



Original Article

Comparing the effects of manual acupuncture, electroacupuncture, and transcutaneous electrical nerve stimulation on chronic tinnitus: a randomized controlled trial

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ABSTRACT

Background: The aim of this study was to investigate the superiority of the effects of manual acupuncture (MA), electroacupuncture (EA), or transcutaneous electrical nerve stimulation (TENS) on chronic consecutive tinnitus.

Methods: Forty-five patients with chronic consecutive tinnitus were allocated into an MA, an EA, or a TENS group at a 1:1:1 ratio. The corresponding patients were treated with MA, EA, or TENS twice a week for 10 sessions (5 weeks). The primary outcome was a change in the tinnitus handicap inventory (THI), and the secondary outcomes were loudness and annoyance of tinnitus, pure-tone audiometry (PTA), and the speech discrimination test. The outcome measures were obtained at baseline, visit 5 (week 3), visit 10 (week 5), and visit 11 (follow-up 4 weeks).

Results: Of the 45 participants, 37 (82.22%) completed the study. There was no difference in the THI score change among the groups at any point. However, the number of participants who had reduced scores of more than 10 points was higher in the EA group than in the TENS or MA groups ($p=0.037$, Fisher's exact test). There was no significant difference in the loudness and annoyance of tinnitus, PTA, and speech discrimination test findings among the groups.

Conclusion: Among the MA, EA, and TENS groups, there was no significant difference in the effects on the treatment of chronic consecutive tinnitus. However, EA could respond to more patients.

Trial registration: Registered on October 21, 2016 (KCT0002117 by CRIS).

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1. Introduction

Tinnitus refers to the perception of sound in the absence of external auditory stimulation. In Korea, the prevalence of tinnitus is almost 20%. In addition, 34.8% of patients who experience tinnitus report being annoyed by tinnitus.¹ Various treatments for tinnitus have been investigated. However, a standard treatment has not yet been established, except for treatable pathologies associated with tinnitus (e.g., otitis media and vestibular schwannoma).² In clinical settings, various treatments, such as cognitive behavioral therapy and sound therapy, are currently used. However, their effects are unsatisfactory.

Manual acupuncture (MA) is considered a treatment for tinnitus. Although several studies attempted to determine the effect of acupuncture on tinnitus, limited efficacy on neuromodulation was shown.³ A previous study reported electroacupuncture (EA) improved the quality of life of patients with tinnitus compared to MA.⁴ Transcutaneous electrical nerve stimulation (TENS) can be considered a useful option for treating tinnitus as it is a safe, non-invasive, and an effective treatment for tinnitus.^{5,6}

Several studies compared MA,^{7,8} EA,⁹ and TENS^{6,10} with a placebo controlled intervention. In addition, one study compared the effects between MA and EA for tinnitus.⁴ However, to the best of our knowledge, no trials have as yet compared the effects between MA and TENS or between EA and TENS. Moreover, no study has simultaneously compared the effects among MA, EA, and TENS on tinnitus at the same time.

Therefore, the objective of this study was to compare the effects of MA, MA with periauricular electrostimulation EA, and periauricular TENS on chronic consecutive tinnitus.

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2. Methods

2.1. Study design

This study was a prospective, randomized, paralleled, and open-labeled pilot trial conducted at Kyung Hee University Korean Medicine Hospital (Seoul, Korea) from July 2016 to December 2017. Our Institutional Review Board approved this research (KOMCIRB-160321-HR-012). In addition, this trial has been registered at the Clinical Research Information Service (CRIS registered number: KCT0002117). The details on the study design have been reported previously.¹¹ All participants provided written informed consent. After randomization, the participants were treated for 10 sessions, twice a week. Follow-up was conducted 4 weeks after the end of the treatment.

2.2. Sample size

This trial was designed as a pilot study. The appropriate sample size of the two-arm or three-arm pilot study was >12.^{12,13} Considering the dropout rate (20%), we assigned at least 15 participants to each group (45 in total). Forty-five participants with chronic (more than 6 months) consecutive tinnitus (age: 20–65 years) were recruited.

