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A COMPILATION OF **WIDEX ZEN THERAPY** EVIDENCE

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INTRODUCTION

Approximately 15% of the world population experiences tinnitus. As many as 70-90% of these individuals also suffer from some degree of hearing loss. For the majority, the attention paid to tinnitus decreases over time, and no treatment is needed; however, 10-20% will seek professional attention (Tyler, 2000).

There are various approaches designed to help sufferers cope with tinnitus. Widely used strategies include Tinnitus Retraining Treatment (TRT) and Cognitive Behavioral Therapy (CBT). TRT entails sound therapy and educational (directive) counseling (Jastreboff, 2000), while CBT focuses on managing the negative thoughts, emotions, and behaviors associated with the individual's tinnitus and how to potentially change those reactions (Hyung and Moo, 2013). Since tinnitus can be a complicated source of distress affecting areas such as emotional state, concentration, anxiety, sleep etc. (Tyler, 2000), a strategy that targets multiple areas may be quite effective.

In 2012, Widex launched Widex Zen Therapy (WZT). This article offers a brief explanation of the therapeutic concepts underlying WZT and summarizes studies investigating efficacy.

DESCRIPTION OF WIDEX ZEN THERAPY

WZT consists of four therapeutic strategies or components, each of which have been proven effective, either in combination or singularly, for certain individuals in the management of tinnitus distress. Not every component is necessary for each individuals. However, by employing an integrated strategy, the hearing care professional has the opportunity to personalize treatment. The WZT components can be seen in Figure 1.

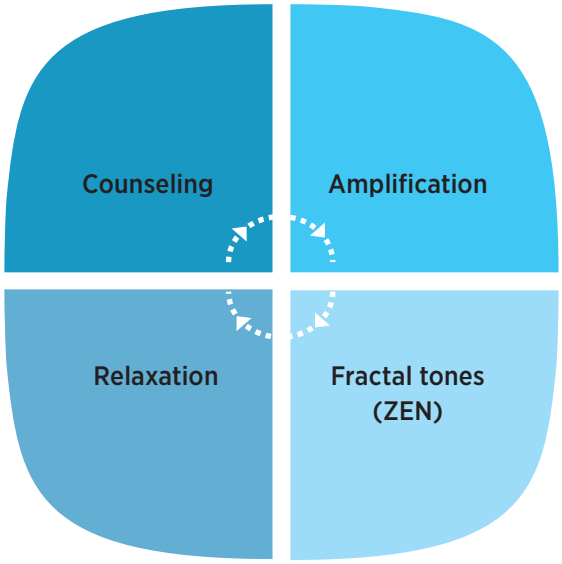


Figure 1: The components of Widex Zen Therapy

To individualize treatment, WZT stresses the importance of getting to know the individual. In order to do so an intake process is performed prior to treatment to gather information on the nature of the tinnitus and the distress experienced by the individual. This process includes a comprehensive intake questionnaire and personal interview, subjective scale measures, and audio-

metric testing. The subjective scale measures are used both as a baseline in helping to determine the therapeutic strategy and later to validate the effect of the treatment. Three commonly used examples of subjective scales are the Tinnitus Handicap Inventory (Newman et al., 1998), Tinnitus Functional Index (Meikle et al., 2012) and Tinnitus Reaction Questionnaire (Wilson et al., 1991). Following the intake process, any or all of the components comprising WZT may be applied and individualized.

