitigate the reaction to tinnitus. Most patients with tinnitus also have hearing loss; some attribute problems caused by hearing loss to their tinnitus. These patients are particularly good candidates for hearing aids. Other patients have clinically normal hearing and may benefit from ear-level sound therapy. The use of external sound is an integral component of tinnitus management. Sound sources encompass nonmedical devices, such as sound apps on phones, to medical devices such as hearing aids and cochlear implants. The focus of this article is on medical devices that are now in use to help reduce the functional impact of tinnitus.

To date, there is no single therapeutic device that has been shown to universally reduce the perception of tinnitus. A multitude of factors play a role in the successful reduction of tinnitus perception and annoyance, including type of tinnitus (tonal vs noise), duration of tinnitus since onset, comorbidities (eg, anxiety, depression, other health issues), and patient willingness and ability to comply with a given treatment protocol.

### **CLINICAL PRACTICE GUIDELINE RECOMMENDATIONS FOR DEVICES FOR TINNITUS**

The American Academy of Otolaryngology–Head and Neck Surgery published clinical practice guidelines for tinnitus in 2014.<sup>3</sup> Evidence for a series of 13 components of evaluation and management was examined to make evidence-based recommendations. The strength of each recommendation was categorically assigned 1 of 5 ratings (strong recommendation, recommendation, option, recommendation against, or no recommendation). With respect to medical devices available at the time the guidelines were developed, clinicians are advised to recommend a hearing aid evaluation for people with hearing loss and bothersome tinnitus. Clinicians may recommend sound therapy, but the evidence was judged to be insufficient to definitively recommend sound therapy. Cochlear implants and other medical devices were not evaluated as treatment options at the time the guidelines were developed.

### **INDICATIONS FOR SOUND THERAPY**

Patients presenting with bothersome tinnitus may benefit from sound therapy to facilitate habituation. Broadly, sound therapy refers to enrichment of the sound environment. The intent of sound therapy is to reduce the perceptual contrast between the internal noise (tinnitus) and external noise (environmental sound). A candle in a dark room is a popular analogy to describe the role of sound therapy in reducing tinnitus intrusiveness. The lack of other visual stimuli makes the candle more prominent and therefore harder to ignore. When the lights are turned on, the candle is less noticeable and thus easier to ignore. Sound therapy can also be used to induce relaxation or to distract attention from the tinnitus, which helps to reduce the stress response that is activated by bothersome tinnitus. In addition to sound enrichment, avoidance of silence is recommended to facilitate habituation to tinnitus.

Sound enrichment can be accomplished with nonmedical and/or medical devices. Ear-level medical devices for sound enrichment include hearing aids, sound generators, and tinnitus treatment–specific devices. Cochlear implants also provide sound enrichment by directly stimulating auditory neurons to code sound in the brain.

There is a significant body of literature supporting the efficacy of sound enrichment when combined with counseling, but little evidence to support sound enrichment in isolation. Counseling is essential for reducing the negative emotional reactions to tinnitus. Sound enrichment is thought to facilitate a reduction in negative emotional reactions by interfering with the usual perception of tinnitus.

No study to date has compared the efficacy of tinnitus-specific counseling (eg, tinnitus retraining therapy) without device-based sound therapy (DBST) with standard-of-care counseling without DBST. It is therefore difficult to determine the relative influence of DBST on reductions in self-perceived tinnitus handicap. Evidence from a recent randomized double-blind clinical trial indicated that DBST did not result in significantly better outcomes than placebo DBST, but other evidence points to the synergistic benefit of sound therapy combined with counseling.<sup>4,5</sup>

### **NONMEDICAL DEVICES FOR MANAGEMENT OF TINNITUS**

Sound has long been used to reduce the intrusiveness of tinnitus. Different types of sound can be used to achieve the patient's desired objective of distraction and/or relief, and these can be categorized as background, soothing, and interesting.<sup>6</sup> Background sound is any type of sound that is neutral and reduces the perceptual contrast between the internal sound of tinnitus and external environmental sound. Soothing sound is any type of sound that facilitates relaxation and is used to reduce the stress caused by tinnitus and provide relief. In addition, interesting sound is any type of sound that directs attention away from tinnitus by actively engaging attention. Although the objectives may differ, the different types of sounds may overlap in that an interesting sound may also be soothing, or a soothing sound may also be background sound.