2.3. Participants

The participants were recruited from July 2016 to December 2017. The inclusion criteria were as follows:

- (1) Age of 20–75 years, either sex
- (2) Presence of tinnitus symptoms for more than 6 consecutive months
- (3) No medical treatment for tinnitus during the entire clinical trial period
- (4) Voluntarily signed informed consent forms

The exclusion criteria were as follows:

- (1) History of TENS or acupuncture treatment within 3 months prior to the study
- (2) History of medication and/or undergoing surgical procedures for cardiac disorders or use of pacemaker implants
- (3) Disease conditions that could clearly cause tinnitus, such as Meniere's disease, otitis media, and otosclerosis
- (4) Metal allergies and needle phobia
- (5) Use of psychotropic drugs to treat tinnitus symptoms
- (6) Infant delivery within 6 months, pregnancy, or lactation
- (7) Inability to undergo evaluation and complete questionnaires
- (8) Unsuitability for inclusion to the study based on the opinion of the investigators

2.4. Randomization and blinding

The 45 participants who met the inclusion criteria were randomly assigned to the MA, EA, or TENS groups ($n=15$ each). Randomization was conducted via balanced block randomization using an R package program (R Foundation for Statistical Computing, version 3.2.5). After the participants completed the screening process, they were randomly assigned to one of the groups at a 1:1:1 ratio by researchers who were not involved in the data collection. Once the group was randomly assigned, changes could not be made.

The randomization results were disclosed to the participants and the therapist but hidden from the assessor. It was difficult to blind the participants or the therapist as the interventions were

clearly identified. The researcher who conducted the randomization did not contact the assessor. Therefore, only the assessor was blinded in this study.

2.5. Interventions

2.5.1. MA

The participants were treated with each treatment for 10 sessions, twice a week. The MA and EA groups were treated with acupuncture at 11 acupoints (TE21, SI19, GB2, TE22, ST7, TE17, and GB20 on the affected side and GB20, TE05, and KI3 on both sides) using a sterilized disposable 0.25-mm diameter, 40-mm length stainless needle (Dongbang Medical Co., Boryeong, Republic of Korea). The acupuncture point was selected based on a previous clinical study methods and findings.^{3,4} The needling depth was approximately 5–10 mm based on the differences in the anatomical structure of the participants and the individual characteristics of the acupoints. The acupuncture needles were inserted until the participants felt “De-qi” and were retained for 20 minutes.

2.5.2. EA

The acupuncture treatment in the EA group was similar to that in the MA group. After treatment with acupuncture, the inserted needles at TE21, SI19, TE17, and GB20 were connected to an EA stimulator (ES-160; Ito Co., Ltd., Tokyo, Japan) and stimulated at a mixed frequency of 30/90 Hz with a 3-second interval. The stimulation intensity was set at a relatively high level and was acceptable to the participants.

2.5.3. TENS

TENS treatment was performed using a low-frequency electrical stimulator (Pointron 801; Dae Yang Medical Co., Ltd., Wonju, Republic of Korea). A pair of electrodes was attached to the tender point of the sternomastoid muscle and mastoid process (C2 dermatome) on the affected side, and the other pair of electrodes was placed at the trigger point of the masseter muscle and the temporomandibular joint in front of the tragus. Subsequently, a 30-Hz electrical stimulation was applied for 20 minutes. The stimulation was adjusted to a relatively high intensity, however it was neither unpleasant nor painful.

In both the MA and EA groups, manual systemic acupuncture was conducted on both sides of the body and periauricular acupuncture and electrostimulation on the affected ear-side alone. In the TENS group, TENS treatment at the tender point of the sternomastoid muscle and mastoid process (C2 dermatome) was performed on the affected ear-side alone. If the participants had bilateral tinnitus and they experienced different loudness of the tinnitus, the louder tinnitus ear-side was selected. If they had bilateral tinnitus and they experienced the same loudness, the right ear was treated for the right-handed participants and the left-ear for the left-handed participants as shown in a previous study.⁷

All interventions were explained to the participants before written consent was obtained and before they were performed by a Korean medical practitioner with more than 2 years of clinical experience after graduating from a 6-year Korean medical school.

2.6. Measurements

The primary outcome measure was the change in the THI score. We measured loudness and annoyance of tinnitus, pure-tone audiometry, and a speech discrimination test for the secondary outcomes.

