

FRACTAL TONES FOR NORMAL HEARING LISTENERS WITH TINNITUS

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Introduction

The effectiveness of using fractal tones and amplification as sound stimulation in managing tinnitus has been shown through recent studies addressing individuals with hearing loss. There is less literature to address these management options with normal hearing individuals or those individuals with mild hearing loss and tinnitus who do not require amplification.

Widex has recently introduced Zen2Go – an ear-level tinnitus device designed specifically for normal hearing individuals with tinnitus or individuals with mild hearing loss and tinnitus who do not require amplification. The device includes three programs for sound stimulation using fractal tones and noise. Together with Zen2Go, a therapy approach has been developed – Widex Zen Therapy (WZT) – which addresses tinnitus stressors in the auditory, attention, and emotion domains. The program combines counseling through cognitive-behavioral intervention (CBI), amplification, fractal tones (Zen), and relaxation. After the characteristics of the tinnitus and the individual's reaction to the tinnitus has been established, the appropriate components of the program are determined and administered, creating an individual approach.

Aim of the study

This clinical trial was conducted to evaluate the effectiveness of the Zen2Go and Widex Zen Therapy in reducing tinnitus distress on normal hearing subjects or those subjects with a mild hearing loss who do not require amplification.

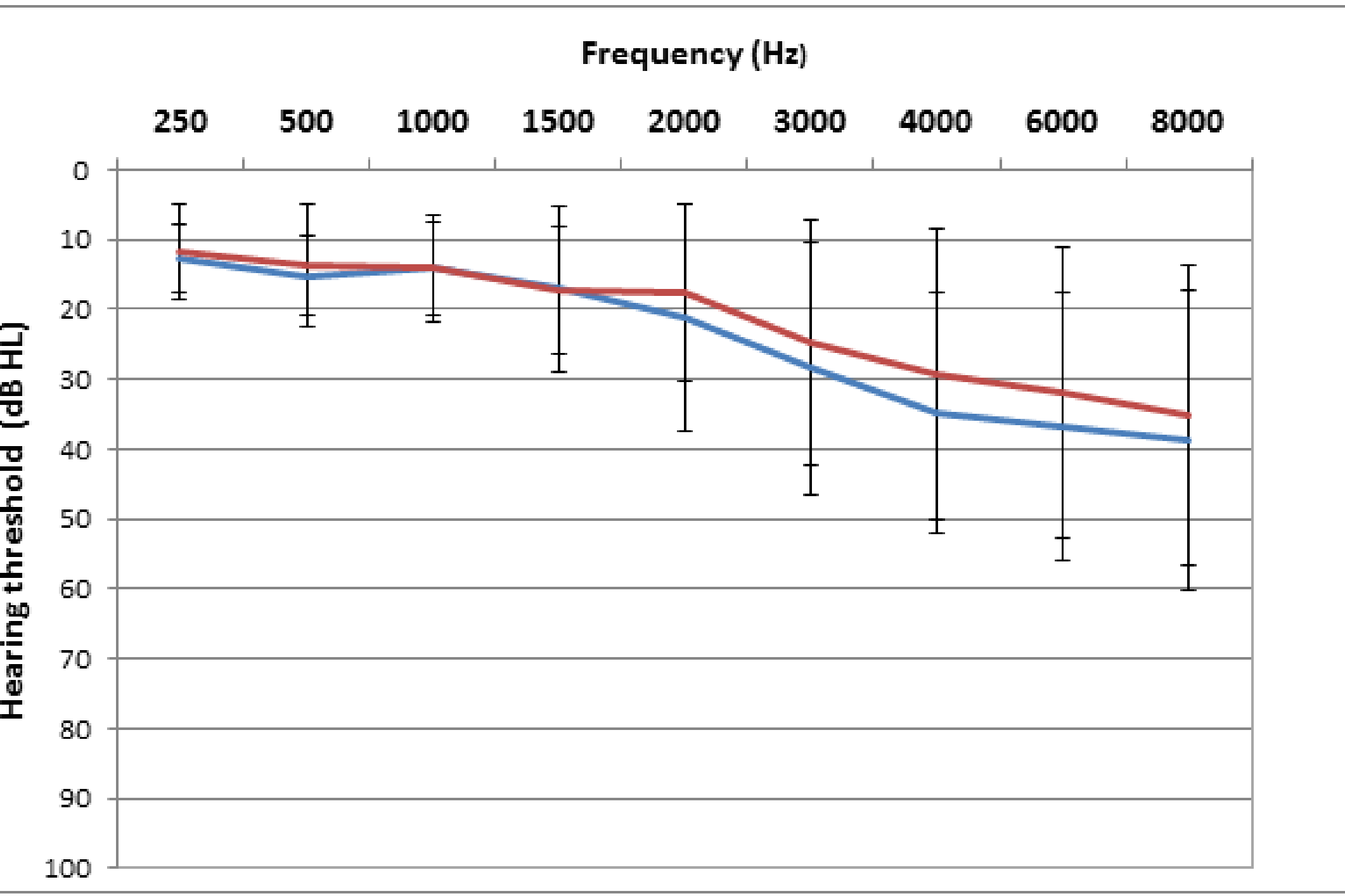


Figure 1: Mean thresholds and 1 standard deviation for the treatment group (blue) and control group (red) are shown.