COUNSELING

The purpose of counseling is to educate the individual and to understand and discuss the emotional and psychological impact of the tinnitus on that person. It may include: instructional information about tinnitus and hearing in general; the connection between tinnitus and emotional reaction; and elements of Cognitive Behavioral Intervention (CBI). The latter is a limited application of Cognitive Behavioral Therapy, a proven approach that helps individuals identify negative thoughts and behaviors and replace them with more constructive ways of handling their situation (Cima et al., 2014). A Cochrane Review meta-analysis indicated that CBT produced "a significant improvement in depression score … and quality of life (decrease of global tinnitus severity) …, suggesting that CBT has a positive effect on the management (reduction of annoyance and distress) of tinnitus" (Martinez-Devesa et al., 2010). More recently, the American Academy of Otolaryngology, Head and Neck Surgery promoted CBT in their 2015 Guidelines as one of the only evidenced based tinnitus therapies (Tunkel et al., 2014). CBI is basically, a condensed version of CBT focused on logical counseling well within the scope of practice of trained hearing health care professionals.

AMPLIFICATION

The usage of hearing aids (amplification) as a source of relief of tinnitus has been investigated in numerous studies (Kochkin & Tyler, 2008; Trotter & Donaldson, 2008). This research shows that about 60% of people with tinnitus experience relief from wearing hearing aids alone. Since the vast majority of people with tinnitus also have hearing loss, hearing aids are a logical potential solution. Although the individual may not view the hearing loss as the primary problem, amplification of soft sounds will act as a partial masker and, in many cases, produce some relief. Amplifying very soft sounds requires a hearing aid with low compression thresholds and high sound quality, which are characteristic of Widex hearing aids.

FRACTAL (ZEN) TONES

ZEN tones are a patented, exclusive source of sound therapy available in all Widex hearing aids. Default settings, based on previous experiments demonstrating their relaxing quality, are available for the various styles of the tones, but they can also be individualized for each individual in pitch, volume and tempo in the Compass fitting software (Figure 2).

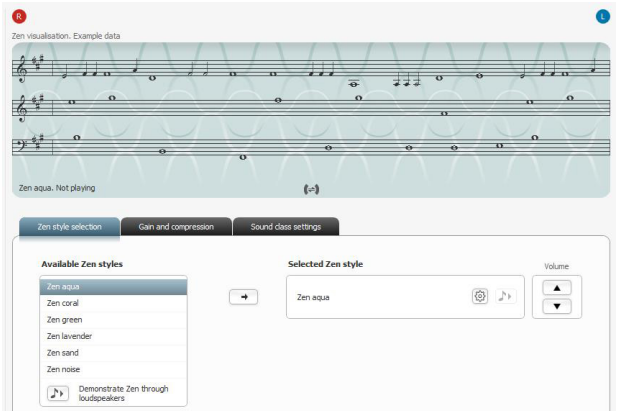


Figure 2: screenshot of the ZEN module in Compass GPS.

ZEN tones are based on fractal technology, ensuring the music is predictable but not repeatable. This is relevant because the brain will typically eventually habituates to any predictable sound and the effect the stimuli has on emotional state may then decrease. Zen tones can be applied in therapy regardless of the level of tinnitus distress.

