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Tinnitus treatment: an experimental study

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Abstract

Objective The objective of the present study was to compare the effectiveness of the selected tinnitus management protocols for the experimental groups, based on the scores obtained for psychosocial variables, quality of life and severity of tinnitus between the four experimental groups following the various treatment protocols.

Method Two-hundred adults ages ranged from 20 to 55 years (mean age 44.14, *SD* = 6.16) with mild-to-moderate sensorineural hearing loss without tinnitus were randomly selected for the control group, whereas the experimental group comprised 200 adults with mild-to-moderate sensorineural hearing loss with tinnitus without any other associated medical problems. Participants of both control and experimental groups underwent audiological tests and were administered the QoL questionnaire. The experimental group, in addition, was also administered the PSQ, TSI and THI questionnaire and psychoacoustic tests, i.e. measuring pitch, loudness and MML of tinnitus. Participants of experimental group were randomly assigned to 4 groups, each of 50 participants, and treatment was given as below: Group 1: only tinnitus masking sound was administered, Group 2: only counselling was given, Group 3: masking with counselling was given and Group 4: tinnitus masking combined with counselling and attention diversion task therapy was given.

Result The patients without tinnitus had significantly better quality of life in comparison to the patients with tinnitus. Pre-post comparisons of the treatment groups revealed that "masking + counselling + attention diversion task" group showed highly significant differences for psychosocial aspects, QoL and severity of tinnitus. Further, pairwise comparison based on differences in mean scores indicated significant impact of "masking + counselling + attention diversion task" as compared to both in combination like "masking + counselling" or independently, i.e. masking or counselling alone.

Conclusion It appears that an integrated package of intervention (masking + counselling + attention diversion task) might be preferable for providing immediate tinnitus relief by masking through reducing tinnitus loudness and pitch by altering neuroplasticity (tonotopicity); in the long term, it reduces tinnitus impact through positive thinking by counselling treatment and also diverts attention to daily activity through attention training.

Keywords Tinnitus, Masking, Counselling, Attention diversion task

Background

According to the American Tinnitus Association (2002), tinnitus is a subjective disorder occurring in the ears in the absence of environmental noise in the form of ringing, roaring, buzzing, humming or hissing. The World Health Organization (WHO, 2004) has warned that hearing-related diseases including tinnitus will be in 1 of the 10 most prevalent disease categories in the near future. Steinmetz, Zeigelboim, Lacerda, Morata and Marques [47] reported that tinnitus has been seen in approximately 17% of the world population.

Tinnitus can be attributable to hearing loss, somatosensory system dysfunction or auditory cortex dysfunction; hence, various physical and psychological reactions have been noted in tinnitus sufferers [8, 12]. Psychological distress that is associated with tinnitus comprises anxiety,

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depression, irritability, worries, disturbance in social life, stress, disturbance in attention and concentration, personality disorder and sleep disturbance. Besides physical and psychological distress, emotional difficulties are also an important feature of patients living with tinnitus. The emotional balance and ability to cope have been severely affected due to excessive stress in people with severe tinnitus [9]. Refaie, Davis, Kayan, Baskill, Lovell and Owen [36] reported that tinnitus has an effect on quality-of-life (QoL) factors rather than just its acoustical properties, in order to evaluate potential treatment and rehabilitation procedures.

Tinnitus affected the quality of life of 0.5–3% of the population [42, 45], and assessing the effect of tinnitus on an individual's quality of life depends on a variety of factors: (a) tinnitus, like pain, is an entirely subjective experience that can only be described by patient report [19, 29], (b) psychological factors may play a critical role in determining an individual's reaction to tinnitus [9], (c) the personality disturbances are greater for male than for female [9] and (d) there are individual differences in daily lifestyle, as well as individually distinct acoustic environments, which make some patients more prone to intrusive tinnitus. Tinnitus is a very common symptom, and due to its clinical characteristics, it may cause impact in social, professional and emotional activities which leads to impact on quality of life of the patients [4].

Tinnitus patients have a significant higher proportion (43%) of somatic disease, psychic disturbances (40%) and one or more psychosomatic disturbances (61%). Development of chronic tinnitus with high psychological distress may be prevented by early psychosocial intervention as reported by Langenbach, Olderog, Michel, Albus and Köhle [23]. They suggest that a higher risk of developing tinnitus-related distress is seen in patients with psychological disturbances and sleeping problem at first presentation shortly following tinnitus onset. This suggests that development of chronic tinnitus with high psychological distress may be prevented by early psychosocial intervention as evidenced by their results. Focusing attention is affected due to extreme sleep deprivation caused by tinnitus which subsequently affects cognition and which further gives rise to associated anger and frustration. As a result, this affects emotional status, which effects can be self-perpetuating with the capability to consequently affect all aspects of life as reported by Henry and Dennis [14].

There is dearth of studies on tinnitus and its management in India even though the problem of tinnitus is as severe as in Western countries. There are no published studies in India nor in the West that have specifically investigated the impact of tinnitus management protocols on severity of tinnitus, psychosocial variables and quality of life. Therefore, the investigation to compare the effectiveness of the selected tinnitus management protocols for the tinnitus sufferers using psychosocial questionnaire, quality-of-life questionnaire and severity of tinnitus was planned.

Aim

The aim of the present study is to compare the effectiveness of tinnitus management protocols with respect to masking, counselling and attention diversion in adults having tinnitus with sensorineural hearing loss.