Method

A total of 41 subjects were recruited for this study, and complete data was obtained on 36 subjects. These subjects had normal hearing or mild hearing loss that did not require amplification, and had THI scores of 19 or greater, suggesting significant distress from tinnitus. All subjects completed tinnitus measurement scales and an audiological evaluation, and were provided with instructional counseling on tinnitus.

Two groups of subjects were formed – one treatment group and one control group. The treatment group received Zen2Go at the fitting appointment, and then returned for follow-up visits at 1, 2, 4, and 6 months. If THI scores did not fall below 19 during the first two months, WZT components were provided in addition to continued Zen2Go use.

The control group returned for 2, 4, and 6-month follow up visits. A 12-month follow-up visit was also conducted to evaluate tinnitus handicap for both groups of subjects. THI, TFI and visual analog scales (VAS) scores were recorded at 2, 4, 6, and 12 month visits.

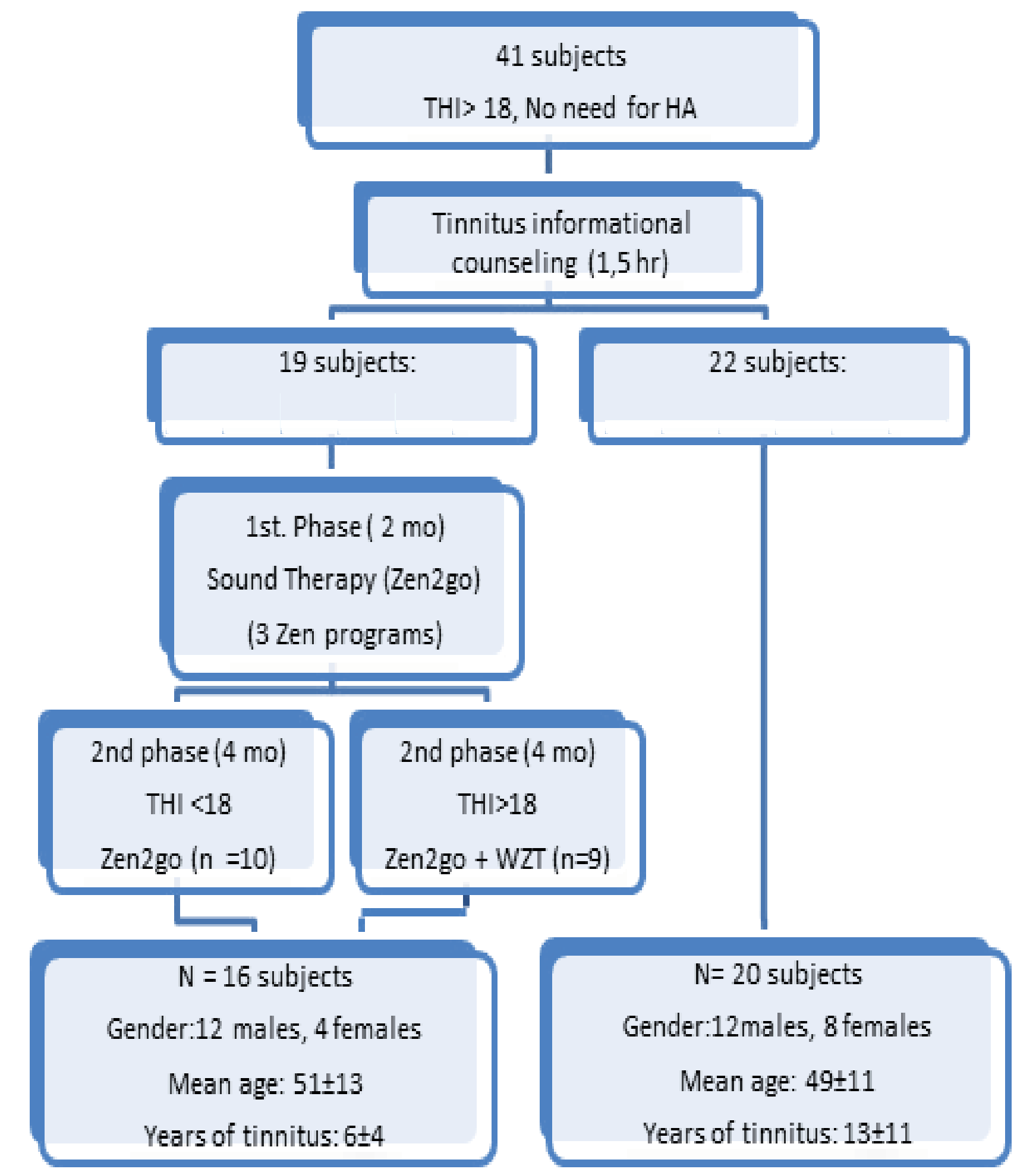


Figure 2. Flowchart describing the different study groups and course of the study phases.

Results

Data analysis revealed significant improvements in tinnitus distress for the treatment group compared to the control group ($p < 0.001$). Significant improvements in mean THI, TFI, and VAS scores were observed after two months in the treatment group, and these improvements continued over the 6 month duration ($p < 0.001$).

Only slight improvements were observed in the control group at 2 months, with no further improvements over the remainder of the study ($p > 0.05$). Non-significant increases in mean scores (greater distress) were found at the conclusion of the study (12 month visit) for the treatment group ($p > 0.05$).

Logging revealed increased Zen2Go use at 4 months and again at 6 months post-fitting.