Sources of background, soothing, and interesting sounds are environmental sounds, music, and speech. Examples of environmental sounds include fans, water fountains, and bedside sound generators (eg, <https://marpac.com/collections/sound-machines>). Soothing sounds include music and nonmusic sound apps, which are widely available for streaming through smart phones and external speakers, as well as sound spas. Music can also be used as an interesting sound when the person is actively listening. Interesting sound can be music or speech, such as a television show, a movie, or a podcast.

Sound therapy can be implemented without the use of medical devices and is therefore readily accessible to patients with bothersome tinnitus. Education about the purpose of sound enrichment is essential for successful outcomes and is available online (eg, <https://www.ncrar.research.va.gov/Education/Documents/TinnitusDocuments/HowToManageYourTinnitus.pdf>; <https://medicine.uiowa.edu/oto/research/tinnitus-and-hyperacusis>).

### **MEDICAL DEVICES FOR MANAGEMENT OF TINNITUS**

The clinical concept of tinnitus masking using ear-level devices to reduce the intrusiveness of tinnitus has been around since the 1970s.<sup>7</sup> There has been considerable debate regarding the efficacy of total versus partial masking of the tinnitus perception; they have been established as equally effective for acute relief, but long-term efficacy seems to be better with partial masking.<sup>8,9</sup> The efficacy of sound therapy, as previously mentioned, has not been well established when studied at the population level.<sup>4</sup> Nonetheless, DBST is currently used and, anecdotally, patients report subjective benefit attributed to relief provided by an external sound that is less bothersome than the internal sound of tinnitus.

The plasticity of the central auditory system has been observed in both animals and humans and is the basis for using sound therapy.<sup>10–12</sup> The functional impact of reduced auditory input secondary to hearing loss is compensatory hyperactivity that may be perceived as tinnitus.<sup>13</sup> Animal models and functional imaging suggest that sound therapy reduces central auditory system hyperactivity to counteract the presumed maladaptive changes associated with the perception of tinnitus.<sup>12,14–16</sup>

### **Sound Generators**

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Ear-level sound generators, also referred to as tinnitus maskers, have been commercially available since 1976. The devices were initially referred to as tinnitus maskers because the original intent was to mask the tinnitus. They are more commonly referred to as sound generators now to achieve either total or partial masking of the tinnitus. Early versions produced broadband noise delivered to the ear via nonoccluding ear-molds; manipulation of the broadband noise is available in current versions. Stand-alone ear-level sound generators are available (eg, <https://generalhearing.com>; <https://solacefortinnitus.net/>) at a lower cost than hearing aids. Recommended use time is at least 8 h/d but there are no studies of sound generator efficacy as a function of use time.

Devices combining amplification and sound generators were introduced to the market in the early 1990s and have grown in popularity since that time.

### **Hearing Aids**

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It has been well established that many patients with tinnitus attribute hearing difficulty to the presence of tinnitus, rather than the reverse.<sup>17–19</sup> Because most patients with tinnitus have some measurable degree of hearing loss, amplification is an appropriate intervention. Hearing aids providing prescribed amplification improve audibility, reducing the strain to hear. They amplify ambient sound, reducing exposure to excessively quiet environments (which tend to make tinnitus more audible) and provide natural sound therapy. Physiologically, compensation for peripheral loss of hearing may decrease the central gain associated with the tinnitus percept.<sup>20</sup>

Although the evidence overwhelmingly points to the efficacy and value of counseling in reducing the functional impact of tinnitus, hearing aid use has been validated as a contributing factor to reducing tinnitus distress,<sup>21–25</sup> and has been shown to reduce tinnitus annoyance without counseling.<sup>26,27</sup>

All of the major hearing aid manufacturers incorporate some form of sound therapy in their hearing aids, which can be used in isolation or combined with amplification. Sound options include broadband noise that can be customized by shaping the frequency response and modulation of the noise and fractal tones. Henry and colleagues<sup>28</sup> examined the validity of combination devices relative to amplification alone for reducing the functional impact of tinnitus as measured by the Tinnitus Functional Index and found that both resulted in a significant decline in subjective tinnitus handicap.

