

In the group of patients who are classified as “same,” there are a number of patients who are perceiving and reporting some improvement. In this group, there is often a large fluctuation of severity of problems, or progress is very slow and if TRT is discontinued it is likely they will relapse. In our experience, those patients satisfying the criterium for significant improvement do not relapse after finishing the treatment, even when assessed several years later.

It is important to impose a clear time limit for assessing tinnitus outcome and to repeat evaluation several times.

It is important to impose a clear time limit for assessing tinnitus outcome, and to repeat the evaluation several times. Too short a time for assessment of outcome will result in influencing results by the placebo effect, which in the case of tinnitus can be approximately 40% (Duckert & Rees, 1984). However, accepting unlimited time for showing improvement, without following all the patients, will result in an artificial increase of success rate, as patients who are not showing improvement will have left the study and only those doing well will return. Therefore, although we have data from as short a period as a few weeks after starting treatment and for several years, for the purpose of evaluation we used data obtained between 6 months and two years.

4.6 Placebo effect and spontaneous recovery

The placebo effect is the temporary improvement of symptoms, not related to the effect of the treatment only its presence.

The placebo effect is the temporary (two to three months) improvement of symptoms not related to the effect of the treatment, only its presence; with tinnitus, the placebo effect ranges around 40%. Therefore, the potential impact of a placebo effect on results should be examined very carefully. With our protocol, the placebo effect should be limited because patients are assessed not only soon after the start of treatment, when the placebo effect can be quite strong, but again, typically more than once and after a long time delay. Sustained results over 6–24 months cannot be a placebo effect.

Our long-term results do not show any evidence of a relapse.

Importantly, long-term results do not show any evidence of a relapse. Although we should expect relapse to occur in some patients, its incidence is so low that we observed only single cases, usually associated with other medical and surgical problems. It is also possible that patients can have a subsequent emergence of completely different tinnitus and triggered by some event unrelated to the first

episode. In such cases, it is common for habituation to start automatically and progress rapidly. Patients alarmed that this might be a relapse or regression of their condition and seeking help for a second time can be reassured that, as they have already learned to habituate to one specific tinnitus signal, the habituation of the new signal is achieved by the same mechanism more rapidly than before by following the basic principles of TRT.

Neither placebo effect, nor spontaneous recovery can explain the results obtained in TRT.

The effect of spontaneous recovery should be taken into account when assessing TRT results. In London, a study was performed on a group of 113 tinnitus sufferers who were not receiving any specific treatment for tinnitus and who belonged to the British Tinnitus Association. They completed the same questionnaires at the start and finish of a 12-month period in which they were asked to estimate the percentage of awareness of tinnitus, its annoyance and the effect of tinnitus on life. Only 6% showed significant changes in their tinnitus according to these measurements. A separate study, comparing tinnitus when it first emerged with just before treatment started, showed that spontaneous recovery is unlikely in patients requiring treatment (Sheldrake *et al.*, 1996). Accordingly, neither placebo effect nor spontaneous recovery can explain the results obtained in TRT.

4.7 Effectiveness of tinnitus retraining therapy

To assess the effectiveness and validity of the treatment, the results of our centers are presented here.

4.7.1 Baltimore

In Baltimore (late 1990s), 223 more recent sequential cases from over 1000 patients, without any initial preselection, were evaluated on the basis of initial interview, follow-up visits or telephone interviews if patients were not contacting the center. These patients were treated according to our TRT protocol and were not a part of a specific trial.

The criteria for significant improvement included at least one activity initially prevented by tinnitus/decreased sound tolerance restored to normal, and at least 20% improvement of the initial value in at least two of the following factors: annoyance, awareness or effect of tinnitus on life.

The criteria for significant improvement were as described above, with at least one activity initially prevented by tinnitus/decreased sound tolerance restored to normal, and at least 20% improvement of the initial value in at least two of the following factors: annoyance, awareness or effect of tinnitus on life. The data were gathered with the help of forms for structured initial and follow-up interviews

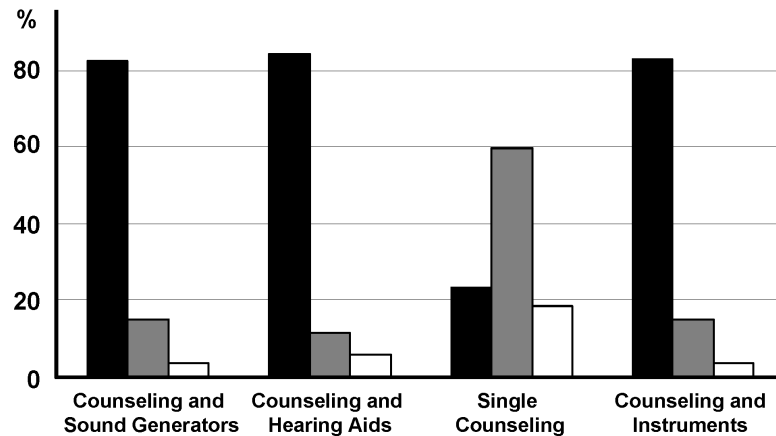


Figure 4.1 Treatment outcome for Baltimore patients. The percentages of patients fulfilling criteria of significant improvement (black bars), not improving significantly (gray bars) and reporting worsening (open bars) are presented for various treatment approaches: multiple counseling and sound generators, counseling and hearing aids, one session of tinnitus retraining counseling only, and combined first two groups.

(see Appendix 1). Patients reporting improvement but not fulfilling these criteria were classified as showing no change. Those who reported worsening of their symptoms were counted as such.

All patients received intensive initial counseling, which included explanation of the model, advice about avoiding silence and using sound enrichment (sounds of nature, radio, television). Two main approaches were implemented for instrumentation: 79% of patients received behind-the-ear sound generators (Viennatone Am/Ti) and 9% were fitted with various kinds of hearing aid according to their needs, with specific, proper counseling following TRT protocol for patients with hearing loss (category 2). The remaining 11% received an initial session of counseling but decided not to continue with the protocol. They were followed mainly by telephone interviews.

The group with sound generators and hearing aids had a similar proportion of patients showing significant average improvement of 82.0%. Notably, in the group which received only one session of counseling, only 22.7% of patients showed significant improvement.

The group with sound generators and hearing aids had a similar proportion of patients showing significant improvement, 81.8% and 83.3%, respectively, with an average of 82.0% (Fig. 4.1). No change was reported by 14.5% and 3.5% reported worsening of their problem. Notably, in the group that received only one session of counseling, only 22.7% of patients showed significant improvement, with 59.1% without significant change and 18.2% reporting worsening of their problems. Comparison of the effectiveness of the full treatment versus