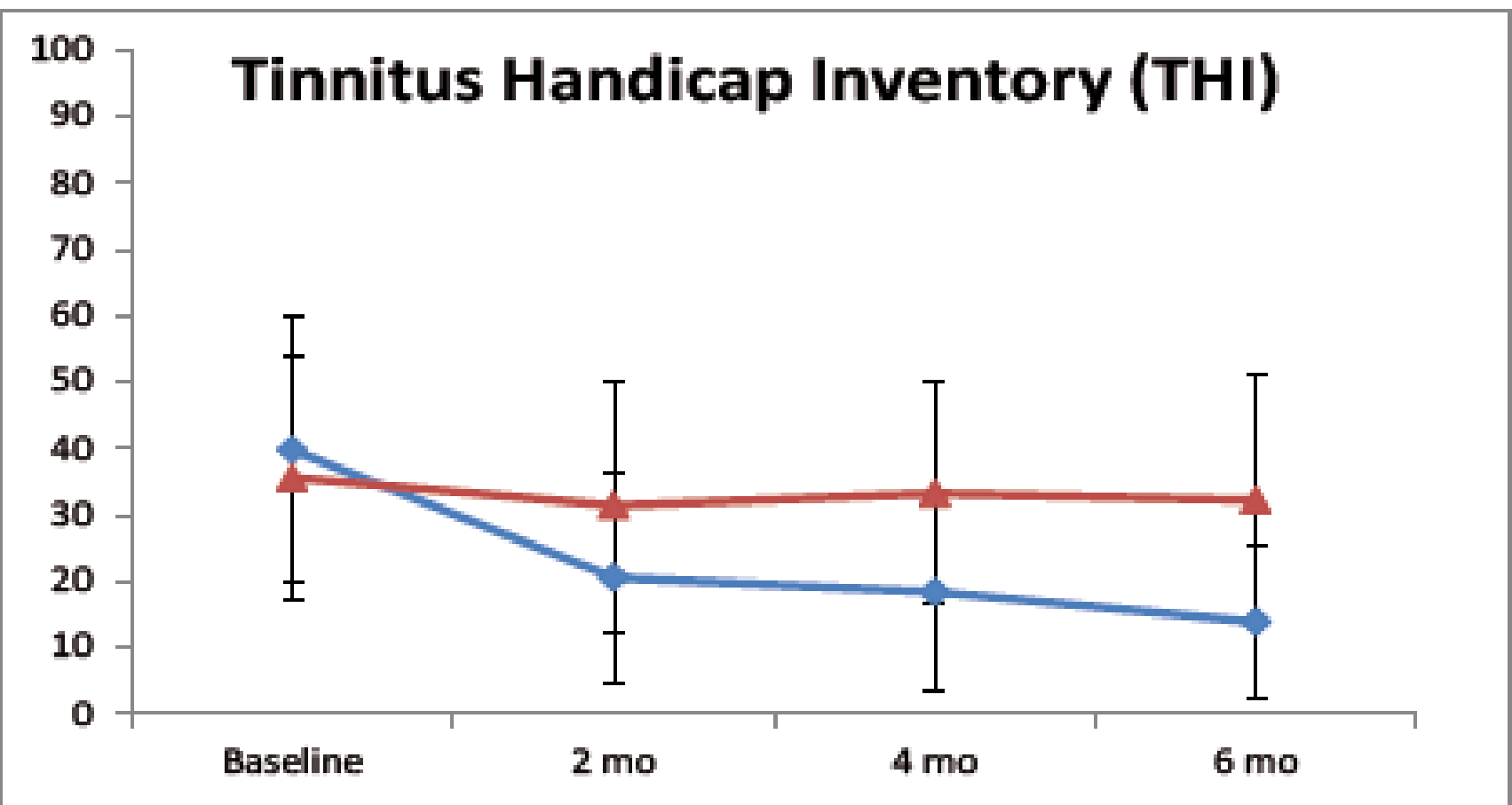


Figure 3. Mean Tinnitus Handicap Scores (THI) for treatment (blue) and control (red) groups at baseline, 2, 4 and 6 month follow-up; Bars indicate 1 standard deviation.

