

Healthy lifestyle consultation based on traditional Chinese medicine versus routine patient education in the treatment of idiopathic sudden sensorineural hearing loss after failure of systemic therapy: Study protocol for a clinical randomised trial

Yingping Fei (✉ feiyingsping@stu.scu.edu.cn)

Sichuan University West China Hospital <https://orcid.org/0000-0002-8844-3708>

Yun Zheng

West China Hospital of Sichuan University

Dan Lai

the affiliated hospital of southwest medical university

Ping Zhong

Sichuan University West China Hospital

Jing-zhe Lu

Sichuan University West China Hospital

Gang Li

Sichuan University West China Hospital

Peng Liu

Guangzhou University of Traditional Chinese Medicine First Affiliated Hospital

Study protocol

Keywords: ISSNHL, TCM, healthy lifestyle, Study protocol, randomized controlled trial

Posted Date: September 24th, 2019

DOI: <https://doi.org/10.21203/rs.2.245/v3>

License: © ⓘ This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Version of Record: A version of this preprint was published on December 2nd, 2019. See the published version at <https://doi.org/10.1186/s13063-019-3733-5>.

Abstract

Background: Idiopathic sudden sensorineural hearing loss (ISSNHL) is an important cause of deafness. Despite the advances in systemic therapy, some cases of ISSNHL are untreated, because the exact ISSNHL aetiology is unclear. Traditional Chinese medicine (TCM) has been used for treating diseases for thousands of years and is popular and widely practiced in Asia. TCM includes guidance on healthy lifestyle. In recent decades, the relationship between lifestyle and disease has been emphasised. Moreover, an unhealthy lifestyle may lead to illnesses. Thus, this study aims to compare the efficacy of lifestyle modification based on TCM with the usual consultation of ISSNHL after failure of a 2 weeks systemic therapy to provide a scientific basis for clinical decisions. **Methods:** This study is a clinical randomised trial that involves 56 patients diagnosed with ISSNHL but with incomplete recovery after initial management (at least 2 weeks routine Western medical treatment). The study is performed in accordance with the sudden hearing loss clinical guideline of the American Academy of Otolaryngology – Head and Neck Surgery, which is published in 2012. Participants are randomly distributed into two groups, namely, the healthy lifestyle modification group based on TCM and the control group (1:1 ratio). Patient follow-up lasted for 3 months. The primary outcome measure is the effective rate of hearing improvement, which is defined as the proportion of patients with at least 15 dB improvement in the average thresholds by the hearing loss frequency. The secondary outcome measures are the improvements in word recognition score, tinnitus handicap inventory for tinnitus and visual analogue scale for ear blockage and dizziness. Assessments are made at baseline after lifestyle modification for 1 and 3 months. **Discussion:** The efficacy of healthy lifestyle modification based on a TCM programme for patients with ISSNHL with incomplete recovery after failure of initial systemic therapy is determined in this trial. Positive results provide clinical evidence on the effects of TCM - based healthy lifestyle, which could be recommended as salvage therapy for patients with ISSNHL.

Background

Idiopathic sudden sensorineural hearing loss (ISSNHL) is a common otologic emergency that presents mostly as an acute hearing loss with an abrupt occurrence. ISSNHL is hearing loss of more than 30 dB that occurs in at least three consecutive frequencies within 72 h¹. Aside from hearing impairment, ISSNHL can be associated with dizziness, tinnitus and/or ear fullness/blockage. The ISSNHL incidence is approximately 5–30/100,000/year in developed countries, such as the United States, Sweden and Japan, as revealed by national surveys¹⁻⁴. Detailed investigations suggested that only approximately 10% of patients with ISSNHL show a specific cause⁵. Several pathophysiological mechanisms, including microcirculation, autoimmune pathology, viral infection, intracochlear membrane rupture or haematologic problems, have been proposed despite the unidentified precise cause of ISSNHL⁶. ISSNHL may not be due to a single pathological change but a spectrum of pathologies affecting the cochlea⁷.