Method

Broadly, the study involved three phases:

- Phase I: Pretreatment evaluation of experimental and control groups using the instruments developed as well as audiological tools
- Phase II: Administration of four management protocols on the experimental groups
- Phase III: Posttreatment evaluation of the four experimental groups

Experimental study, i.e. interventional study with pre-test and posttest evaluation with four experimental groups and one control group. Participants were drawn from Ali Yavar Jung National Institute of Speech and Hearing Disabilities (Divyangjan), Regional Centre, Kolkata.

Sample size was estimated for impact evaluation (experimental group) and required sample size $n=175$. Therefore, 200 participants were selected for the main study and randomly assigned into four experimental groups. Finally, each experimental group comprised 50 participants. Random number table was used for assignment of study participants to four experimental groups: Group 1: only tinnitus masking sound was given, Group 2: Only counselling was given, Group 3: both masking with counselling was given and Group 4: tinnitus masking combined with counselling and multisensory attention diversion therapy was given. Therapy was given for 30 sessions, and each session was of 30-min duration.

The mean age of Group 1 participants was 42.24 ± 5.67 ($M=31$; $F=19$), Group 2: 43.9 ± 6.71 ($M=29$; $F=21$); Group 3: 44.5 ± 5.47 ($M=30$; $F=20$); and Group 4: 43.86 ± 6.24 ($M=29$; $F=21$). The mean value of the duration of tinnitus of participants in the experimental group ranged from 9.06 to 15.24 months. A control group consisting of 200 participants in the age range 20–55 years (mean age: 41.21, *SD*: 7.49) was selected for the study and had mild-to-moderate sensorineural hearing loss (pure-tone average 26 to 55 dBHL) without tinnitus. Those with the

any other associated medical problems such as hypertension, high blood pressure, diabetes mellitus, hypothyroidism, recruitment and any other ENT and/or neurological condition were excluded from the study.

Audiological tools

All the participants of control and experimental group had to undergo a detailed *tinnitus history* of the patients was recorded. This included the following: onset of tinnitus, duration of tinnitus, nature of tinnitus (single or multiple) as well as a verbal description of the pitch and loudness of tinnitus, any information regarding the way the tinnitus may have changed in nature (fluctuation) since it was first noticed, impact of both hearing loss and tinnitus on daily living, etc.

Pure-tone audiometry (PTA), including high frequency up to 12 kHz (9 kHz, 10 kHz, 11.2 kHz, 12.5 kHz), was carried out following the standard procedure [18] to determine the hearing threshold using MAICO MA-53 or Resonance r37a well-calibrated dual channel audiometer with HDA280 circum-aural headphones with MX-41 cushion in a sound-treated room (ANSI, 1991). Pulse tone was used in conducting pure-tone audiometry [55]. In *tympanogram and acoustic reflex*, tympanometry was carried out using GSI-38 immittance audiometer with 226-Hz probe tone for each participant to rule out middle ear pathology, if any. Ipsilateral and contralateral acoustic reflex assessment was done with presentation of tonal stimuli at 226-Hz probe tone with 110-dBSL stimulus level to elicit a reflex response from the stapedius muscle.

Pretreatment baseline evaluation

Psychosocial questionnaire

The Bangla version of psychosocial questionnaire [24] was administered on the experimental group only for measuring psychosocial impact. It is a 30-item questionnaire to measure (a) employment status, (b) somatic disease, and (c) psychosomatic disturbances. If the score is greater, it indicates more impact on psychosocial aspect.

Quality-of-life questionnaire

The developed Bangla version of quality-of-life questionnaire [25] was administered on both groups, i.e. control and experimental groups, for measuring quality of life.

Tinnitus severity index and tinnitus handicap inventory on experimental group

a) The Bangla version of Tinnitus Severity Index questionnaire was developed by Mandal, Chatterjee, Makar and Khemka [26] and was used to estimate the severity of the tinnitus.

b) The Bangla version of Tinnitus Handicap Inventory [7] was administered to determine the presence of perceived tinnitus handicap based on total THI score.

Measuring pitch, loudness, RI and MML for experimental group

Standardized tinnitus measurement procedure was developed by the Ciba Foundation in London [10] and the National Academy of Sciences [28]. These groups recommended a battery tests including pitch matching and loudness matching, residual inhibition and tinnitus maskability (MML). Pitch matching, loudness matching and tinnitus maskability were measured using MAICO MA-53 or Resonance r37a dual channel audiometer.

Phase II: Administration of management protocols

Four therapeutic processes were administered to the four experimental groups, respectively. *Group 1* participants were administered tinnitus masking/suppression therapy. The masking signal at the level of MML + 20 dB [49] was presented to the ipsilateral ear continuously for 30 min for consecutive 30 sessions. Masking was done in a sound-treated room using calibrated MAICO MA53 or Resonance r37a diagnostic audiometer with HDA280 headphones. For *Group 2*, only formal counselling for 30 sessions of 40 min each was provided. In the formal counselling method given by Tyler [48], the objective of this method was to promote habit and thus eliminate the problem, by removing any negative association to tinnitus. It comprised exhaustive discussions about the hearing loss, meaning of tinnitus, attention and habituation as well as about the treatment option of tinnitus to understand and demystify the symptom. Counselling session consisted of the following general categories of information that are typically provided to tinnitus patients [48]:

a. Hearing—Anatomy and physiology of hearing and hearing loss
b. Tinnitus epidemiology—Prevalence, causes and impact of tinnitus
c. Tinnitus mechanisms—Neurophysiological model
d. Central nervous system—Role of the brain in perceiving and reacting to sound
e. Attention—Factors that contribute to attention
f. Sleep—Factors that influence sleep
g. Concentration—Factors that contribute to concentration
h. Lifestyles—How our overall lifestyle, including eating, exercise and activities, influences our health
i. Self-image—How our self-image influences our beliefs and reactions

j. Treatment option for tinnitus—Variety of treatment option available for tinnitus, including coping strategies, relaxation therapy, cognitive behaviour therapy and sound therapies.