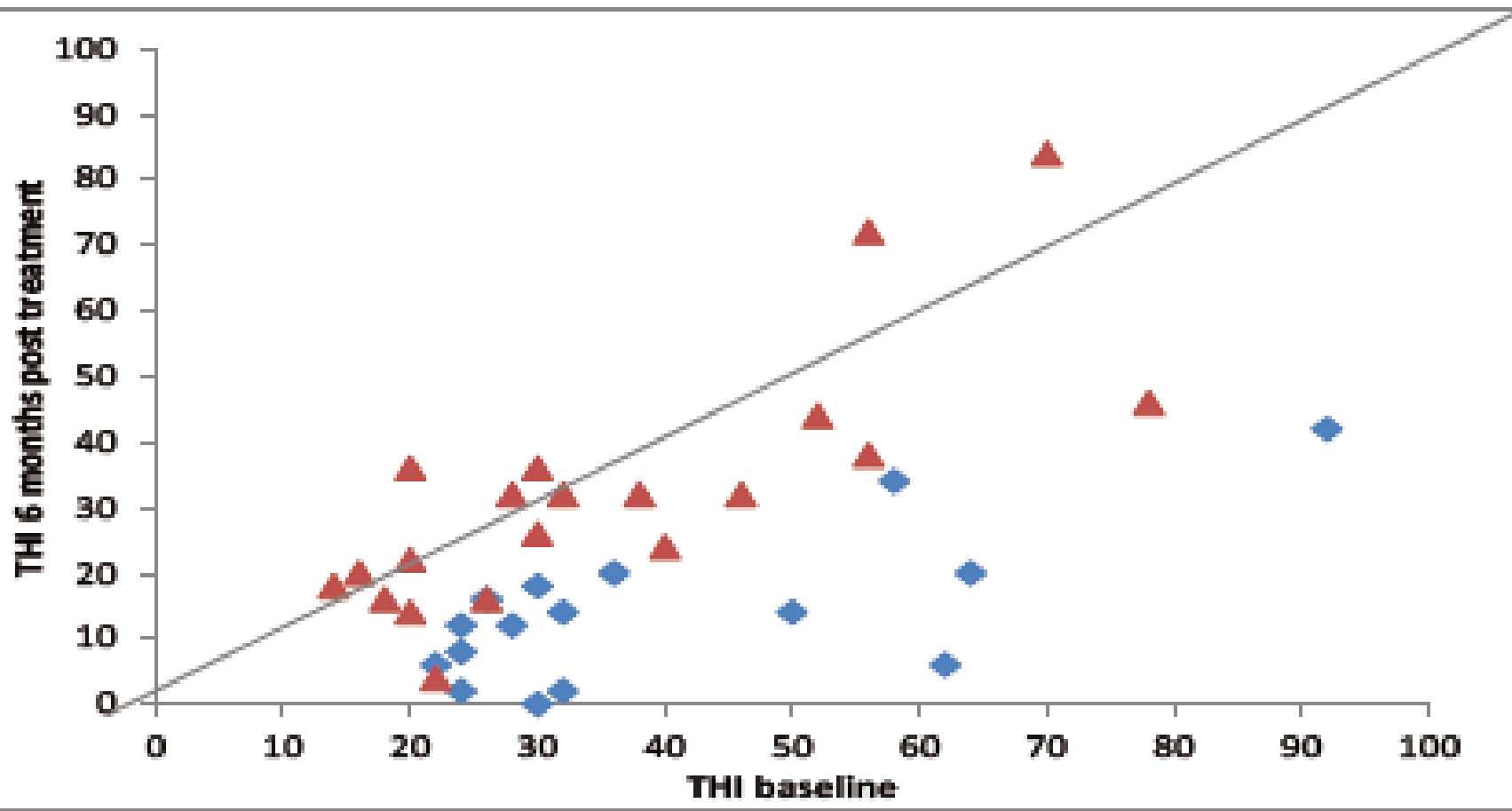


Figure 4: Individual subject THI scores at baseline and at 6 month follow-up for treatment (blue) and control (red) groups.