The most common treatment option for ISSNHL is administration of corticosteroids within the first 2 weeks⁴. A total of 49% to 89% of patients with ISSNHL showed recovery via systemic steroid therapy,

whereas therapy displayed no effects on other patients⁸. Spontaneous recovery occurs in 32% to 65% of the cases, usually within the first 14 days^{9,10}. However, recovery amongst patients who did not show improvement after 2 weeks is low¹¹. Intratympanic steroid perfusion described in the US guidelines has been recommended as salvage therapy¹. However, its clinical evidence remains controversial, and no existing consensus suggests the efficacy of intratympanic steroid therapy for ISSNHL^{1,12,13}. Therefore, the failure of a two-week treatment amongst patients with ISSNHL should be further studied, and alternate therapies should be developed.

Traditional Chinese medicines (TCMs) are from ancient China and have been used in therapeutic approaches in East Asia for more than 2,500 years. TCM includes well-known herbal medicine acupuncture, massage (tui na) and lifestyle modifications, such as dietary therapy and exercise (taiji and qigong). TCMs originated from Huang Di Nei Jing, a famous work of ancient TCM literature, which introduced the maintenance of the Yin–Yang balance of the internal organs by following a healthy lifestyle. From the TCM perspective, all diseases originate from a broken balance. In China, Chinese patients prefer using TCM methods with complementary and alternative medicines for disease treatment. Lifestyle change guided by TCM is also acceptable amongst Chinese people with diseases.

Lifestyle change has been suggested amongst patients with otological diseases whose conditions are not controlled well by medicine. Dietary habits, such as low sodium diet, can alter the inner ear's fluid homeostasis and auditory function. The endolymph compartment maintains a low sodium concentration, whereas ionic balance is maintained in the surrounding perilymph and serum¹⁴. Evidence shows that more than 85% of patients with Meniere's disease are helped by lifestyle changes along with either medical treatment or surgical procedures. Lifestyle changes include reducing the consumption of salt, caffeinated products, chocolate, alcohol and salt products¹⁵. A cross-section study indicates the relationship between benign paroxysmal positional vertigo and inadequate carbohydrate and fibre intake and a diet rich in polyunsaturated fatty acids. Food readjustment is suggested amongst patients with this condition¹⁶. Furthermore, a descriptive longitudinal cohort study amongst 159 adult patients with chronic primary tinnitus and sleep problems has shown that TCM-based lifestyle counselling may relieve chronic primary tinnitus. After 6–26 months of follow-up, sleep quality and tinnitus loudness improved, and the effects of tinnitus on sleep, concentration and emotional state were also alleviated¹⁷.

Therefore, this randomised controlled clinical trial was designed to evaluate the efficacy of TCM-based lifestyle modification as a salvage therapy for patients who have not recovered 14 days after the onset of ISSNHL through the use of systemic steroid therapy.

Methods/design

Objective

Given the significant spontaneous recovery rate and existing standard therapy for ISSNHL by using systemic glucocorticoids, patients are enrolled in the study only if no or insufficient recovery of hearing

threshold is observed after the initial 14 days of systemic therapy. In addition, patients are excluded if they are reluctant to continue receiving salvage therapy. This randomised controlled trial evaluates the effectiveness of healthy lifestyle treatment based on TCM therapy for patients with ISSNHL who have no or insufficient recovery of hearing threshold after the initial systemic therapy for 14 days and are reluctant to continue receiving salvage therapy.

Study design

Fifty six patients are recruited for the trial. Participants who meet the inclusion criteria and submit written informed consent are enrolled in the trial, which lasts for 3 months. Fig. 1 shows the trial procedure flowchart.

This trial is registered in the China Clinical Trials Registry (Registration number: ChiCTR-INR-17011459) and has been approved by the Biomedical Branch of Ethics Committee of West China Hospital of Sichuan University (identifier: 2016-180). The study is performed according to the Declaration of Helsinki guidelines for clinical trials. The protocol is written in line with the Standard Protocol Items: Recommendations for Interventional Trials checklist (Additional file 1), as shown in Fig. 2.

Recruitment

Participants diagnosed with ISSNHL but did not respond to initial systemic treatment for at least 14 days are recruited by posters in the West China Hospital of Sichuan University.