RELAXATION

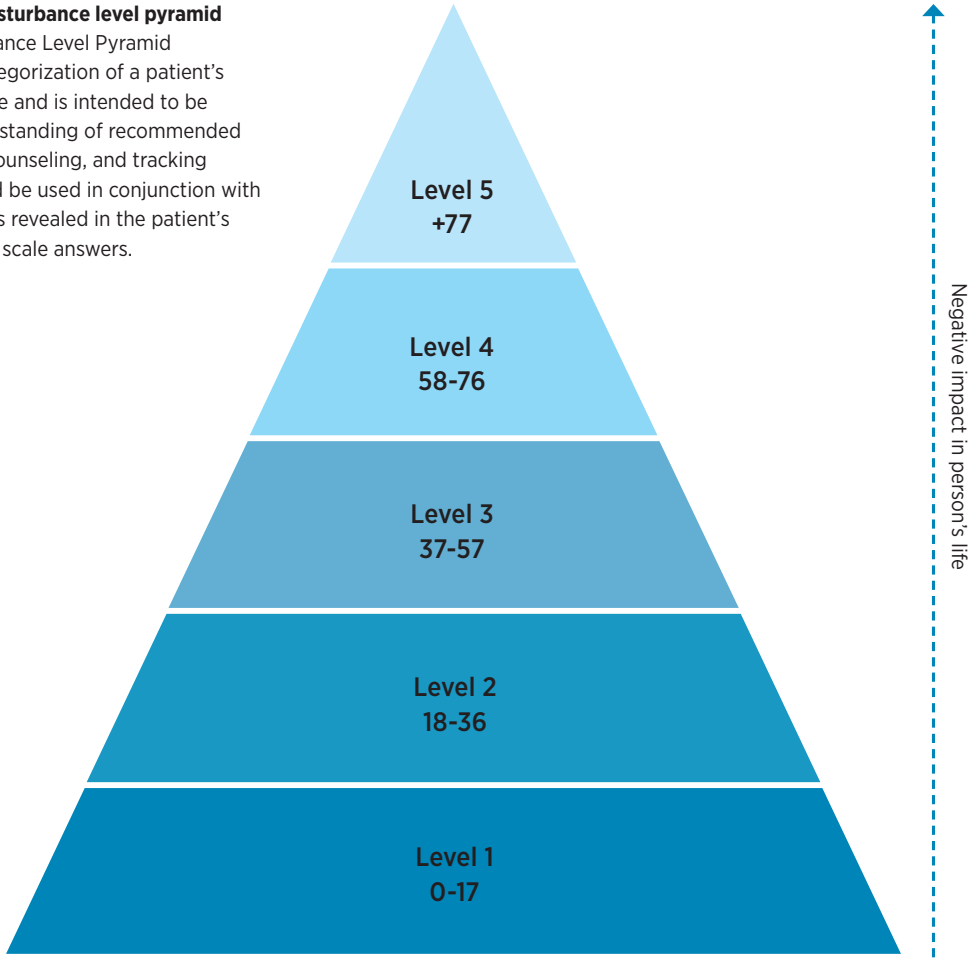
Tinnitus often causes stress for the individual, and because stress often increases tinnitus perception, tools for enhancing relaxation skills can be very important. WZT includes relaxation exercises the individuals can do at home. In addition, because stress can be increased by lack of sleep, WZT also provides advice for establishing good sleeping patterns.

Figure 3: Combination of elements of WZT.

WZT is relevant for individuals with a range of distress levels and needs. The level of distress is established via

a comprehensive intake questionnaire, subjective scale scores, and interviews with the individual. A general guideline regarding how to individualize the approach based on level of distress based on subjective scale measures is seen in Figure 4.

Figure 4: Tinnitus disturbance level pyramid
The Tinnitus Disturbance Level Pyramid provides a visual categorization of a patient's subjective scale score and is intended to be used for initial understanding of recommended WZT components, counseling, and tracking progress. This should be used in conjunction with addressing the needs revealed in the patient's individual subjective scale answers.



WZT RECOMMENDATIONS BASED ON SUBJECTIVE SCALE MEASUREMENTS:

Level 5: Catastrophic tinnitus reaction with or without hearing loss
1) Instructional and adjustment based counseling, cognitive behavioral intervention
2) Amplification (when hearing loss exists)
3) Avoidance of silence, ZEN all day
4) Relaxation exercises 2-3 times a day

Level 4: Severe negative tinnitus reaction
1) Instructional and adjustment based Counseling, cognitive behavioral intervention
2) Amplification (when hearing loss exists)
3) Avoidance of silence, ZEN all day
4) Relaxation exercises

Level 3: Moderate negative tinnitus reaction
1) Instructional and adjustment based Counseling, cognitive behavioral intervention
2) Amplification (when hearing loss exists)
3) Avoidance of silence, ZEN all day
4) Relaxation exercises might be useful

Level 2: Mild negative tinnitus reaction
1) Instructional and adjustment based Counseling
2) Amplification (when hearing loss exists)
3) ZEN for quiet environments. Relaxation exercises might be useful