2.6.1. Tinnitus handicap inventory (THI)

The THI questionnaire consists of 25 questions. Each question is answered by “yes,” scored as four points; “sometimes,” scored

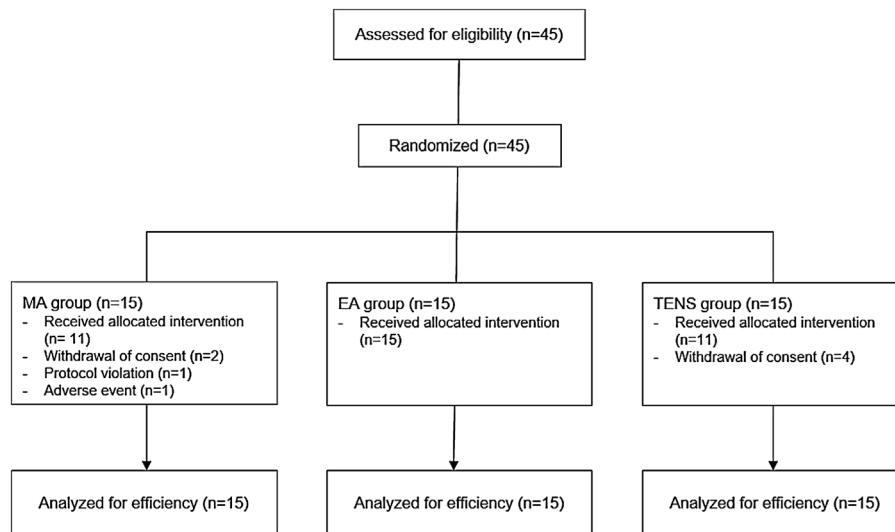


Fig. 1. Study flow diagram. MA, manual acupuncture; EA, electroacupuncture; TENS, transcutaneous electrical nerve stimulation; ITT, intention-to-treat.

as two points; or “no,” scored as zero points. The total score can be categorized into the following five categories: slight (0–16 points), mild (18–36 points), moderate (38–56 points), severe (58–76 points), and catastrophic (78–100 points). In addition, it can be categorized into four subscales: functional subscale (11 questionnaire items), emotional subscale (9 questionnaire items), and catastrophic subscale (5 questionnaire items). The THI questionnaire was completed at visits 1 (week 1), visit 5 (week 3), visit 10 (week 5), and at the follow-up visit, which was 4 weeks after the end of treatment. When the total pretreatment and post-treatment THI scores differed by more than 10 points, we defined the outcome of such interventions as a positive response.^{6,14}

2.6.2. Loudness and annoyance of tinnitus

The loudness and annoyance of tinnitus were measured using the visual analog scale. The symptoms were rated on a scale of 0 (no symptoms) to 10 (greatest discomfort). After the participants placed a mark on the 10-cm horizontal line, the distance from zero to the mark was measured and evaluated as the score. The VAS score was assessed at every visit, both before and after the treatment.

2.6.3. Pure-tone audiometry (PTA) and speech discrimination (SD) test

PTA and SD test were performed at visits 1 (week 1), visit 5 (week 3), visit 10 (week 5), and the follow-up session using a clinical audiometer (GSI 61™ Audiometer: Grason-Stadler, MN, USA).

2.7. Adverse event monitoring

Any adverse events that occurred during the study period were documented in the case report form. Vital signs were checked and recorded at the screening visit.

2.8. Statistical analysis

All collected data were analyzed using the SPSS v. 19.0 software for Windows (SPSS Inc., Chicago, IL, USA), and the corresponding 95% confidence intervals (CIs) were calculated. We used the intention-to-treat analysis and applied the last observation carried forward method for missing data. Descriptive statistics were used to summarize the data. To analyze the effectiveness, we compared the changes in each value with time among the groups and with time changes. For the response rate, the visit 1 (week 1) and

visit 10 (week 5) values were compared. For the discrete variables (e.g., response rate), the chi-square test or Fisher’s exact test were used. For the continuous variables (e.g., THI and VAS scores), if the normality test results followed a normal distribution, data were analyzed by analysis of variance (ANOVA). The Kruskal–Wallis test was used when a normal distribution was not observed.

3. Results

3.1. Demographic data

From July 2016 to December 2017, a total of 45 participants were enrolled, randomized, and analyzed. Thirty-three participants (73.3%) were men. The mean age of all participants was 47.38 years (median: 49 years). The symptom duration was 103.67 months (median: 60 months). Eight participants dropped-out, and 37 participants completed the protocol. The reasons for drop-out were as follows: withdrawal of consent ($n=6$), protocol violation ($n=1$), and adverse event ($n=1$) (Fig. 1). For the demographic data, including sex, age, and degree of symptoms, there were no significant differences among the groups. There was also no significant difference in the THI, loudness, annoyance, PTA, and SD test findings (Table 1).