For *Group 3*, same masking level (MML + 20 dB) was presented in ipsilateral ear for 30 min continuously combined with 15-min counseling, for a total of 30 sessions. Masking signal was presented using calibrated MAICO MA53 or Resonance r37a diagnostic audiometer with HDA280 headphones. For *Group 4*, same masking levels (MML + 20 dB) were administered in ipsilateral ear by using Resonance r37a. This was combined with "multisensory attention diversion task" which was given by Spiegel et al. [46]. It is a combination of auditory, visual and tactile stimulation. Both auditory and tactile stimulation were provided to the contralateral ear. For auditory stimuli, pure tone was presented through TDH39 headphone, while for tactile stimulation, vibration was given through bone vibrator. For visual stimulation, presentation was made using a flash light. All three modes of stimulation were given for a total duration of 30 min, and stimulus duration was 2 s with 2-s interval. The participant was seated 32 cm away from the flash light of visual stimulation. The centre flash light was at 0° azimuth of the participants, and the other two lights were placed at a distance of 8 cm on both sides of it. The patients were instructed to look towards the glowing light and to listen to the pure-tone stimulus without attention to the contralateral tinnitus [46].

Phase III: Posttreatment evaluation

Following the treatment of 30 sessions, participants of the experimental group were required to once again undergo the following: administration of psychosocial questionnaire, administration of quality-of-life questionnaire, administration of TSI and THI, measuring pitch, loudness and MML.

Data analysis

The data was analysed by using a standard statistical programme called "SPSS version 17.0" as well as by using percentile method, ANOVA, Pearson correlation and parametric "*t*"-test.

Results

The tinnitus history research questionnaire yielded the information plurality of participants reported they perceive their tinnitus like noise in the left ear (45%) and in the right ear (37.5%). Also, 44.5% had high-pitched tinnitus, and 50.5% had very loud tinnitus. A comparison of subjective responses of tinnitus perception as tonal type, noise type or multiple type in relation to loudness ($n = 200$) shows no significant difference ($p = 0.77$) between the loudness of tinnitus and tonal, noise or multiple-type tinnitus. A comparison of subjective perceptions of loudness and pitch of tinnitus with negative effects shows that there was no significant difference ($p = 0.969$) between subjective perceptions of loudness and pitch of tinnitus with negative impacts on tinnitus sufferers. Comparison of subjective perception of loudness and pitch of tinnitus with negative effects or impacts of tinnitus may show that there was a highly significant difference ($\chi^2(3) = 18.15$, $p = 0.001$) between subjective perception of loudness and pitch of tinnitus with negative impact on tinnitus sufferers. Further, in the current study, it was found that the negative impact of tinnitus, such as sleep disturbance and concentration problems, is higher with noise like tinnitus.

Pure-tone audiometry

The mean value of pure tone average was found to be 43.68 dBHL SD ± 10.57 in the left ear and 43.56 dBHL SD ± 10.51 in right ear of control group participants. For the 4 experimental group participants, it was observed that lowest mean value was 37.86 dBHL SD ± 10.68, and highest mean value was 50.46 dBHL SD ± 15.51. Thus, it indicates that pure-tone average of both control and experimental groups ranges from mild to moderately severe hearing loss, and large standard deviation indicates the data was more spread out about the mean.

Psychoacoustic assessment of experimental group

The standard deviation of pitch (mean 2527.5, SD ± 2722.41) of tinnitus in Group 1 was larger than mean indicating that it is a nonnegative scale, and tinnitus pitch distribution was very right skewed in these participants. Also, the standard deviation of pitch of tinnitus was large indicating that the pitch data was more spread out about the mean in Group 2 (mean 2915, SD ± 2515.94), Group 3 (mean 3227.5, SD ± 2764.99) and Group 4 participants (mean 2665, SD ± 2479.82).

Results of questionnaire administration

Quality-of-life scores

Overall mean value of quality of life of Group 1 was 1012.64, Group 2 was 920, Group 3 was 932 and Group 4 was 1016. Higher mean value of quality of life represents the most favourable health status. From the mean value of different subscales, it can be inferred that tinnitus impact was more on emotional aspect and less on physical functioning. Sleep disturbance, cognition, anxiety and depression were main effects of tinnitus on quality of life.

Tinnitus severity

Mean value of the tinnitus severity Group 1 was 44.32, Group 2 was 44.74, Group 3 was 45.1 and Group 4 was 47.22. Larger mean value indicates the severity of tinnitus to be more.