Level 1: Minimal or no negative tinnitus reaction
1) Basic Counseling about the cause and likely course of tinnitus
2) Amplification (when hearing loss exists)
3) ZEN might be useful for quiet environments

EVIDENCE

EVIDENCE SUPPORTING THE USE OF FRACTAL TONES

ZEN fractal tones were developed based on the evidence that certain types of music have a relaxing effect on the brain. In 2008, Widex launched the first hearing aid with a built-in fractal tone generator. Kuk et al. (2008) investigated the relaxing effect of the Widex MIND 440 hearing aid with ZEN tones. Fourteen adults with mild to moderately severe hearing loss were fit with Mind 440 hearing aids. They were asked to rate their relaxation levels to 4 ZEN styles. Subjects rated most ZEN programs to be either very relaxing or somewhat relaxing.

The authors concluded that the ZEN program had a significant relaxing nature and that the Zen tones could be used by adult hearing aid wearers as a way of achieving a higher level of relaxation in their lives.

Sweetow and Henderson-Sabes (2010) investigated the effect of amplification, ZEN tones, and white noise on tinnitus annoyance, handicap, and relaxation in 14 adults with hearing loss. The subjects' primary complaint was tinnitus. Prior to the investigation, each subject reported significant negative reaction to their tinnitus even after an extensive counseling and in many cases, sound therapy. For the study, subjects were fit with MIND 440 devices and were evaluated over a period of 6 months. The Tinnitus Handicap Index (THI) and Tinnitus Reaction Questionnaire (TRQ) were used to monitor progress. The mean reduction in THI and TRQ scores are seen in Figure 5. For both measures the reduction in tinnitus handicap was significant at the 1- and 3-month visits. At the 6-month visit the results were consistent with the results from the 3-month visit, suggesting a robust and lasting effect. Furthermore, 13 out of 14 subjects rated their tinnitus as less bothersome post treatment. In addition, 86% of the participants indicated it was easier to relax while listening to the fractal tones.

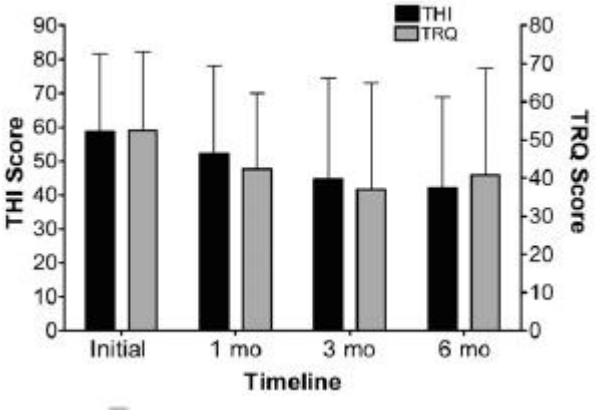


Figure 5. Mean THI and TRQ scores as a function of visit.

A study by Kuk et al. (2010) reported similar results. Clinicians with experience in tinnitus treatment were asked to apply the treatment to hearing impaired subjects with tinnitus and to measure the efficacy pre- and post-treatment with the TRQ. The clinicians reported that 100% of the 49 respondents indicated a reduction in tinnitus distress. The subjects with the most severe tinnitus distress prior to treatment experienced the most beneficial effect.

The authors concluded that ZEN was a highly effective way of treating tinnitus distress. The option of having the ZEN tones simultaneously with amplification was particularly beneficial, because since it could lessen the tinnitus distress while also providing the individuals with the ability to communicate better. They also reported that 2/3 of the subjects tried more than one ZEN style, implying that multiple options are important.

Herzfeld et al. (2011) assessed the effectiveness of ZEN tones on 48 tinnitus subjects with a range of tinnitus handicapping distress. Results showed a clinically significant (>17 points) reduction on the TRQ scale (40-100% reduction) on 90% of subjects. There was also a tendency towards a greater reduction for subjects suffering from more severe levels of distress. The 10% not experiencing a significant reduction in distress had a low degree of distress prior to treatment.