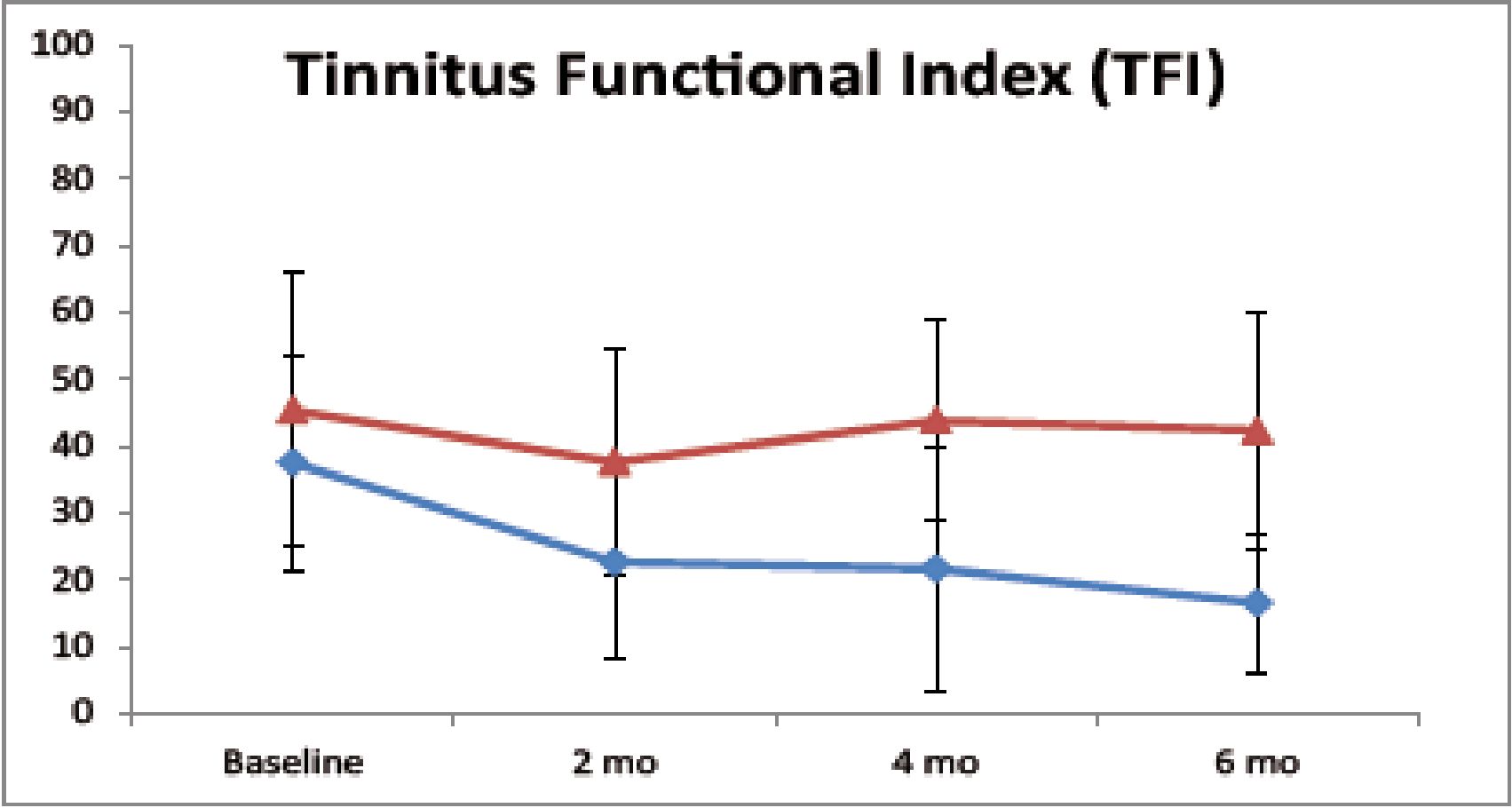


Figure 5: Mean Tinnitus Functional Index (TFI) for treatment (blue) and control (red) groups at baseline, 2, 4 and 6 month follow-up; Bars indicate 1 standard deviation.

Tinnitus Numerical Scales

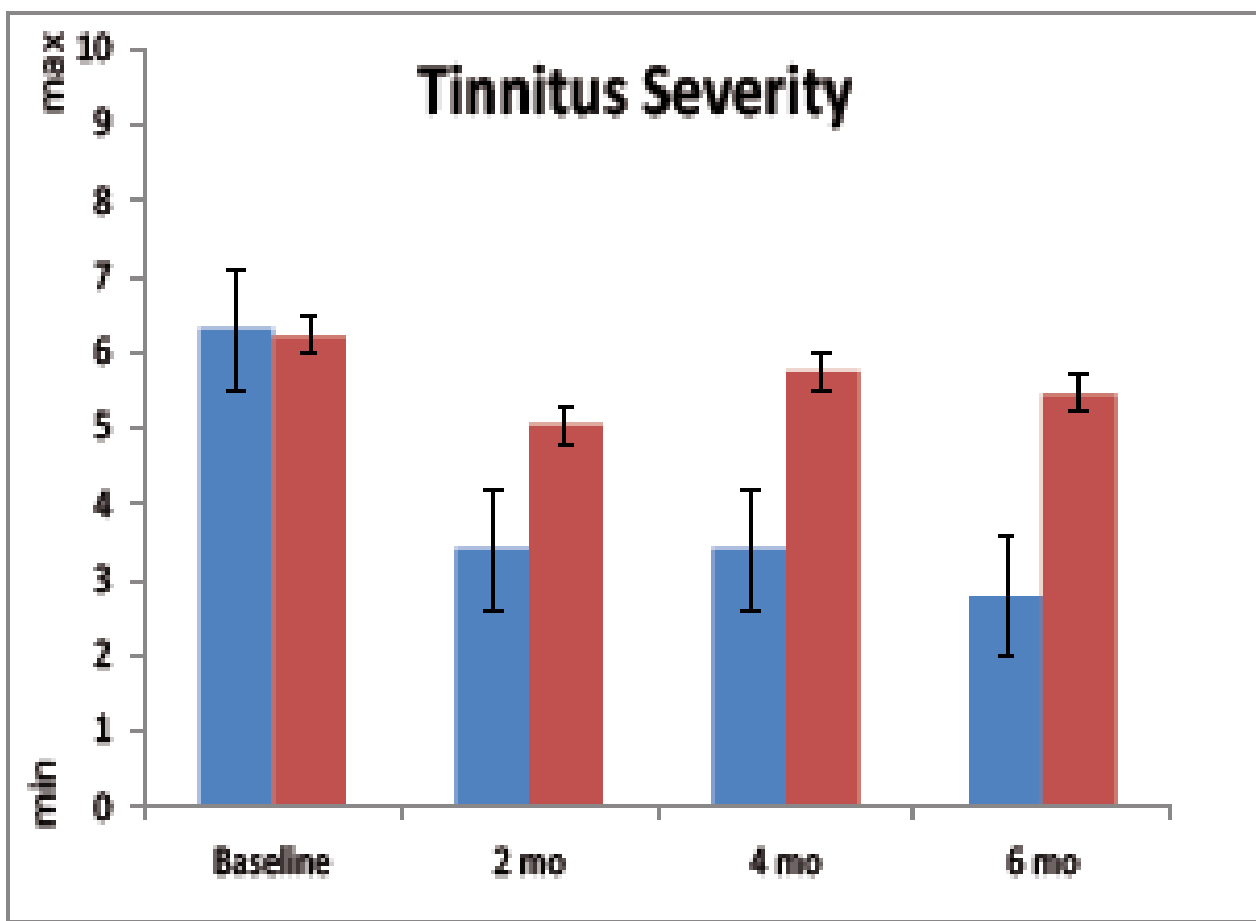


Figure 6. Mean ratings for Tinnitus Severity for treatment (blue) and control (red) groups at baseline, 2, 4 and 6 months.