### **Notch Therapy**

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Notch therapy is based on the premise that decreasing external stimulation in the frequency region of the tinnitus may decrease hyperactivity in the corresponding regions of the central auditory system, thereby diminishing the perception of tinnitus. Tailor-made notched music training (TMNMT) has been shown to reduce tinnitus loudness<sup>29</sup> and is available online (<https://www.audionotch.com/>). TMNMT requires dedication to daily listening, which is disruptive to the normal daily routine for some patients.

An alternative to TMNMT is notched amplification, available from one of the hearing aid manufacturers (<https://pro.signiausa.com>). The advantage of notch therapy in hearing aids is the easy implementation of the therapy, combined with amplification to facilitate ease of listening. Study results provide evidence of greater subjective and objective improvements in tinnitus distress with notch therapy compared with traditional amplification.<sup>30</sup> Candidacy for this option is limited to patients with tonal tinnitus that is pitch-matched at less than 8000 Hz.

### ***Other Medical Devices for Tinnitus Management***

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The use of music to reduce stress has been studied extensively, across medical and mental health care.<sup>31</sup> A novel device-based approach to tinnitus treatment using music was introduced in the United States in 2006 (<http://neuromonics.com>). Neuro-monics Tinnitus Treatment (NTT) uses spectrally modified music customized to the patient's hearing loss to retrain the neural pathways. Recommended use time is 2 to 4 h/d for a minimum of 6 months. Nonrandomized, uncontrolled clinical trials have revealed significant declines in tinnitus intrusiveness.<sup>32</sup> The therapeutic sound is currently available for use through a patient's iPhone or iPad, under the direction of an audiologist. Recommended use time is substantially less than that for sound generators, but dedicated use time is required.

Newman and Sandridge<sup>33</sup> compared benefit and economic value between sound generators and NTT from a sample of clinical patients. Reductions in self-perceived tinnitus handicap were comparable. The sound generators were the more cost-effective alternative, but the investigators pointed out that patient preference variables (eg, lifestyle, acceptability of passive sound generator use vs active NTT use, and sound preference for broadband noise vs NTT music) are important considerations for individual management.

One medical device uses sound that mimics the patient's tinnitus to decrease tinnitus perception and is used while the patient is sleeping (<https://otoharmonics.com>). The device uses proprietary software, loaded onto an Apple iPad Air. A tinnitus sound print is created based on the patient's tinnitus pitch match. The sound print is loaded onto an Apple iPod touch and the patient is directed to use the device for 3 months, every night while sleeping. Sound is delivered to the ears via flexible ear buds and the patient adjusts the volume each night to match the volume of the tinnitus. The system incorporates the Tinnitus Functional Index to monitor the functional impact of tinnitus over time.

There is limited evidence to support the efficacy of this system, but a randomized controlled trial showed greater average reduction in the self-perceived functional impact of tinnitus as measured by the Tinnitus Functional Index and subjective tinnitus loudness for study participants using the device (sound print or broadband noise) compared with a bedside sound generator over a 3-month period.<sup>34</sup>

### ***Cochlear Implants***

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Evidence from the earliest days of cochlear implantation has shown that most cochlear implant candidates have tinnitus, and, for many, tinnitus perception decreases following surgery and/or with use of their implants. Brackmann<sup>35</sup> reported that 80% (40 out of 50) of patients implanted with a House monopolar cochlear implant had varying degrees of preoperative tinnitus, and that, out of 29 of these 40 for whom data were available, 27% reported elimination and 52% reduction of tinnitus in the operated ear. A review of the literature from 1990 to 2006 revealed an incidence of tinnitus in cochlear implant candidates ranging from 65% to 100%, with a mean of 80%, although the percentage of those with bothersome tinnitus was unclear from

the data.<sup>36</sup> Furthermore, most of the studies cited in the review showed a reduction in or elimination of tinnitus in the operated ear with monaural implantation. Another review showed many studies reporting contralateral tinnitus suppression as well.<sup>37</sup> A recent study, with newer generation devices, showed elimination of tinnitus and a decrease in tinnitus handicap in 28% of patients, with an estimated 75% of patients having some reduction in their symptoms.<sup>38</sup> Variables potentially affecting tinnitus outcomes are not known, and it is unclear what effect hearing preservation, electroacoustic stimulation, and bimodal stimulation would have on tinnitus. In addition, it has been shown that optimal stimulation parameters for hearing may not be the same as those for tinnitus suppression, and also that imperceptible electrical stimulation can suppress tinnitus. This finding implies that the benefit is not simply from enhanced sound perception but also from direct neuromodulation.<sup>39,40</sup> There have been analogous findings in hearing aid programming for tinnitus suppression.<sup>41</sup> For those patients in whom use of the cochlear implant itself does not provide sufficient tinnitus relief, sound therapy through a cochlear implant is potentially beneficial.<sup>42</sup>