3.2. Primary outcome

There was no statistical differences among the groups. However, in the within-group analysis, the MA group and EA group showed significant decreases over time in THI score (Table 2). In the response rate, seven participants in the MA group, eleven participants in the EA group, and four participants in the TENS group had THI scores that decreased by more than 10 points at visit 10 (week 5). The EA group had more participants who showed a reduced THI score than the other groups ($p=0.037$; Fisher’s exact test).

3.3. Secondary outcome

The loudness and annoyance of tinnitus showed no significant differences among the groups at any time point. In the within-group analysis, the EA group showed differences in the loudness over time. The MA and TENS group showed differences in the annoyance at some evaluations (Table 2). However, the PTA and SD test findings did not change significantly during the trial.

Table 1
Demographic Characteristics of the Participants at Baseline

Characteristics	MA group (n = 15)	EA group (n = 15)	TENS group (n = 15)
Sex (M/F)	12/3	8/7	13/2
Age (year)	48.6 ± 7.84	46.20 ± 11.03	47.33 ± 9.49
Duration (month)	105.13 ± 142.02	107.80 ± 115.92	98.07 ± 97.67
Bilateral tinnitus (%)	6 (40)	8 (53.3)	7 (46.7)
Somatosensory tinnitus (%)	3 (20)	8 (53.3)	7 (46.7)
THI score	41.73 ± 23.84	44.00 ± 19.00	49.47 ± 22.90
Loudness (10 cm-VAS)	5.70 ± 1.95	6.07 ± 1.78	6.76 ± 1.74
Annoyance (10 cm-VAS)	5.30 ± 2.12	5.37 ± 1.81	5.76 ± 2.46
PTA ^a	23.33 ± 18.47	19.25 ± 20.71	18.08 ± 10.62
Speech discrimination ^a	82.13 ± 19.12	85.60 ± 25.20	86.60 ± 7.38

Values are expressed as means ± standard deviations and analyzed using ANOVA. There was no significant difference among the groups. MA, manual acupuncture; EA, electroacupuncture; TENS, transcutaneous electrical nerve stimulation; THI, tinnitus handicap inventory; VAS, visual analog scale; PTA, pure-tone audiometry.

^a If the participants had bilateral tinnitus, the louder side was selected; when equal, the right ear was examined for the right-handed patients and the left ear for the left-handed patients.

Table 2
Change in the Total THI Score and Loudness and Annoyance of Tinnitus

	MA group	EA group	TENS group	p-value*
THI				
Visit 1 (week 1)	41.73 ± 23.84	44.00 ± 19.00	49.47 ± 22.90	
Visit 5 (week 3)	-7.07 ± 8.10 (-13.49, -0.65)	-9.07 ± 9.68 (-16.73, -1.40)	-1.02 ± 12.21 (-10.87, 8.47)	0.088
Visit 10 (week 5)	-11.33 ± 12.23 (-21.02, -1.64)	-12.00 ± 10.85 (-20.60, -3.40)	-5.33 ± 12.53 (-15.26, 4.59)	0.134
Visit 11 (follow up 4 weeks)	-8.67 ± 10.55 (-17.02, -0.31)	-12.00 ± 14.48 (-23.48, -0.53)	-5.60 ± 12.26 (-15.32, 4.12)	0.318
Loudness (10 cm-VAS)				
Visit 1 (week 1)	5.70 ± 1.95	6.07 ± 1.78	6.76 ± 1.74	
Visit 5 (week 3)	-0.78 ± 1.57 (-2.03, 0.47)	-1.50 ± 1.61 (-2.78, -0.22)	-1.10 ± 1.53 (-2.32, 0.12)	0.481
Visit 10 (week 5)	-1.03 ± 2.00 (-2.62, 0.55)	-2.14 ± 2.25 (-3.92, -0.36)	-1.35 ± 1.56 (-2.59, -0.12)	0.302
Visit 11 (follow up 4 weeks)	-0.75 ± 1.70 (-2.09, 0.60)	-1.30 ± 1.25 (-2.29, -0.31)	-1.04 ± 1.58 (-2.30, 0.21)	0.638
Annoyance (10 cm-VAS)				
Visit 1 (week 1)	5.30 ± 2.12	5.37 ± 1.81	5.76 ± 2.46	
Visit 5 (week 3)	-1.17 ± 1.44 (-2.30, -0.03)	-1.07 ± 1.55 (-2.31, 0.16)	-0.92 ± 1.60 (-2.19, 0.35)	0.823
Visit 10 (week 5)	-1.77 ± 2.26 (-3.56, 0.02)	-1.27 ± 2.00 (-2.85, 0.32)	-1.11 ± 1.29 (-2.14, -0.09)	0.548
Visit 11 (follow up 4 weeks)	-1.38 ± 1.55 (-2.61, -0.15)	-0.97 ± 1.58 (-2.22, 0.29)	-0.62 ± 1.24 (-1.61, 0.37)	0.269

Values are expressed as means ± standard deviations (95% confidence intervals). THI, tinnitus handicap inventory; MA, manual acupuncture; EA, electroacupuncture; TENS, transcutaneous electrical nerve stimulation.