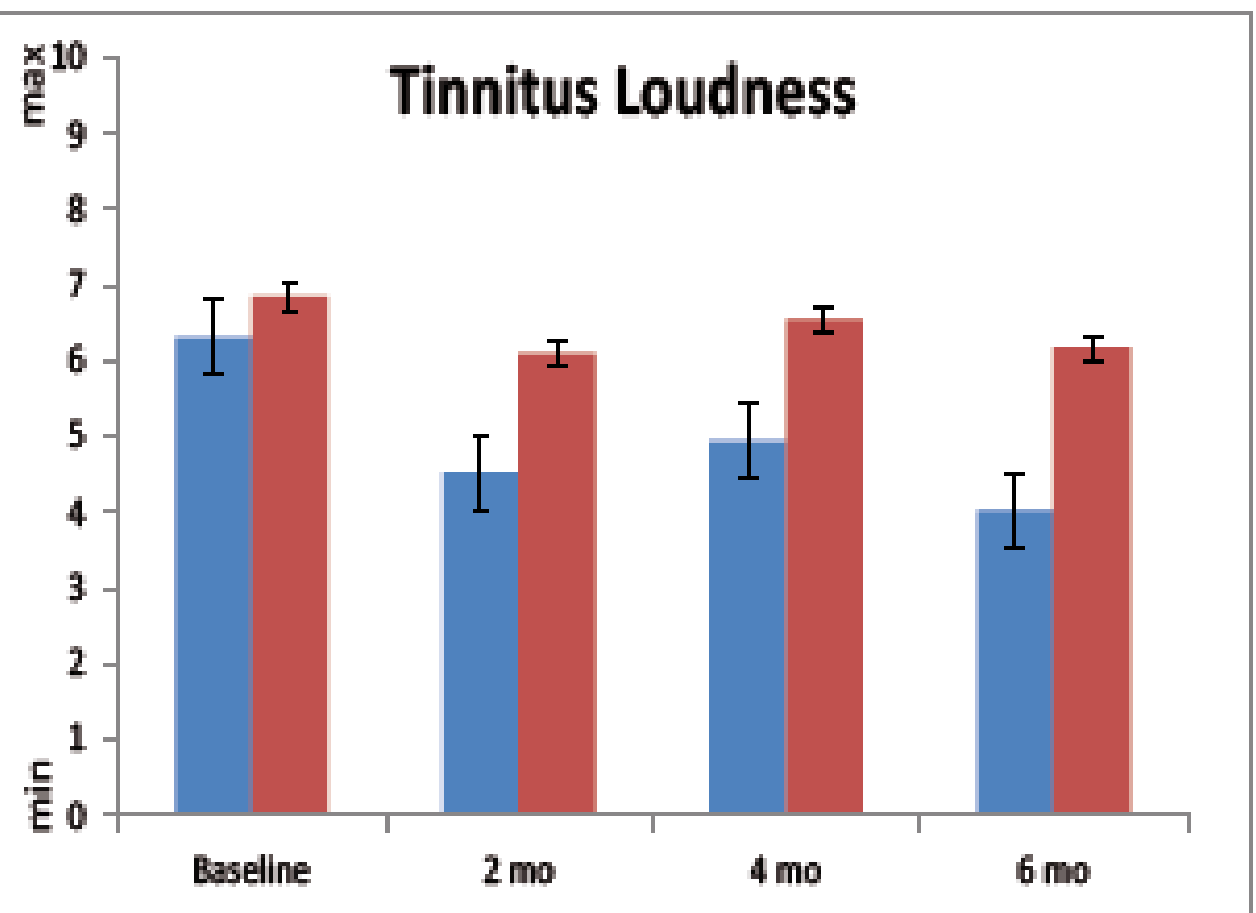


Figure 7: Mean ratings for Tinnitus Loudness for treatment (blue) and control (red) groups at baseline, 2, 4 and 6 months.