Tinnitus handicap

Mean value of overall tinnitus handicap of Group 1 participants was 67.48, Group 2 was 60.72, Group 3 was 68.32 and Group 4 was 81.6. Groups 1, 2 and 3 participants fall under the severe handicap categories (58–76), and Group 4 falls under catastrophic handicap (78–100) [32].

Phase III: Performance of participants — post treatment

The mean value of loudness, pitch and minimum masking level is lowest for Group 4 (loudness mean = 23.7 SD ± 19.81, pitch mean = 655, SD ± 770.78, MML mean = 30.9, SD ± 25.42) and highest for Group 2 (loudness mean = 44.5 SD ± 15.22, pitch mean = 2715, SD ± 2529.29, MML mean = 63, SD ± 17.64).

Results of questionnaire administration

Psychosocial questionnaire

Overall mean value of psychosocial impact for Gr-1 was 77.46, and Group 2 was 91.36. Group 3 was 64.6, and Group 4 was 56.96, and overall mean value was lowest for Group 4 and highest for Group 2 after treatment.

Quality-of-life questionnaire

Overall mean value of quality of life of Gr-1 was 2541.6, Gr-2 2408.9, Gr-3 2695.6 and Gr- 4 3127.7, and overall mean value was lowest for Group 2 and highest for Group 4 participants after treatment.

Tinnitus severity index

Mean value of tinnitus severity of Group 1 participants — 26.08, Group 2 — 27.82, Group 3 — 18 and Group 4 — 14.36 post treatment may be seen. Mean value of the tinnitus severity was lowest for Group 4 and highest for Group 2 post treatment.

Comparison between control and experimental groups

Quality of life

Mean overall value of experimental group pre-treatment was 812.37, while that of control group was 2852.4. It was observed that mean score of control group was significantly higher than the mean score of experimental group. This indicates that the control group had better level of functioning in comparison to the experimental group. This may be attributed to the presence of tinnitus in the experimental group. Similar results were found for all the comparisons made, as well as individually for the various subscales and the overall score. Comparison between control and experimental group data value of t-statistics was found to be 70.76 with a degree of freedom 398 (400–2) and p-value (two-tailed test) as 0.001 which was less than 0.05. Thus, the overall results indicate that there was a significant difference between the control and experimental groups in terms of QoL.

Comparison between pre- and post-treatment scores within groups

Overall results indicate that there was a significant difference ($p = 0.001$, $df = 49$) between the pre- and post-therapy condition as measured by PSQ ($t = 27.76$), QoL ($t = 30.32$), THI ($t = 13.68$), pitch ($t = 4.65$), loudness ($t = 11.97$) and MML ($t = 12.47$) for Group 1 participants. For Group 2 participants, PSQ ($t = 12.9$), QoL ($t = 23.20$), THI ($t = 2.95$), TSI ($t = 18.94$), pitch ($t = 1.564$), loudness ($t = 1.75$) and MML ($t = 1.92$) indicate that there was a significant difference ($p = 0.001$, $df = 49$) between the pre- and post-counselling therapy condition.

These are pre- and post- "masking + counselling" therapy score PSQ ($t = 34.41$, $p = 0.001$), QoL ($t = 33.9$, $p = 0.001$), THI ($t = 17.44$, $p = 0.001$), TSI ($t = 51.88$), pitch ($t = 6.14$), loudness ($t = 16.13$) and MML ($t = 15.31$, $p = 0.001$) of tinnitus participants — Group 3. For Group 4 participants, PSQ ($t = 68.88$), QoL ($t = 82.02$), THI ($t = 63.14$), TSI ($t = 63.21$), pitch ($t = 6.40$), loudness ($t = 11.59$) and MML ($t = 12.85$) indicate that there was a significant difference ($p = 0.001$, $df = 49$) between the pre and post therapy condition. Thus, overall results indicate that there was a significant difference between the pre and post therapeutic condition through tinnitus masking, tinnitus counselling and masking + counselling + attention diversion task.

Pairwise comparison of pre-test-post-test change in post-treatment score between two subgroups (experimental)

Two sample t-test between only *masking (Group1) and only counselling (Group 2)* therapy scores of p-value shows that there was a highly significant difference between Group treatment procedures in bringing about changes in psychosocial aspects ($p = 0.001$), tinnitus severity ($p = 0.001$), tinnitus handicap ($p = 0.003$), loudness ($p = 0.001$), pitch ($p = 0.003$) and masking level ($p = 0.001$) among tinnitus participants. However, the p-value of quality of life ($p = 1.0$) indicates that there was no significant difference. Changes in QoL which are not observed at present may perhaps be observed after a longer period because such changes are gradual. Two samples t-test between *counselling (Group 2) and "masking + counselling" (Group 3)* therapy scores of tinnitus participants — the p-value of PSQ ($p = 0.001$),