These studies confirmed the effectiveness of Zen tones and ultimately inspired Widex to include the ZEN tones in a more holistic approach, the Widex Zen Therapy.

EVIDENCE SUPPORTING THE USE OF WIDEX ZEN THERAPY

Based on the success of the fractal tone and amplification studies, and the growing body of research indicating the importance of both informational and adjustment-based counseling, Widex introduced the integrated tinnitus program, WZT, in 2012. The following investigations report on the efficacy of WZT.

Herzfeld et al. (2014) studied the effects of WZT on 24 hearing impaired tinnitus subjects over a period of 6 months. The Tinnitus Functional Index (TFI) and THI were measured at baseline and repeated 2 and 6 months later. The devices used in this study were the Widex DREAM products of different performance levels depending on the needs and economical resources of the test subjects. Results 2 months post baseline yielded a highly significant mean improvement on the TFI score of 28 points. The TFI scores continued to drop between 2 and 6 months, indicating a further improvement for the subjects, but the difference was not statistically significant. The results also suggested that the reduction of tinnitus distress was maintained at 6 months post baseline. These results are depicted in Figure 6. Similar results were found for the THI.

The importance of these data is that not only do the improvements persist for at least six months, but that, unlike many other tinnitus treatments that may require as long as 12-24 months to be achieved, subjects receiving WZT appear to achieve beneficial results as early as 2 months (and many almost immediately after fitting).

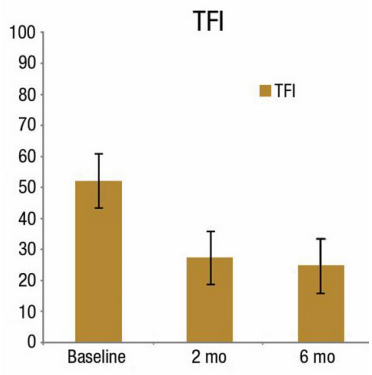


Figure 6: TFI scores for study by Herzfeld et al. (2014).

The effectiveness of WZT for longer time periods also has been confirmed. Sweetow et al. (2015a) conducted a study of benefits of WZT on 19 subjects (18 of which were first time hearing aid users) over a 12-month period. TFI and THI scales were measured at baseline and at 2, 4, 6, 9 and 12 months post baseline (Figure 7). Subjects were fit with Widex CLEAR or Widex DREAM hearing aids, depending on their individual need. All subjects received initial, brief counseling and relaxation exercises. Additional CBI counseling was provided if the clinician deemed it appropriate.

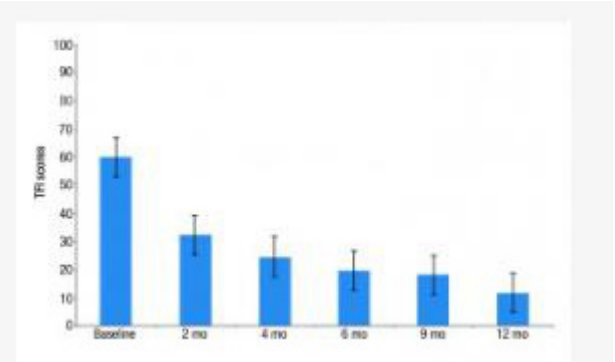


Figure 7: Mean Tinnitus Functional Index Scores at Baseline, 2, 4, 6, 9 and 12 months.

Results showed a progressive reduction in TFI score. The greatest reduction was seen between baseline and 2 months with average reduction on TFI of 32 points. Reductions in TFI between other measurement times were not statistically significant. Once again, it was found that the greatest degree of improvement occurred quickly, within the first two months of treatment. Moreover, the benefits persisted at least out to 12 months, where it was found that the average final TFI score was 11.76, a clinically insignificant level of tinnitus distress. Of further interest was the fact that the relative use of the Zen programs containing noise decreases over time while the use of amplification alone and/or amplification plus fractal tones increases even after a successful resolution of the tinnitus distress has been achieved.