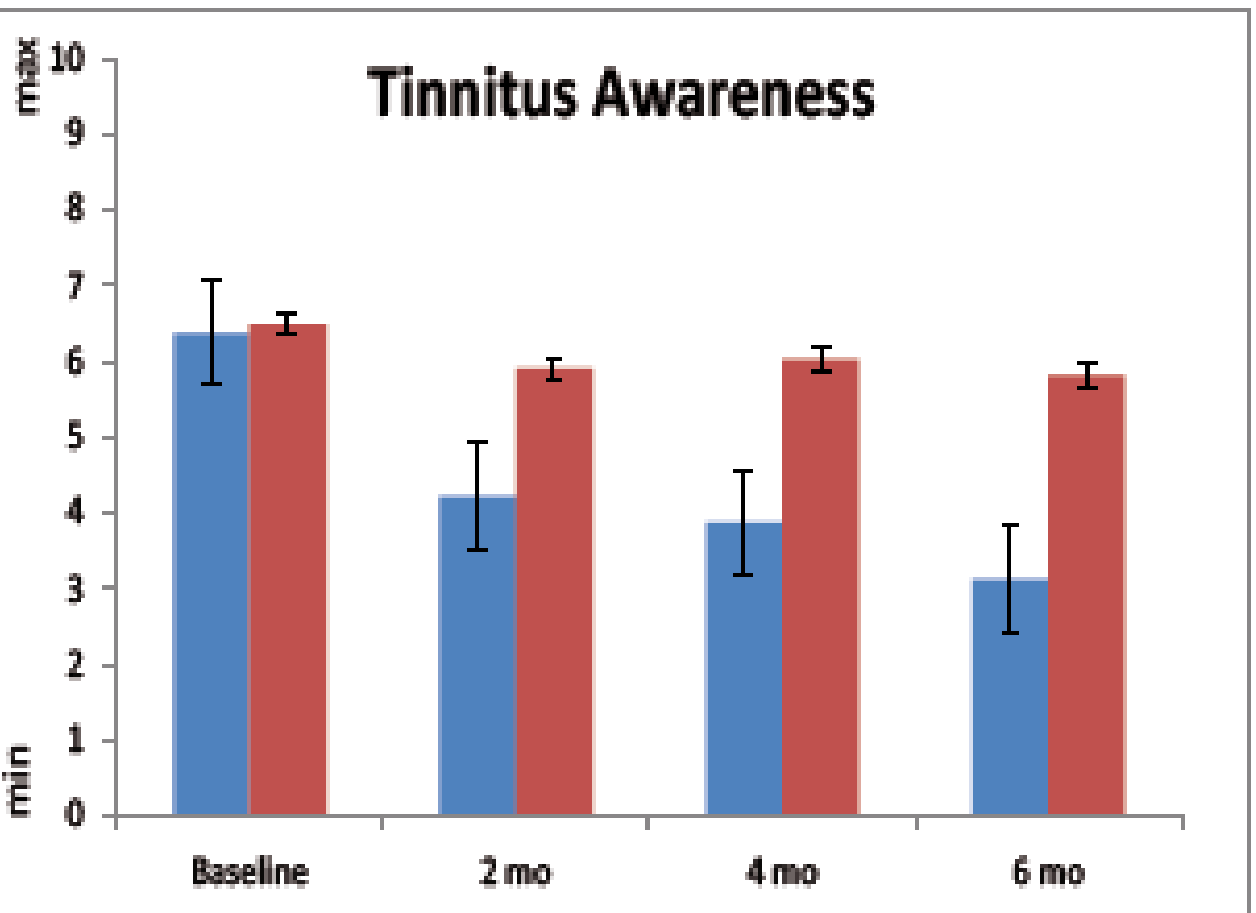


Figure 8: Mean ratings for Tinnitus Awareness for treatment (blue) and control (red) groups at baseline, 2, 4 and 6 months.

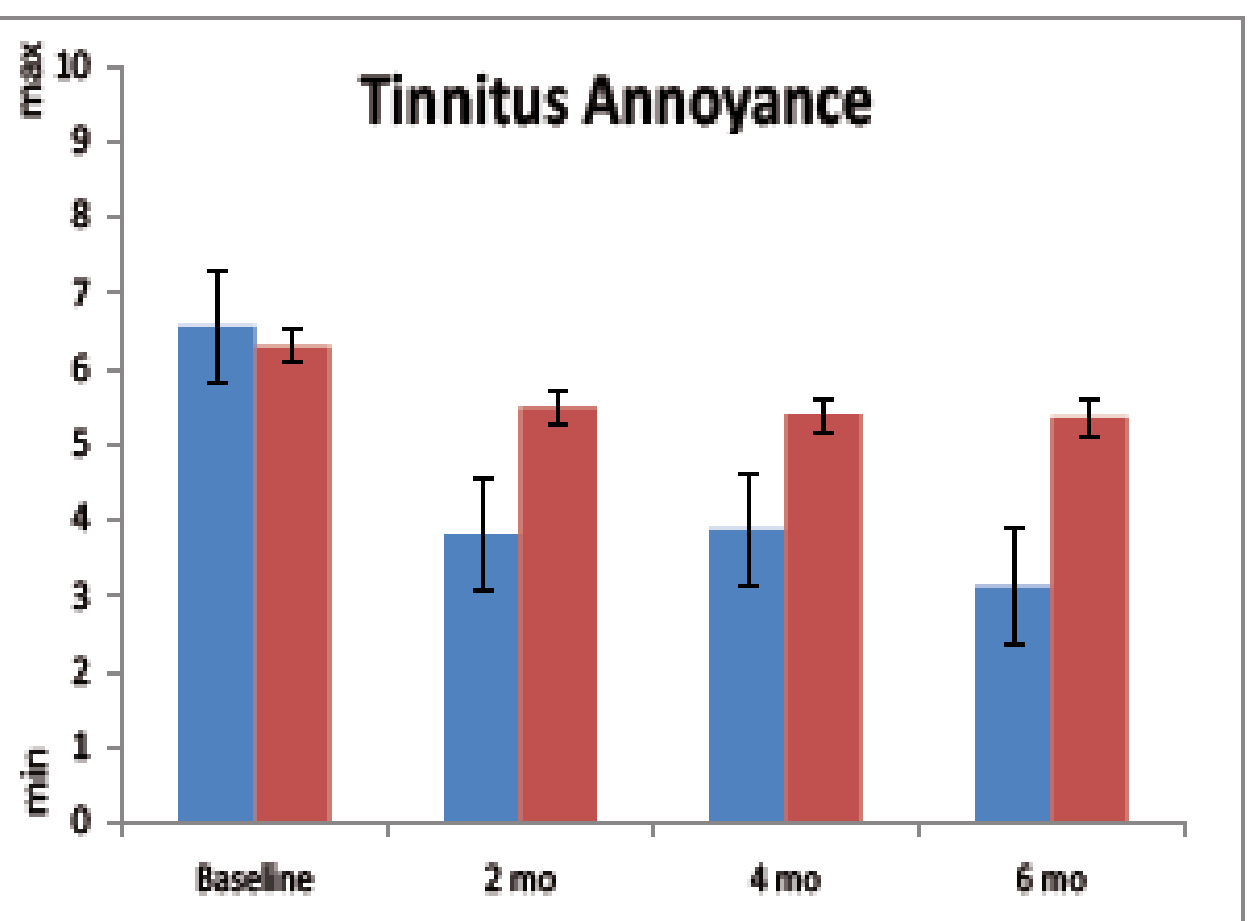


Figure 9: Mean ratings for Tinnitus Annoyance for treatment (blue) and control (red) groups at baseline, 2, 4 and 6 months.