QoL ($p=0.001$), tinnitus severity ($p=0.001$), tinnitus handicap ($p=0.001$), tinnitus loudness, pitch, and MML ($p=0.001$), shows that there was a highly significant difference between Group 2 and Group 3 therapeutic procedures in changes/impact among tinnitus participants. Two samples *t*-test between only *masking and "masking + counselling"* therapy scores of tinnitus participants — the *p*-value of PSQ ($p=0.001$), QoL ($p=0.001$), tinnitus severity ($p=0.001$) and tinnitus handicap ($p=0.001$), shows that there is a highly significant difference between these group therapeutic procedure in changes/impact among tinnitus participants. However, the *p*-value of tinnitus pitch ($p=1.00$), loudness ($p=1.00$) and MML ($p=1.00$) shows that there was no significant difference. Two samples *t*-test between *masking vs "masking + counselling + attention diversion task"* — therapy scores of tinnitus participants — the *p*-value of PSQ ($p=0.001$), QoL ($p=0.001$), tinnitus severity ($p=0.001$), and tinnitus handicap ($p=0.001$), loudness ($p=0.004$), MML ($p=0.009$), shows that there is a highly significant difference between these group therapeutic procedure in changes/impact among tinnitus participants. However, the *p*-value of tinnitus pitch ($p=1.00$) shows that there was no significant difference. In two samples *t*-test between *"masking + counselling" vs "masking + counselling + attention diversion task"* therapy scores of tinnitus participants — the *p*-value shows that there was a highly significant difference between Group 3 therapy procedure and Group 4 therapy procedure in bringing about changes/impact on QoL, TSI and THI. While significant impact was observed for PSQ, loudness and MML, no significant changes occurred for tinnitus pitch. Two samples *t*-test between only *counselling and "masking + counselling + attention diversion task"* therapy scores of participants — the *p*-value of PSQ ($p=0.001$), QoL ($p=0.001$), TSI ($p=0.001$), tinnitus handicap ($p=0.001$), tinnitus loudness ($p=0.001$), MML ($p=0.001$) and pitch ($p=0.001$), indicate that there was a highly significant difference between these group therapeutic procedure in bringing about changes/impact among tinnitus participants.

Pairwise comparison of pre-test-post-test change in post-treatment score between two subgroups (experimental)

Impact on psychosocial aspects

Participants experienced statistically significant improvements in psychosocial scores (ANOVA, $F=60.82$, $p<0.001$)). Post hoc analysis (Bonferroni multiple comparison test) comparing the treatment procedures shows statistically significant improvements post-masking ($p<0.001$), post-counselling ($p<0.01$), post masking + counselling" ($p<0.003$) and post- "masking + counselling + attention task" ($p<0.001$). The magnitude of improvement on psychosocial aspects after 30 sessions of treatment by different approaches is dependent on the Cohen *d*-value. Here, Cohen *d*-value of masking vs counselling was $d=0.39$ (medium), counselling vs "masking + counselling" $d=0.79$ (medium), masking vs "masking + counselling" $d=0.53$ (medium), masking vs "masking + counselling + attention diversion task" $d=1.08$ (large) and counselling vs "masking + counselling + attention diversion task" $d=1.17$ (large). Highest improvement in psychosocial aspects was attained by "masking + counselling + attention diversion task" and least improvement by counselling.

Impact on quality of life

Participants experienced statistically significant improvements in quality of life from baseline to 30 sessions post-masking, 30 sessions post-counselling, 30 sessions post- "masking + counselling" and 30 sessions post- "masking + counselling + attention task" (ANOVA $F=32.53$, $p<0.001$). Post hoc analysis (Bonferroni multiple comparison test) comparing the treatment procedures shows statistically significant improvements for all four treatments. Cohen *d*-value of masking vs counselling was $d=0.2$ (small), counselling vs "masking + counselling" $d=0.33$ (small), masking vs "masking + counselling" $d=0.32$ (small), masking vs "masking + counselling + attention diversion task" $d=1.03$ (large) and counselling vs "masking + counselling + attention diversion task" $d=0.9$ (large). Hence, highest improvement in quality of life was obtained by "masking + counselling + attention diversion task" and least improvement by counselling.

Impact on tinnitus severity index

Participants experienced statistically significant improvements in tinnitus severity from baseline to 30 sessions post-masking, 30 sessions post-counselling, 30 sessions post- "masking + counselling" and 30 sessions post- "masking + counselling + attention task" (ANOVA, $F=138.74$, $p<0.001$)). Here, Cohen *d*-value of masking vs counselling was $d=0.7$ (medium), counselling vs "masking + counselling" $d=0.98$ (large), masking vs "masking + counselling" $d=1.16$ (very large), masking vs "masking + counselling + attention diversion task" $d=1.93$ (very large) and counselling vs "masking + counselling + attention diversion task" $d=1.54$ (very large). Hence, it is observed high improvement in tinnitus severity by "masking + counselling + attention diversion task" and least improvement by Counselling.

Tinnitus handicap scores

Participants experienced statistically significant improvements in tinnitus handicap from baseline at 30 sessions

post-masking, 30 sessions post-counselling, 30 sessions post- "masking + counselling" and 30 sessions post- "masking + counselling + attention task" (ANOVA, $F = 295.31$, $p < 0.001$)). Post hoc analysis (Bonferroni multiple comparison test) comparing the treatment procedure shows statistically significant improvements for all four treatments. Cohen d value of masking vs counselling was $d = 0.53$ (medium), counselling vs "masking + counselling" $d = 1.33$ (very large), masking vs "masking + counselling" $d = 1.16$ (very large), masking vs "masking + counselling + attention diversion task" $d = 3.76$ (huge) and counselling vs "masking + counselling + attention diversion task" $d = 3.25$ (huge). Hence, highest improvement in tinnitus handicap scores was attained by "masking + counselling + attention diversion task" and least improvement by counselling. According to Newman, Sandridge and Jacobson [32], a change in the total THI score of at least 20 points suggests that treatment is statistically and clinically effective.