Participants

Inclusion criteria

1. Signed informed consent form; participants must be willing and able to provide consent for
2. Diagnosis of unilateral ISSNHL, defined as onset within 72 h affecting three consecutive frequencies of unknown aetiology¹
3. Hearing loss occurs at least 14 days but less than or equal to 1 year
4. Insufficient recovery from ISSNHL for at least 14 days after onset and after receiving the Chinese ISSNHL guideline-recommended standard therapy
5. Reluctance to receive drugs, including steroid therapy
6. More than 18 years old but less than 60 years old
7. Hearing in the contralateral ear of at least 20 dB HL
8. Stopped receiving medication for more than 3 days

Exclusion criteria

1. Previous disease or surgery in the affected ear

2. Hearing loss from an identified aetiology, including head trauma, conductive hearing loss Meniere's disease and tumour
3. Inability to complete relevant assessments, such as cognitive impairment and mental disorder assessments
4. Serious comorbid conditions, such as progressive central disorder or life-threatening conditions
5. Any reason, in the investigator's opinion, that prohibits inclusion

The criteria for trial termination and dropout are as follows. The patient develops a severe disease unrelated to participation in the trial. The patient chooses other treatments and drugs. The patient requests termination or withdraws. The patient no longer receives the trial treatment regimen and examination.

Randomisation

When patients want to participate in the trial and meet the requirements, a research assistant who reviews and explains the study collects the patient basic demographic information and previous clinical data. Eligibility is ascertained in the patient, followed by written consent form. Before randomisation, the patients must have reassessed their hearing status with otoscopic examination, hearing threshold (air conduction hearing thresholds measured at 250–8000 Hz, bone conduction hearing thresholds measured at 500–4000Hz), word recognition scores and ear-specific immittance measurements (including tympanometry, static immittance and acoustic reflex measures). These measures can assess the patient's baseline hearing state and exclude conductive hearing loss. According to the classification standard of hearing loss degree published by the World Health Organization in 1997, the average values of hearing thresholds of 500, 1000, 2000 and 4000 Hz were calculated and then divided into mild (26–40 dB HL), moderate (41–60 dB HL), severe (61–80 dB HL) and profound (≥ 81 dB HL). Patients were stratified by gender, age and degree of hearing loss. Patients of the same gender, with age differences within 3 years and have the same degree of hearing loss were classified in the same stratification.

A statistician who is not part of the clinical intervention uses the Statistical Package for Social Sciences (SPSS) 21.0 (IBM, Chicago, IL, USA) to generate a randomisation code. This code is embedded into serially numbered, opaque and numbered envelopes. After a participant completes the baseline measures, and when the same stratification reaches two or even number of patients, another research assistant opens the next envelope in the series to determine the participant group allocation. Patients in the same stratification are randomised for the two treatments with 1:1.

Intervention

Participants in the control group receive routine care, whereas those in the intervention group receive additional lifestyle counselling based on TCM. In this system, patient care focuses on health maintenance and prevention by encouraging patients to adhere to simple health and lifestyle practices¹⁸.

Routine care includes two aspects, as follows:

- Educating participants about the natural history of ISSNHL and the limitations of existing evidence regarding efficacy; answering patients' questions about ISSNHL
- Counselling participants about the benefits of amplification, hearing-assistive technology and other supportive measures, especially for those whose hearing loss has lasted more than 3 months

Lifestyle counselling consists of four sessions. The first step is the completion of the lifestyle survey of each participant and one-to-one targeted counselling based on the survey results.

- Diet According to the theory of Yellow Emperor's Inner Canon (Huang Di Nei Jing), a classical Chinese medicine book¹⁹, yang qi is an important reason for maintaining normal human function. In addition, food's energy can have a remarkable effect on health. Therefore, diet should be dominated by staple food, whereas 'cold' energy food should be avoided. In simple terms, the central components of the dietary strategy are the staple Chinese food ('neutral' energy), such as rice and wheat. According to TCM principles, 'cold' energy food includes most fruits. The diet adopted in this study encourages participants to consume staple Chinese food.
- Sleep. Patients sleep at night, avoid staying up late and wake up at dawn. The recommended time range for the patients to fall asleep was 10 p.m. to 11 p.m. and they need to be up by 5 a.m. to 7 a.m., thereby ensuring a sleeping window between 10 p.m. and 5 a.m. Thus, reducing water intake prior to sleep is necessary to avoid waking up at night to urinate. Participants should not sleep during the day. A less than 30 min short nap before 2 p.m. is advised for nonadaptive patients.
- Mood. A physician communicates with the participants to answer their doubts and discuss the relationship between mood and ISSNHL and the importance of good mood to health. Participants' fear, despair and anxiety should be minimal.
- Physical activity. All participants are encouraged to be moderately physically active by doing taiji (a traditional Chinese sport) and housework and by walking and participating in leisure activities. Patients are discouraged from engaging in deliberate strenuous physical exercise, especially before going to bed. They are also discouraged to eat too much before go to bed.