* p-value for ANCOVA with covariate baseline score.

3.4. Adverse event monitoring

There were no serious adverse effects observed. Mild side effects were reported in two patients in MA group and two patients in EA group (In the MA group, one participant had transient ear numbness near the acupoint, and one had vertigo. In the EA group, one participant had transient numbness of the right arm near the acupoint, and one had a worsening of symptoms). One participant with vertigo was diagnosed with Meniere's disease. This participant was excluded in accordance with the exclusion criteria.

4. Discussion

The analysis in this study revealed no significant difference in the THI score among the three groups. However, when improvement was set at a 10-point reduction in the THI score, the number of participants showing improvement in the EA group was significantly higher than that in the TENS and MA groups. Similar to previous study results,^{4,15} EA was more effective than MA.

When MA is conducted around the ear, an effect on tinnitus is observed through neuromodulation.³ However, MA can cause various biomedical changes, such as vagus nerve stimulation and autonomic regulation. These effects are generally known to occur on distal body parts (mainly hands or feet). Some studies reported that distal-part acupuncture also has some effect on tinnitus.^{15,16} EA was expected to have a similar effect as MA, with electrical stimulation on the target areas.

The mechanism of electrical stimulation in tinnitus is suggested to be neuromodulation. Electrical stimulation can affect the somatosensory system and thus relieve pain. If tinnitus has some form of pain, it can be relieved when the pain is reduced. In fact, direct electrical stimulation of the surface of the cochlea with cochlear implants can markedly reduce tinnitus.¹⁷ However, direct electrical stimulation is very invasive. Thus, electrical stimulation on the skin to substitute this invasive treatment has been attempted, including TENS treatment.¹⁸

MA, EA, and TENS can be expected to produce a similar effect: neuromodulation. However, EA showed more response than TENS. These results suggest that EA, including electrical stimulation on target areas and other types, such as meridian system acupuncture, may be effective for tinnitus.

We also found some interesting aspects. In the TENS group, four participants were highly affected, while the other participants were not. Among these four participants, three were classified as having somatic tinnitus according to the criteria of previous research.¹⁹ According to the mechanism of TENS, we can hypothesize that somatic tinnitus may be a factor affecting this result. However, the number of participants was too small to reach a definite conclusion. Further studies are needed to clarify this hypothesis.

The limitation of our study was the lack of a control group. Consequently, we could not conclude that EA was the most effective treatment for tinnitus, although EA was shown to be more effective than MA and TENS. All three treatment methods have been proven to be effective for treating tinnitus^{4,6,7,9,10,20} and are

most commonly used as physiotherapy treatments. In this study, we compared these treatments and determined which one was the optimal treatment for actual clinical use. This method resembles that of a comparative effectiveness study. The results of this comparative study may assist clinicians as they make informed decisions that may improve health care.^{21,22}

In conclusion, among MA, EA, and TENS, there was no significant differences in the effects on the treatment of chronic consecutive tinnitus. However, EA could respond to more patients. Further research is essential to determine the effect of EA on tinnitus and to discover what factors may improve the effectiveness of each treatment.

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YKM and BHK drafted the manuscript equally.

Data availability

Conceptualization: YKM. Methodology: YKM and MHK. Formal analysis: BHK. Investigation: YKM. Writing – original draft: BHK and YKM. Writing – review & editing: MHK. Supervision: HJN.

The authors declare that they have no conflict of interest.