Tinnitus pitch and loudness scores

Participants experienced statistically significant improvements in tinnitus pitch from baseline to 30 sessions post masking, 30 session post counselling, 30 session post- "masking + counselling" and 30 sessions post- "masking + counselling + attention task" (ANOVA, $F = 8.57$, $p < 0.001$). Post hoc analysis (Bonferroni multiple comparison test) comparing the treatment procedures shows statistically significant improvements for all the four treatments. Cohen d value of masking vs counselling was $d = 0.39$ (small), counselling vs "masking + counselling" $d = 0.52$ (medium), masking vs "masking + counselling" $d = 0.8$ (large), masking vs "masking + counselling + attention diversion task" $d = 0.06$ (very small) and counselling vs "masking + counselling + attention diversion task" $d = 0.53$ (medium). Hence, highest pitch changes were observed for "masking + counselling + attention diversion task" and least improvement for counselling.

The magnitude of improvement on pitch, loudness and MML after 30 sessions treatment by different approaches is dependent on the Cohen d value. Cohen d value of masking vs counselling was $d = 0.69$ (medium), counselling vs "masking + counselling" $d = 0.9$ (large), masking vs "masking + counselling" $d = 0.16$ (small), masking vs" masking + counselling + attention diversion task" $d = 0.31$ (small) and counselling vs "masking + counselling + attention diversion task" $d = 0.85$ (large). Hence, it was observed that highest improvement was obtained for "masking + counselling + attention diversion task" and least improvement for counselling.

Discussion

De Barros Suzuki, Suzuki, Yonamine, Onishi and Penido [6] reported that PT tinnitus (whistle) has a better response to the treatment with masking than the noise-type tinnitus because of large area spectrum activity involved in central nervous system with respect to noise than tonal tinnitus. Hébert and Carrier [13] reported that tinnitus patients complained more of sleep difficulties than their non-tinnitus counterparts because of subclinical depressive symptoms. Therefore, they recommended the tinnitus treatment goal should focus on decreasing sensitivity of tinnitus along with coping with depressive symptoms.

Pure-tone audiometry

Ukaegbe, Ezeanolue and Orji [50] and Gudwani, Munjal, Panda and Verma [11] also reported similar findings on conventional audiometry; tinnitus ears had normal, mild, moderate and severe hearing loss. Those tinnitus patients, who had normal hearing in conventional audiometry, had mild hearing loss in extended high-frequency audiometry (PTA2). All tinnitus patients had greater hearing loss at high frequency [27].

Psychoacoustic assessment of experimental group

Several efforts have been made to explore why tinnitus pitch is perceived as high pitched and the relationship between tinnitus pitch and audiogram. Two main theories, i.e. "edge effect" and "homeostatic" mechanism, are popular. König, Schaette, Kempter and Gross [22] and Moore, Vinay and Sandhya [31] suggested a positive correlation between tinnitus pitch and edge frequency (the first frequency at which the hearing threshold dip 20 dBHL). While Norena [33] and Schaette and Kempter [39] believed in "homeostatic" mechanism, i.e. discordant damage of hair cells leads to reduction in sensory input to the auditory nerve, to compensate this reduced input, homeostatic mechanism comes into play. This homeostatic mechanism increases central gain and reduces cortical inhibition, leading to amplification of neural noises which are perceived as tinnitus. According to this hypothesis, the tinnitus pitch should fall in the hearing loss region. Another hypothesis given by Shekhawat, Searchfield and Stinear [41] proposed that strongest audiometric predictor for tinnitus pitch was the frequency at which threshold was 50 dBHL. This threshold intensity is important in tinnitus generation as it represents the approximate degree of hearing loss required for transition from OHCs to IHCs loss. The IHCs provide the afferent input to the auditory nerve; hence, IHCs damage (beginning at approximately hearing threshold of 50 dBHL) may contribute to tinnitus pitch

as a result of central plasticity changes of the frequency of deafferentation. Sereda, Hall, Bosnyak, Edmondson, Roberts, Adjamian and Palmer [44] opined that this suggests that damage of IHCs accompanying OHCs dysfunction may be the underlying factor for tinnitus generation. To confirm this hypothesis, psychoacoustics tuning curve test results require identifying dead region in the cochlea [41]. In the present study, majority of the patients matched their tinnitus pitch from 2 to 8 KHZ; this supports the findings of Shekhawat, Searchfield and Stinear [41], Schecklmann, Vielsmeier, Steffens, Landgrebe, Langguth and Kleinjung [40], and Pan, Tyler, Ji H., Coelho, Gehringer and Gogel [35].

Results of questionnaire administration

Quality-of-life scores

From the mean value of different subscales, it can be inferred that tinnitus impact was more on emotional aspect and less on physical functioning. Sleep disturbance, cognition, anxiety and depression were main effects of tinnitus on quality of life. Similar findings were reported by Riedl, Rumpold, Schmidt, Zorowka, Bliem and Moschen [37] who investigated the influence of tinnitus acceptance on QoL in 97 patients with chronic tinnitus. They found that highly significant differences between patients with "low-to-mild tinnitus acceptance" and patients with "moderate-to-high tinnitus acceptance" regarding their QoL ($t=4.48$, $p<0.001$). However, no significant difference was found between the two groups regarding the physical aspects of their quality of life ($t=0.61$, $p=0.26$). Higher tinnitus acceptance was strongly correlated with higher QoL.