The following measures are taken to improve patient compliance and reduce the drop-out rate. All participants are entitled to free assessments, including audiology tests, one-to-one consultation and lifestyle assessment. In addition, no registration fee is required for the first-level expert outpatient service from the West China Hospital. At the end of the experiment, a free online consultation service is provided for 1 year.

Weekly one-on-one consultations and periodic check-ups are provided over the phone, especially with the lifestyle modification group to reinforce the importance of lifestyle change and answer related questions. Participants are encouraged to keep a symptom log on ear-associated and systemic symptoms. The patients need to provide daily email updates regarding their lifestyle journal, including information on sleep and wake times and daily diet (Additional file 2). Participants are required to fill in the form daily for 1 month.

Outcome measures

The outcomes are evaluated at baseline, 1 month and 3 months after intervention.

Primary outcome measure

The primary outcome measure will be the effectiveness of hearing improvement. It is the percentage of patients with an improvement of at least 15 dB in their impaired frequency compared with the baseline. On the basis of the 2012 practice guideline on ISSNHL published in America, an improvement within 10 dB HL of initial HL or within 10 dB HL range of the unaffected ear's hearing threshold is defined as complete recovery. An improvement of more than 30 dB HL improvement in PTA (dB HL) from pretreatment hearing levels is defined as significant recovery, an improvement of 15–30 dB HL is defined as effective recovery. In addition, an improvement of less than 15 dB HL in PTA is defined as no recovery^{1,20}.

Secondary outcome measure

Based on the visual analogue scale, the secondary outcome includes improvement of adherence to TCM lifestyle, evaluation of changes in word recognition score (WRS)²¹, tinnitus handicap inventory (THI)²² for patients with tinnitus and change in common symptoms, such as dizziness and ear blockage. These outcomes are measured at the first and during protocol visits.

Blinding

The audiologist, research assistants and statisticians involved in the study are blinded to the allocations. Given the nature of counselling, blinding amongst consultants and patients is impossible. Thus, consultants and other researchers do not communicate amongst one another about the patient group during the trial. Patients also keep their treatment methods confidential. At the completion of the trial, patients in the control group are offered access to the lifestyle modification intervention.

Sample size

To the best of our knowledge, no randomised pilot study has been conducted to assess the effectiveness of lifestyle changes on ISSNHL. Therefore, we are not able to calculate the sample size based on previous studies. On the basis of our retrospective analysis (unpublished) and clinical experience, the efficiency ratio of the intervention group is conservatively estimated to be 50%, and the natural recovery rate of over 2 weeks is 10%⁹. Using a formula²³ to calculate the sample size of optimal treatment in the clinical trial and considering $\alpha=0.05$, $\beta=0.1$, by the table of normal distribution quantifiers $U_{\alpha(0.05)}=1.65$, $U_{\beta(0.1)}=1.28$, we require a patient sample size of 23 per group. We allow for a 20% loss to follow-up (approximately 10 cases), with a total sample size of 56 patients (28 per group) in the study.

$$n=(U_{\alpha}+U_{\beta})^2P(1-P)/(P_1-P_0)^2,$$

$$P=(P_1+P_0)/2\times 100\%,$$

P_0 : Original efficacy, P_1 : expected efficacy.

Safety

Any adverse events and discomfort throughout the course of the trial are recorded by patients and data collectors. Participants may withdraw from the study for any reason at any time. The researchers record the reason in case report forms.