Although these data are encouraging, cochlear implantation is still not indicated or considered the standard of care specifically for purposes of tinnitus treatment in patients who are not otherwise candidates for the procedure. However, where these data have become more relevant is in treatment of patients with single-sided deafness (SSD). Several studies over more than a decade have shown a significant decrease in tinnitus handicap in most patients with SSD undergoing cochlear implantation.<sup>43–46</sup> In this population, it is conceivable that implantation would be undertaken if not solely then at least more so, or even primarily, for purposes of tinnitus reduction in place of different hearing rehabilitation options such as Contralateral Routing of Signal (CROS), Bilateral Contralateral Routing of Signal (BiCROS), or implantable bone conduction devices.

Other, non-sound-based devices have been used or trialed for purposes of tinnitus reduction, but none has achieved universal recognition or become standard of care. These devices include repetitive transcranial magnetic stimulation,<sup>47</sup> direct auditory cortex stimulation,<sup>48</sup> and direct cochlear nerve stimulation.<sup>49</sup> None of these has been shown to be consistently beneficial over a sufficiently wide range of patients.

## **WILLINGNESS TO ACCEPT AND PAY**

It is important for patients with bothersome tinnitus to have realistic expectations about tinnitus management using medical devices. Most, if not all, patients with tinnitus are seeking a solution that completely eliminates tinnitus perception. However, such a solution does not exist at this time for most patients with tinnitus.

A significant factor to consider regarding clinical device-based therapy is financial cost because the cost may present a potential barrier to willingness and/or ability to pursue a given device-based treatment option. Tinnitus-specific devices are generally not covered by insurance; out-of-pocket costs can reach more than \$4000. Hearing aids with features such as notch therapy, sound therapy, and frequency lowering may be partially covered by insurance, but patients are likely to bear at least some of the cost, in the range of \$2000 to \$4000. Invasive devices such as cochlear implants are usually fully covered by insurance but involve surgical risk.

The individual's lifestyle and tinnitus symptoms are additional factors to consider. Commercially available medical devices for tinnitus management differ in the type and implementation of stimulation. Patient preference, psychosocial factors, tinnitus self-efficacy, and clinician expertise play a significant role in the successful management of tinnitus.<sup>50</sup> As such, a patient-centered approach that takes into consideration

all of these factors has the greatest likelihood of resulting in a favorable outcome. In particular, tinnitus self-efficacy, which refers to the patients' confidence in their ability to perform specific skills (eg, use hearing aids or sound generators) to achieve a specific goal (ie, habituation to tinnitus), is central.<sup>51</sup>

Tyler<sup>52</sup> surveyed a large group of tinnitus self-help group attendees to determine what kinds of treatment and what costs people with tinnitus are willing to accept. The survey considered these 2 factors against 2 possible outcomes: reduction of tinnitus by half (eg, reducing perceived loudness and annoyance by half) and complete elimination of tinnitus. The survey revealed that noninvasive devices are more acceptable than invasive devices regardless of partial versus complete elimination. Most patients surveyed indicated willingness to spend \$1000 to reduce tinnitus by half; most shifted to a willingness to spend \$5000 to completely eliminate reduce tinnitus. Correlations between subjective ratings of loudness and annoyance were positive with the likelihood of using any type of treatment, but were not correlated with the amount participants were willing to pay. Individual financial circumstances and acceptance of risk influence willingness to pay for medical devices.

## SUMMARY

In summary, current device-based clinical treatments for tinnitus encompass sound generators, hearing aids, cochlear implants, and tinnitus treatment devices. The primary indication for device use is tinnitus that is bothersome to the point of disrupting sleep and/or concentration, perceived as causing difficulty with hearing, and/or causing or increasing anxiety and/or depression. Devices vary in prescribed use time, application of sound, risk to patient, and cost. It is important to be aware that patients can experience significant reductions in self-perceived tinnitus handicap during and after DBST.

## DISCLAIMER

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## DISCLOSURE

The authors have nothing to disclose.

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