Tinnitus severity

Bhatt, Lin and Bhattacharyya [3] attempted to quantify the severity of tinnitus in the United States. Cross-sectional analysis of 75,764 representative samples of adults (age ≥ 18 years) who experienced tinnitus in the past 12 months was undertaken. Among those who reported tinnitus, 27% had symptoms for longer than 15 years, and 36% had nearly constant symptoms. In terms of severity, 7.2% reported their tinnitus as a big or very big problem, 20.2% as moderate problem and 41.6% reported it as a small problem; remaining 31% was not bothered by tinnitus.

Tinnitus handicap

Yenigün, Doğan, Aksoy, Akyüz and Dabak [56] aimed to classify tinnitus symptoms on the basis of Tinnitus Severity Index (TSI) and Tinnitus Handicap Inventory (THI) [4] in patients with and without hearing loss. Of a total of 102 patients, 48 had normal hearing, and 54 had hearing loss. In the group with normal hearing, tinnitus severity was in range of 14–55 (average 33 ± 12) and THI in range of 4–78 (average 44 ± 22). In the group with hearing loss, TSI was in range of 12–60 (average 32 ± 12) and THI in range of 4–84 (average 41 ± 25). Tinnitus severity was significantly higher in patients with hearing loss compared to patients with normal hearing ($p<0.05$). TSI and THI results showed a significant similarity between the two groups ($p<0.05$). Thus, tinnitus patients were affected by tinnitus at the same rate whether they have hearing loss or not.

Comparison between control and experimental groups

Quality of life

Adoga, Kokong, Nimkur and Okwori [1] investigated the impact of tinnitus on health-related quality of life, psychological and emotional wellbeing of 49 patients and age range 22–79 years (mean = 36.8; $SD = \pm 12.7$) consisting of 44.9% males and 55.1% females. Depressive symptom was observed in 28.6% female and 22.4% male patients. Anxiety was found in 36.7% female and 32.6% male patients. A total of 69.4% patients scored low on all quality-of-life (QoL) domains except pain levels. All patients irrespective of age and gender showed statistically significant positive correlations between all the QoL domains (p-value 0.5). Univariate analysis shows statistically significant inverse correlation between emotional distress scores and each of emotional wellbeing scores. The study looked into the impact of tinnitus on the QoL and psychological and emotional wellbeing of tinnitus patients with a view to improving treatment outcome for tinnitus sufferers.

Comparison between pre- and post-treatment scores within groups

Patients whose tinnitus pitch matched with the masking sound frequency had a large treatment effect than those for whom tinnitus pitch was not matched with masking sound frequency. It may be due to central plastic reorganization as a consequence of the degree of neural excitation by sound [34]. Results indicated that tinnitus pitch match is a useful tool to predict the effects of tinnitus masking. The results of the present study show that 76% of the patients (114/150) prefer narrow band masking noise (NBN) compared with other sounds for tinnitus masking. This may be because of the bandwidth of the patient's tinnitus itself. That is, those patients having tinnitus-like sound with large bandwidth may prefer NBN or the masking sound with large enough bandwidth obtained from a sound reproduction system. Therefore, it is concluded that the centre frequency of tinnitus and the bandwidth of masking noise must be similar to treat tinnitus patients. Psychoacoustic characteristics are helpful to estimate treatment outcome; however, it is insufficient

to explain why tinnitus with the same character gives comfort for one but discomfort for other. Therefore, only psychoacoustic tests are not sufficient to assess treatment outcome; it is important to evaluate how tinnitus is psychosomatically perceived. It is possible to obtain information on the severity of tinnitus using THI and TSI questionnaires. THI and TSI are reliable scales with a high level of consistency in the symptom evaluation of patients with tinnitus [32, 30]. The available research on tinnitus masking supports the viewpoint that tinnitus masking may be an effective tool in reducing a patient's perception of tinnitus loudness when the patient's tinnitus pitch falls within the stimulated frequency range; it also provides long-term effect as it improves quality of life.

The tinnitus patient has to adjust to not only the perception of internal noise but also high level of emotional distress, sleep difficulties, loss of concentration, attention problems and disruption to their personal, occupational and social lives [48]. It produces sufficient annoyance with day-to-day activities and quality of life [52]. One of the goals of the tinnitus treatment is to reduce the negative impact; counselling helps the patient to understand their tinnitus, which can reduce the occurrence and level of distress caused by tinnitus due to an individual's inability to habituate to the signal [15]. Andersson, Baguley and McKenna [2] suggested that those patients who have moderate to high-level anxiety and/or depression associated with tinnitus are suitable candidates for counselling treatment.