Statistical analysis

Data are analysed using SPSS V.21.0 (Chicago, IL, USA), with the significance level set at 0.05 (two-tailed) by statisticians who are independent of the research team. Patient baseline characteristics are summarised by a treatment arm by employing appropriate summary statistics to assess baseline comparability only. Data analysis is conducted with the intention-to-treat (ITT) principle and the per-protocol (PP) analysis. To ensure the comparability of baseline conditions between the two groups and allow the presence of noncompliant patients, the ITT population consists of all randomised participants. In addition, at least one follow-up was recorded after the intervention. According to the patients' actual lifestyle adjustment after random grouping, the PP analysis the patients who completed the trial and did not violate the protocol. This process is an explanatory analysis as a supplementary, contributing to the study objectivity. We calculate the effective rates at 1 and 3 months for the primary outcome and compare the intervention and control groups by using the χ^2 test. For secondary outcomes, continuous variables, including THI, visual analogue scale and WRS, are compared between the two groups at all follow-up time points by using t -test or the Wilcoxon signed-rank test as appropriate. Categorical variables, such as different degrees of hearing loss, are compared using the Chi-square test or Fisher's exact test. For dropout analysis, we use multiple imputations for ITT analysis. Sensitivity analysis is performed to assess the effect of missing data assumptions.

Data management

Data accuracy is ensured by completing the paper copies of the case report form. Two independent researchers blinded to the group allocation input the data on an Excel spread sheet, and the data are checked twice. Data are validated using original case report forms when any discrepancy is discovered. Paper files and electronic documents are stored in a locked filing cabinet and protected computer separately. Only the principal researchers are allowed access to data. Researchers are unable to modify the data and keep the information strictly confidential and shall not disclose it under any circumstances. The researchers sign a confidentiality agreement.

Discussion

ISSNHL, in which the aetiology remains unknown, is an acute disorder that occurs throughout life. Although 49% to 89% of patients achieved normal hearing through existing therapy with oral or intravenous steroids and with 32% to 65% spontaneous recovery rate, treatment amongst patients who have incomplete recovery from ISSNHL after failure of initial management remains a problem⁸⁻¹⁰. Some patients are reluctant to receive recommended glucocorticoid treatment because of concerns regarding side effects, contraindications and drug-to-drug interactions. The salvage therapy recommended by the 2012 ISSNHL guidelines is steroid perfusion that results in hearing improvement ranging from 53% to 90% in the treatment group^{24,25}. The dose and concentration of steroids vary similar to the criteria used to define hearing improvement.

Previous studies indicated that patients who do not show any improvement within the first 14 days are unlikely to show remarkable recovery afterwards^{9,10}. Thus, patients usually lose hope and discontinue therapy. Therefore, an acceptable and simple therapy is required to improve the effects of refractory ISSNHL for these patients.

TCM has been used for thousands of years and is widely accepted in treating diseases in China. Lifestyle, as part of TCM, has been integrated into the Chinese culture. Tradition and sustained interest in the benefits of TCM-recommended lifestyle have remained, especially for patients whose conditions have not been effectively treated by Western medicine. We designed this trial to verify that TCM-based lifestyle can provide help concerning hearing loss and concomitant symptoms amongst patients with ISSNHL. If successful, this intervention may help patients with refractory ISSNHL in China.

The study is designed to explore the efficacy of TCM-based lifestyle change for patients with ISSNHL with no or insufficient recovery after initial systematic Western medicine treatment. Although IT steroid perfusion for this kind of ISSNHL has been used in Western treatment, the evidence of its efficacy remains unclear. In this study, the effective rate of hearing improvement is used as the primary outcome measure and is the most common parameter for ISSNHL. Secondary outcome measures include WRS, THI and accompanying symptoms, including dizziness and fullness of the ear. In addition to hearing loss, many people with ISSNHL complain of poor hearing, tinnitus and dizziness. The exact mechanisms that explain the effects of TCM-based lifestyle change on ISSNHL require further detailed research and discussion in the future.

Study limitations

One of the major drawbacks of this study is that the currently widely adopted lifestyle questionnaire is not used. Lifestyle includes sleep, diet, mood and exercise. Thus, the factor that plays a key role in improving ISSNHL remains unknown. Therefore, well-designed and randomised controlled trials that compare different lifestyle factors with one another are necessary in the future.