Bars represent standard error. A statistically significant difference between groups was found for the four tinnitus measures ($p < 0.01$). Significant improvements from baseline were seen in the treatment group at 2, 4 and 6 months ($p < 0.05$). No significant improvements occurred in the control group at any time ($p > 0.05$).

Zen2Go Use (Sound Therapy)

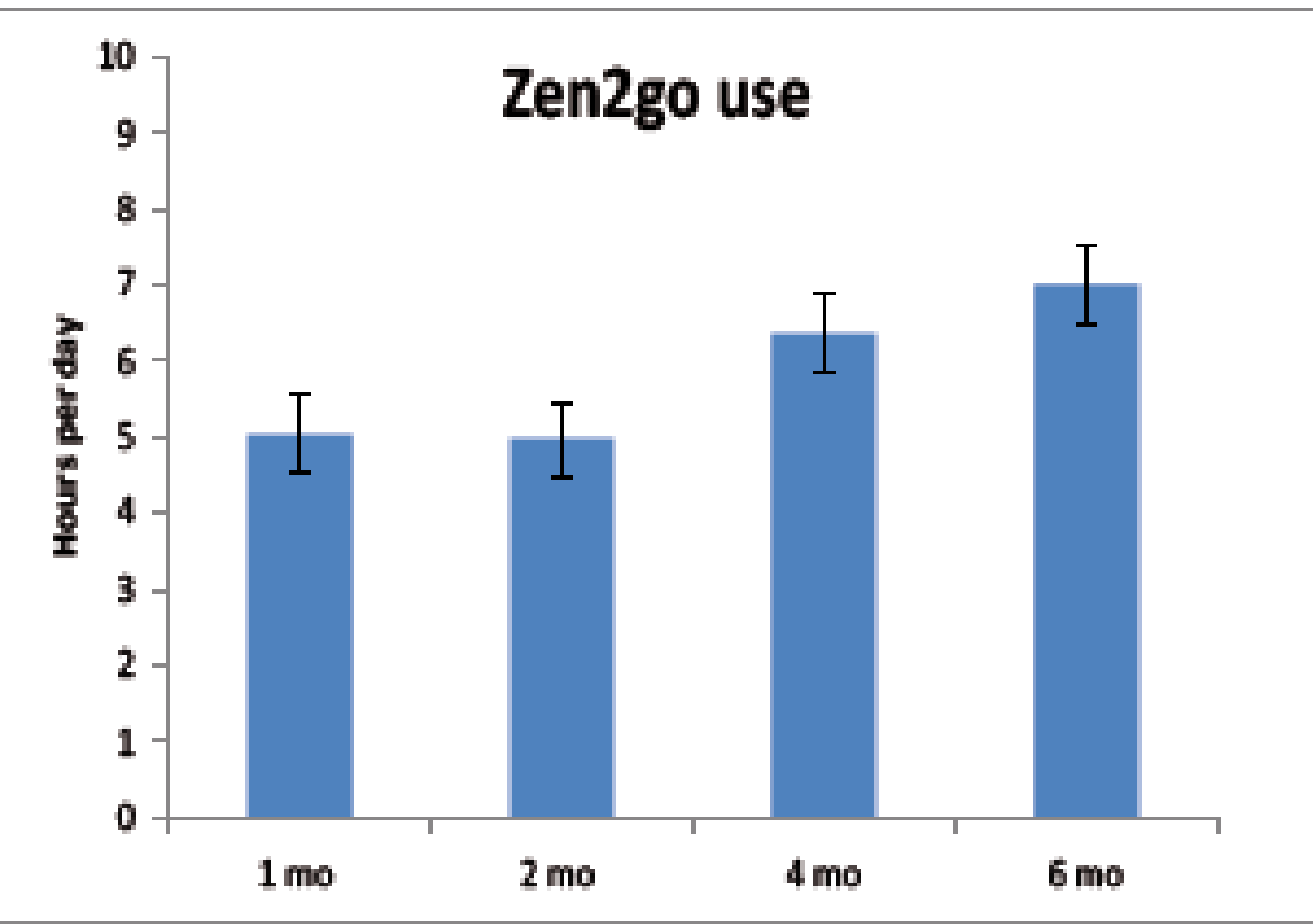


Figure 10: Mean hours of Zen2Go use according to the logging at 1, 2, 4 and 6 months post-fit.

Conclusion

Over the first six months, significant improvements were observed on the tinnitus measurement scales for the treatment group. The control group did not show any significant improvement.

After only 2 months, significant improvements were seen for half of the subjects in the treatment group, indicating that Zen2Go with fractal tones and noise is a very effective sound stimulation tool when used in combination with counseling. The other half of the subjects benefitted from adding additional Widex Zen Therapy components into their treatment plan during that last four months.

In unison, the combination of Zen2Go and Widex Zen Therapy showed a significant improvement in health related quality of life (HRQoL), and thereby demonstrated effectiveness in reducing tinnitus distress in normal hearing subjects and those subjects with mild hearing loss who do not require amplification.