It is believed that sound therapy increases extrinsic sound-driven activity of the auditory system which reduces tinnitus. However, it is important to highlight that in spite of clinically sound therapy approach applied, the effect of intervention programme is associated with counselling [38, 48]. Counselling helps in breaking the vicious cycle caused by the tinnitus and helps the patients in decision-making, coping and behaviour changes. It was observed that there was a greater effectiveness of treatment from the use of masking with counselling compared to masking alone. The goal of combined masking and counselling was to suppress the tinnitus audibility and desensitize negative emotional reaction towards tinnitus. Masking therapy is designed to suppress and desensitize tinnitus audibility using pitch and loudness matched sound above the effective masking level (EML). The treatment utilizes a spectrally modified neural stimulus in the form of matched stimulus (noise/tone), customized for each individual's audiometric profile to re-modify tonotopicity of the auditory neural pathway [5]. Tinnitus is considered as being caused by an aberrant signal in the auditory nervous system that has been conditioned to activate the limbic and autonomic nervous systems, resulting in emotional reactions and stress. Through structured educational counselling, the aberrant signal undergoes reconditioning to be reclassified by brain processing centres as a meaningless and unimportant signal. This is also called "retraining" the brain to habituate to the tinnitus signal [21]. The main components are directive counselling and use of noise on tinnitus ear through audiometer for 45 min for 30 sessions. Observational studies have reported significantly improved patient outcome after treatment with masking and counselling combined and is superior to masking treatments. Improvement depends on successful counselling and appropriate matched masking stimulus presentation.

A number of individual treatment approaches are available such as masking [51], counselling [48], attention diversion training [46], TRT [20] and cognitive behaviour therapy [16]; however, traditional methods are not sufficient to treat tinnitus. New approaches are needed which would deal with auditory system, limbic system and autonomous nervous system. The multisensory attention training method involves auditory, visual and somatosensory stimulation and is a new approach for tinnitus management [46]. There is evidence which supports the fact that attention training method comes as an effective procedure for a number of cortically based disorders such as tinnitus [43, 54]. The findings of Wise et al. [53] also support the present study. An experimental attention training game was introduced to 15 participants, and it was concluded that the attention training game not only reduced the severity of tinnitus but also potentially improved selective attention. Herraiz, Diges, Cobo and Aparicio [17] indicated that tinnitus-related activity leads to changes in tonotopic representation in auditory cortex rather than periphery pathway. Auditory discrimination training could partially reverse the changes in tonotopic reorganization, thus suppressing the tinnitus perception.

In the present study, the specific trends in positive effects have been demonstrated more empathetically (Table 1), probably due to large (Cohen's $d=0.8$) or very large (Cohen's $d=1.2$) effect sizes for some of the domains like PSQ, TSI and THI. However, in some domains like QoL, pitch, loudness and MML where the effect size (d) was found to be relatively smaller (Cohen's $d=0.2$), such effects were found less pronounced. It therefore appears that the inclusion of an integrated package of intervention (masking + counselling + attention diversion) is essential so as to get bigger effect sizes and better impact on various domains affecting the tinnitus population. In general, tinnitus masking provided better results to reduce tinnitus pitch, loudness and minimum masking level, whereas counselling showed reduction in impact of tinnitus, i.e. anxiety, depression, improved emotional and

Table 1 Pairwise comparison of magnitude of impact across various scales using Cohen's d

Group comparison		Significance and impact						
		Instruments						
		PSI	QoL	TSI	THI	Pitch	Loudness	MML
Masking vs counselling	*p*-value	HS	NS	HS	HS	HS	HS	HS
	d-value	M	S	M	M	S	M	M
Counselling vs masking + coun	*p*-value	HS	HS	HS	HS	HS	HS	HS
	d-value	M	S	L	VL	M	L	L
Masking vs masking + counselling	*p*-value	HS	HS	HS	HS	NS	NS	NS
	d-value	M	M	VL	VL	L	S	S
Masking vs mask + coun + attention div	*p*-value	HS	HS	HS	HS	NS	HS	HS
	d-value	L	L	VL	H	VS	S	S
Masking + counselling vs mask + coun + attention div	*p*-value	S	HS	HS	HS	NS	S	S
	d-value	S	M	M	M	VS	S	S
Counselling vs mask + coun + attention div	*p*-value	HS	HS	HS	HS	HS	HS	HS
	d-value	L	L	VL	H	M	L	L
NS—not significance ($p \geq 0.05$)		VS—very small ($d = 0.01$)						
S—significance ($p < 0.05$)		S—small ($d = 0.2$)						
HS—highly significance ($p < 0.01$)		M–medium ($d = 0.5$)						
VHS—very high significance ($p < 0.001$)		L—large ($d = 0.8$)						
		VL—very large ($d = 1.2$)						
		H—huge ($d = 2$)						

social function, sleep and quality of life. Therefore, when treatment is combined, it reduces tinnitus and its impact on a patient's life.

Summary and conclusion

The differences in outcomes suggest that "masking + counselling + attention diversion task" might be preferable for providing immediate tinnitus relief by masking through reducing tinnitus loudness and pitch by altering neuroplasticity (tonotopicity); in the long term, it reduces tinnitus impact through positive thinking by counselling treatment and also diverts attention to daily activity through attention training. The treatment should be conducted in a longitudinal manner to achieve optimal benefit.

Abbreviations

QoL Quality of life
PSQ Psychosocial questionnaire
TSI Tinnitus Severity Index
THI Tinnitus Handicap Inventory
RI Residual inhibition
MML Minimum masking level

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Authors' contributions

The author declares that he is the single author of this manuscript. The author read and approved the final manuscript.

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Availability of data and materials

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Declarations

Ethics approval and consent to participate

The research proposal was presented before and approved by the Board of Ethics of AYJNIHH, Mumbai, on 05/01/2012 (Office Order no. F/NIHH/PhD/2012). All information regarding participants was kept confidential. Participants were required to provide informed consent in writing.

Consent for publication

Not applicable.

Competing interests

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