Trial status

The trial is currently recruiting patients. We expect this process to be completed in October 2019.

Abbreviations

ISSNHL: Idiopathic sudden sensorineural hearing loss, TCM: Traditional Chinese medicine, PTA: pure tone average, WRS: word recognition score, THI: tinnitus handicap inventory.

Declarations

Ethics approval and consent to participate

This trial has been approved by the Biomedical Branch of Ethics Committee of West China Hospital of Sichuan University (identifier 2016-180). Study participation is voluntary and can be cancelled at any time without provision of reasons and without negative consequences for their future medical care. The informed consent will be obtained from all study participants before they enroll in the trial.

Consent for publication

All authors and investigators give their consent for publication.

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

Funding

There is no funding for this protocol. This trial will be conducted with no external funding and will be instead from the education fund for graduate students and Professor zheng's individual research fund.

Authors' contributions

DL designed this trial. YPF drafted the manuscript. YZ and PL contributed to supervise this study and participated in revising the manuscript. PZ and JZL provided advice and support. GL was responsible for reasonable statistical analysis. All authors read and approved the final manuscript.

Acknowledgements

The authors acknowledge Professor Meng Hongdao from University of south Florida for his encouragement in the preparation of the protocol.

Authors' information

¹Hearing Center/Hearing and Speech Science Laboratory, Department of Otolaryngology Head and Neck Surgery, West China Hospital of Sichuan University, No. 37, GuoXue Xiang, Chengdu, Sichuan 610041, People's Republic of China

²Department of Otolaryngology Head and Neck Surgery, The Affiliated Hospital of Southwest Medical University, 25 Taiping street, Jiangyang District, Luzhou, Sichuan 646000 , People's Republic of China

³Department of Otolaryngology Head and Neck Surgery, The first affiliated Hospital of Guangzhou University of Chinese Medicine, No. 16Yard, airport road, Guangzhou 510405, People's Republic of China.

References

1. Stachler RJ, Chandrasekhar SS, Archer SM et al. Clinical practice guideline: sudden hearing loss. *Otolaryngology–head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery* 2012; 146:S1-35.
2. Nosrati-Zarenoe R, Arlinger S, Hultcrantz E. Idiopathic sudden sensorineural hearing loss: results drawn from the Swedish national database. *Acta oto-laryngologica* 2007; 127:1168-1175.
3. Teranishi M, Katayama N, Uchida Y, Tominaga M, Nakashima T. Thirty-year trends in sudden deafness from four nationwide epidemiological surveys in Japan. *Acta oto-laryngologica* 2007; 127:1259-1265.
4. Schreiber BE, Agrup C, Haskard DO, Luxon LM. Sudden sensorineural hearing loss. *Lancet (London, England)* 2010; 375:1203-1211.
5. Penido NO, Cruz OL, Zanoni A, Inoue DP. Classification and hearing evolution of patients with sudden sensorineural hearing loss. *Brazilian journal of medical and biological research = Revista brasileira de pesquisas medicas e biologicas* 2009; 42:712-716.
6. Lazarini PR, Camargo AC. Idiopathic sudden sensorineural hearing loss: etiopathogenic aspects. *Brazilian journal of otorhinolaryngology* 2006; 72:554-561.
7. Chau JK, Lin JR, Atashband S, Irvine RA, Westerberg BD. Systematic review of the evidence for the etiology of adult sudden sensorineural hearing loss. *The Laryngoscope* 2010; 120:1011-1021.
8. Moskowitz D, Lee KJ, Smith HW. Steroid use in idiopathic sudden sensorineural hearing loss. *The Laryngoscope* 1984; 94:664-666.
9. Mattox DE, Simmons FB. Natural history of sudden sensorineural hearing loss. *The Annals of otology, rhinology, and laryngology* 1977; 86:463-480.
10. Wilson WR, Byl FM, Laird N. The efficacy of steroids in the treatment of idiopathic sudden hearing loss. A double-blind clinical study. *Archives of otolaryngology (Chicago, Ill : 1960)* 1980; 106:772-776.
11. Moon IS, Kim J, Lee SY, Choi HS, Lee WS. How long should the sudden hearing loss patients be followed after early steroid combination therapy? *European archives of oto-rhino-laryngology :*