The authors concluded that "the inverse relationship between the use of ZEN programs versus amplification alone over time suggests that patients perceive a continued benefit for using amplification for improving their hearing, and possibly for tinnitus relief, even post habituation or successful resolution. This, despite the fact that all subjects reported tinnitus, rather than hearing loss, as their primary complaint."

The before mentioned studies investigated the benefit of WZT on hearing impaired subjects with tinnitus. However, tinnitus individuals with a minimal need for amplification can also benefit from the WZT approach. Sweetow et al. (2015) studied 41 subjects, most of whom had normal hearing thresholds below 2kHz. None of the subjects expressed a need for amplification. Subjects were divided into matched treatment and waiting (control) groups (the control group receiving only an initial evaluation and brief instructional counseling on the nature of tinnitus and hearing). Subjects in the treatment group were fitted with Zen2Go (non-amplifying) devices with fractal tones.

In the next phase of treatment, subjects that had not met the criterion of a significant reduction in tinnitus distress had additional components of WZT added, such as amplification, CBI and relaxation exercises. Progress was monitored at 2, 4, 6 and 12 months post baseline (Figure 8).

Results showed minimal changes for the control group, but highly significant improvements (consistent with past studies) on the TFI for the group receiving WZT.

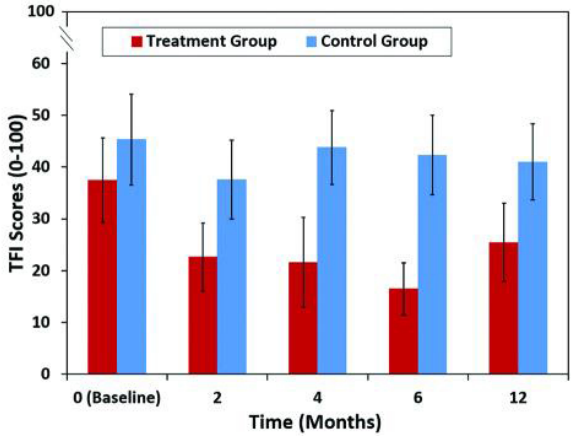


Figure 8. Mean TFI scores at baseline, 2, 4 and 6 months for the 2 treatment sub-groups.

It is also relevant to investigate the separate contribution of certain WZT components. Johansen et al. (2014) investigated the effectiveness of components of tinnitus treatment (specifically counseling, amplification, and Zen tones) applied sequentially on 35 primarily tinnitus subjects with initial THI scores greater than 20 and mild-severe hearing loss. Eighty percent of the subjects were first time hearing aid users. Initially, they were all given instructional counseling. Two months after the counseling the subjects were fit with Widex CLEAR 440 hearing aids. Two months post fitting, the Zen tones were added in a second program, which the subjects could manually switch to from their universal program. A final session of counseling was applied two months post the activation of Zen. THI was measured at each appointment. As shown in Figure 9 there was a reduction in the mean THI score following each additional tinnitus treatment component.

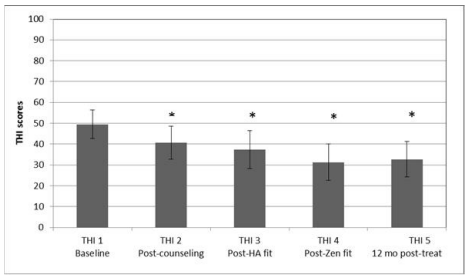


Figure 9. Mean values for THI at baseline, post-counseling, post-amplification and post-Zen.

Data showed that 85.7% of subjects had a reduction of tinnitus distress at the end of the study when all components had been applied, indicating a cumulative effect.