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The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

References

- Park KH, Lee SH, Koo J-W, Park HY, Lee KY, Choi YS, et al. Prevalence and associated factors of tinnitus: data from the Korean National Health and Nutrition Examination Survey 2009–2011. *J Epidemiol* 2014;24:417–26.
- Baguley D, McFerran D, Hall D. Tinnitus. *Lancet* 2013;382:1600–7.
- Kim J-I, Choi J-Y, Lee D-H, Choi T-Y, Lee MS, Ernst E. Acupuncture for the treatment of tinnitus: a systematic review of randomized clinical trials. *BMC Complement Altern Med* 2012;12:97.
- Wang K, Bugge J, Bugge S. A randomised, placebo-controlled trial of manual and electrical acupuncture for the treatment of tinnitus. *Complement Therap Med* 2010;18:249–55.
- Vanneste S, De Ridder D. Noninvasive and invasive neuromodulation for the treatment of tinnitus: an overview. *Neuromodulation: J Int Neuromod Soc* 2012;15:350–60.
- Lee SK, Chung H, Chung JH, Yeo SG, Park MS, Byun JY. Effectiveness of transcutaneous electrical stimulation for chronic tinnitus. *Acta Oto-laryngol* 2014;134:159–67.
- Jeon SW, Kim KS, Nam HJ. Long-term effect of acupuncture for treatment of tinnitus: a randomized, patient- and assessor-blind, sham-acupuncture-controlled, pilot trial. *J Altern Complement Med (New York, NY)* 2012;18:693–9.
- Rogha M, Rezvani M, Khodami AR. The effects of acupuncture on the inner ear originated tinnitus. *J Res Med Sci: Off J Isfahan Univ Med Sci* 2011;16:1217–23.
- Doi MY, Tano SS, Schultz AR, Borges R, Marchiori LL, de M. Effectiveness of acupuncture therapy as treatment for tinnitus: a randomized controlled trial. *Brazilian J Otorhinolaryngol* 2016;82:458–65.
- Vanneste S, Plazier M, Van de Heyning P, De Ridder D. Transcutaneous electrical nerve stimulation (TENS) of upper cervical nerve (C2) for the treatment of somatic tinnitus. *Exp Brain Res* 2010;204:283–7.
- Moon Y-K, Kim MH, Nam HJ. Comparison of the effectiveness between transcutaneous electrical nerve stimulation, manual acupuncture, and electroacupuncture on tinnitus: study protocol for a randomized controlled trial. *Trials* 2018;19:342.
- Johanson GA, Brooks GP. Initial scale development: sample size for pilot studies. *Educ Psychol Meas* 2010;70:394–400.
- Julious SA. Sample size of 12 per group rule of thumb for a pilot study. *Pharmaceut Stat* 2005;4:287–91.
- Zeman F, Koller M, Figueiredo R, Aazevedo A, Rates M, Coelho C, et al. Tinnitus handicap inventory for evaluating treatment effects: which changes are clinically relevant? *Otolaryngol Head Neck Surg: Off J Am Acad Otolaryngol* 2011;145:282–7.
- Kim BH, Kim K, Nam HJ. A comparative study on the effects of systemic manual acupuncture, periauricular electroacupuncture, and digital electroacupuncture to treat tinnitus: a randomized, paralleled, open-labeled exploratory trial. *BMC Complement Altern Med* 2017;17:85.
- De Ridder D, Vanneste S, Engineer ND, Kilgard MP. Safety and efficacy of vagus nerve stimulation paired with tones for the treatment of tinnitus: a case series. *Neuromodulation: J Int Neuromod Soc* 2014;17:170–9.
- Blasco MA, Redleaf MI. Cochlear implantation in unilateral sudden deafness improves tinnitus and speech comprehension: meta-analysis and systematic review. *Otology Neurotol: Off Publ Am Otol Soc* 2014;35:1426–32.
- Møller AR. Sensorineural tinnitus: its pathology and probable therapies. *Int J Otolaryngol* 2016;2016:1–13.
- Sanchez TG, Rocha CB. Diagnosis and management of somatosensory tinnitus: review article. *Clinics (Sao Paulo, Brazil)* 2011;66:1089–94.
- Liu F, Han X, Li Y, Yu S. Acupuncture in the treatment of tinnitus: a systematic review and meta-analysis. *Eur Arch Oto-rhino-laryngol: Off J Eur Federat Oto-Rhino-Laryngol Soc (EUFOS)* 2016;273:285–94.
- Luce BR, Kramer JM, Goodman SN, Connor JT, Tunis S, Whicher D, et al. Rethinking randomized clinical trials for comparative effectiveness research: the need for transformational change. *Ann Intern Med* 2009;151:206–9.
- Sox HC, Greenfield S. Comparative effectiveness research: a report from the Institute of Medicine. *Ann Intern Med* 2009;151:203–5.