- official journal of the European Federation of Oto-Rhino-Laryngological Societies (EUFOS) : affiliated with the German Society for Oto-Rhino-Laryngology - Head and Neck Surgery 2009; 266:1391-1395.
12. Plontke SK. Diagnostics and therapy of sudden hearing loss. *GMS current topics in otorhinolaryngology, head and neck surgery* 2017; 16:Doc05.
 13. Lai D, Zhao F, Jalal N, Zheng Y. Intratympanic glucocorticosteroid therapy for idiopathic sudden hearing loss: Meta-analysis of randomized controlled trials. *Medicine* 2017; 96:e8955.
 14. Sanchez-Munoz LA, Martin Merino M, Zalama Sanchez D. Disease-related malnutrition: A transversal improvement area. *Medicina clinica* 2017; 149:89-90.
 15. Sajjadi H, Paparella MM. Meniere's disease. *Lancet (London, England)* 2008; 372:406-414.
 16. Schultz AR, Neves-Souza RD, Costa Vde S, Meneses-Barriviera CL, Franco PP, Marchiori LL. Is There a Possible Association between Dietary Habits and Benign Paroxysmal Positional Vertigo in the Elderly? The Importance of Diet and Counseling. *International archives of otorhinolaryngology* 2015; 19:293-297.
 17. Liu YQ, Chen ZJ, Li G, Lai D. Effects of Educational Counseling as Solitary Therapy for Chronic Primary Tinnitus and Related Problems[J]. *BioMed Research International*, 2018; 2018:1-9.
 18. Rosenberg ZE. HUANG DI NEI JING SU WEN: An annotated Translation of Huang Di's Inner Classic Basic Questions (2 Volumes). *Journal of Chinese Medicine* 2011.
 19. Ni M. *The Yellow Emperor's Classic of Medicine: A New Translation of the Neijing Suwen With Commentary*. Shambhala Pubns 2015.
 20. [Guideline of diagnosis and treatment of sudden deafness (2015)]. *Zhonghua er bi yan hou tou jing wai ke za zhi Chinese journal of otorhinolaryngology head and neck surgery* 2015; 50:443-447.
 21. Jan TA, Kozin ED, Kanumuri VV, Sethi RK, Jung DH. Improvement in word recognition following treatment failure for sudden sensorineural hearing loss. *World journal of otorhinolaryngology - head and neck surgery* 2016; 2:168-174.
 22. Ding X, Zhang X, Huang Z. The Characteristic and Short-Term Prognosis of Tinnitus Associated with Sudden Sensorineural Hearing Loss 2018; 2018:6059697.
 23. Carlin JB, Doyle LW. Sample size. *Journal of Paediatrics & Child Health* 2002; 38:300.
 24. Ho HG, Lin HC, Shu MT, Yang CC, Tsai HT. Effectiveness of intratympanic dexamethasone injection in sudden-deafness patients as salvage treatment. *The Laryngoscope* 2004; 114:1184-1189.
 25. Xenellis J, Papadimitriou N, Nikolopoulos Tet al. Intratympanic steroid treatment in idiopathic sudden sensorineural hearing loss: a control study. *Otolaryngology-head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery* 2006; 134:940-945.

Additional Files

Additional file 1: SPIRIT Checklist. The Recommended items to address in a clinical trial protocol and related documents.

Additional file 2: Lifestyle Diary. Participant accomplish the table to record the journal of their sleep time and daily diet.