Another point of interest in the study was to investigate how the subjects perceived the benefit of the fractal ZEN tones. These results showed that 70% of the subjects reported a good/very good effect on relaxation effect with the ZEN tones. Also, 50% of the subjects reported that the ZEN tones had a good/very good effect in reducing stress. Lastly, 63% of the subjects reported that the ZEN tones had a good/very good effect in reducing tinnitus awareness and 52% experienced that ZEN helped reducing tinnitus annoyance.

Consistent with previous studies, there was a tendency for subjects with more severe tinnitus to benefit more from the treatment than those with a milder tinnitus distress level. It seems that combination of components applied individually initially in the tinnitus treatment can promote significant reduction of tinnitus distress in a shorter time (Herzfeld et al. (2014); Sweetow et al (2015a, b).

Most recently, Stocking et al. (2016) also investigated the individual components of WZT. Twenty subjects with TFI scores greater than 38 were studied. Subjects were fit with Widex CLEAR 440 Fusion hearing aids and were seen 8 times over a period of 12 months. For subjects with no or minimal hearing loss, the hearing aid was set with minimal or no amplification. The four components of WZT were applied sequentially at two week intervals. Extensive counseling was only applied if the individual needed it. Bi-weekly outcome measures were done with TFI (Meikle et al., 2012) (Figure 10). Seventeen subjects completed the study. The mean improvement in TFI score was a statistically and clinically significant 28 points.

An end-of-study-questionnaire was completed (Figure 10). Subjects were asked if they felt the components had helped them. All subjects felt informational counseling was of benefit, 73% rated the hearing aids as "great", 67% rated the ZEN tones as "great" and 73% of subjects felt the follow-up was of great benefit.

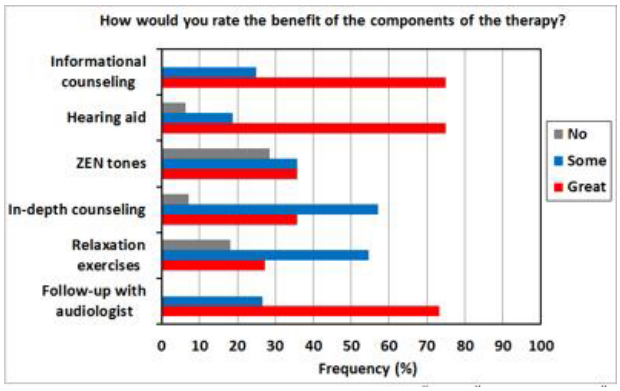


Figure 10; Perceived benefit for each component of WZT by subjects.

The authors indicated that the WZT approach can successfully be used in the management of tinnitus individuals. The authors concluded that the strength of WZT may be due to a cumulative effect of the components.

PERSPECTIVE:

Widex Zen Therapy has now existed for several years and ZEN fractal tones for almost 10 years. The benefits have withstood the test of time, not only in these studies, but in hundreds of anecdotal reports from clinicians and tinnitus sufferers. However, as time passes, new customer needs will likely become apparent. As such, Widex is releasing a new and more basic Widex Zen Therapy Manual, making it even easier for hearing care professionals to implement Widex Zen Therapy into their clinics.

WIDEX BEYOND hearing aids featuring 2.4 GHz and the
Widex Zen – Tinnitus Management App provide an even stronger basis for WZT, as elements can now be incorporated into the individuals everyday life. While an app made for people with tinnitus can provide support and direction, it can not replace the personal relationship hearing care professionals can establish with their individuals through administering a dedicated, comprehensive tinnitus management protocol like Widex Zen Therapy.

CONCLUSION:

The evidence supporting the efficacy of WZT is strong. The studies of the fractal Zen tones and WZT relaxation have provided an evidence based foundation. WZT has given clinicians the honest opportunity to tell their patients that there is something that can be done about their tinnitus and that the "you just have to live with it"- myth is not true.

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For further reading:

https://www.widex.pro/en/products/tinnitus-solutions/widex-zen-therapy-tinnitus-treatment

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