Figures

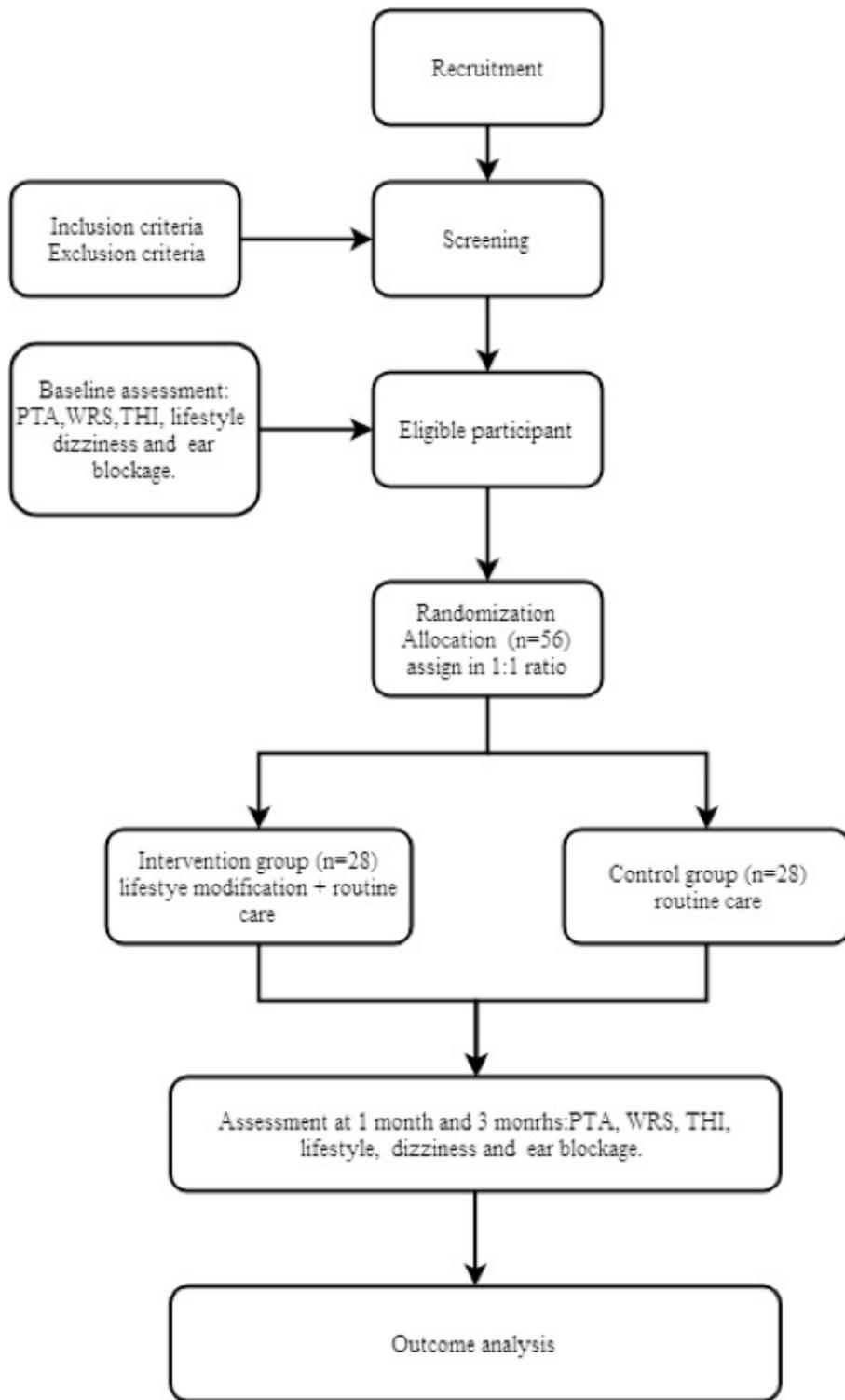


Figure 1

Trial flow chart. PTA pure tone average, WRS word recognition score, THI tinnitus handicap inventory.

	STUDY PERIOD			
	Enrolment	Allocation	Post-allocation(months)	
	Recruitment stage	Pre-intervention 0 months	1	3
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
Hearing tests: PTA,WRS	X			
Lifestyle assessment	X			
Assessment of dizziness and ear blockage	X			
Allocation		X		
INTERVENTIONS:				
Intervention group (Lifestyle modification+ routine care)			◆—————◆	
Control group (routine care)			◆—————◆	
ASSESSMENTS for intervention group and control group				
Primary outcome variables: The effective rate of hearing improvement			X	X
Secondary outcome variables: WRS, THI and Assessment of dizziness and ear blockage			X	X

Figure 2

Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Figure: proposed schedule for enrolment, intervention and assessment. PTA pure tone average, WRS word recognition score, THI tinnitus handicap inventory.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Additionalfile1SPIRITChecklist.doc](#)
- [Additionalfile2LifestyleDiary.docx](#)