Purpose: The aim of this study was to measure the progression of benefits to individuals with tinnitus from providing informational counseling, hearing aids, a brief tinnitus activities treatment and Zen therapy.

Method: Several magnitude estimation scales and tinnitus handicap scales were administered for the duration of the study to 20 participants.

Results: Results indicated that all participants benefited from this sequential approach of providing different components of this tinnitus treatment. Large benefits were observed following the tinnitus activities treatment and the Zen treatments.

Conclusion: We conclude that the progressive approach of treatment demonstrated here should be of benefit to most individuals with tinnitus and that the Widex Zen sound therapy is a worthwhile treatment for many tinnitus sufferers.

Individuals with tinnitus can suffer from the primary problems of concentration, hearing, sleep, thoughts, and emotions; these problems can lead to a variety of secondary effects on everyday life (e.g., Andersson, Eriksson, Lundh, & Lyttkens, 2000; Andersson, Ingerholt, & Jansson, 2003; Andersson, Kyrre Svalastog, Kaldo, & Sarkohi, 2007; Andersson, Lyttkens, & Larsen, 1999; Budd & Pugh, 1995; Coles & Hallam, 1987; Erlandsson, 2000; Erlandsson & Holgers, 2001; Holmer & Carroll, 2006; Holmer & Griest, 2000; Holmer, Griest, & Martin, 2001; Holmer, Griest, Meikle, & Martin, 1999; Hébert & Carrier, 2007; Kaluzny, Durko, & Pajor, 2004; McMenna & Daniel, 2006; Newman, Wharton, & Jacobson, 1997; Rossiter, Stevens, & Walker, 2006; Stevens, Walker, Boyer, & Gallagher, 2007; Stouffer & Tyler, 1990; Tyler & Baker, 1983). Providing help to individuals with tinnitus has advanced considerably since the early counseling strategies of habituation training introduced by Hallam (1989a; see also Hallam & Mackenna, 2006) together with cognitive behavior therapy for tinnitus proposed by Sweetow (Sweetow, 2000; see also Sweetow & Jeppesen, 2012) and Henry and Wilson (2001a). Several counseling strategies include cognitive behavior therapy such as the tinnitus activities treatment (TAT; Tyler, Gehringer, et al., 2006; Tyler, Gogel, & Gehringer, 2007; see Tunkel et al., 2014), whereas other strategies focus on acceptance (e.g., tinnitus person-centered therapy; Mohr & Hedelund, 2006; see also Tyler, 2006a, 2006b; Tyler & Babin, 1986). Additionally, the wearable sound therapy strategy initiated by Vernon (1976; see also Vernon & Meikle, 2000) and the focus on low levels of partial masking (Bentler & Tyler, 1987; Tyler & Bentler, 1987) has been helpful for many individuals with tinnitus and has become the standard of care. Indeed, the progression of tinnitus management recommended by Tyler, Stouffer, and Schum (1989) is now widely used.

There is a long history of the benefits of hearing aids (HAs) for individuals with tinnitus (e.g., Kuk & Peeters, 2008; Melin, Scott, Lindberg, & Lyttkens, 1987; Moffat et al., 2009; Saltzman & Ernsr, 1947; Searchfield, 2006; Stacey, 1980; Surr, Montgomery, & Mueller, 1985; Trotter & Donaldson, 2008; Tyler & Bentler, 1987). Indeed, most HA users report benefits to their tinnitus (Kochkin & Tyler, 2008). Sound therapies initially focused on broadband noise but have now blossomed to include a wide variety of options. These include broadband noise whose spectrum can be adjusted, process music, amplitude modulate tonal complex, and notch noise or music (see Kemp & George, 1992; Tyler, Stocking, Secor, & Slattery, 2014; Tyler & Bentler, 1987).

A sound therapy introduced by Widex (™) includes a particularly unique set of stimuli referred to as Zen tones. This program generates music based on a patented fractal algorithm. There are three steps in music

Disclosure: This study was partially funded by Widex. The authors report no other conflicts of interest.
The present study explores the benefit of Zen tones in the context of the Zen therapy. We attempted to delineate the relative contribution of different components of the Widex Zen therapy. This includes a brief instructional counseling, amplification with hearing instruments, Zen sound therapy, and a brief component of tinnitus activities therapy (Tyler, Gehringer, et al., 2006; Tyler, Gogel, & Gehringer, 2007).

### Methods

All study procedures were conducted after approval from the Institutional Review Board at the University of Iowa.

### Participants

Twenty participants (15 men and 5 women) were recruited (from our database of tinnitus patients interested in participating in research) for the present study. Their biographical data are shown in Table 1. The mean age was 58 years (range = 29–80 years; standard deviation = 10 years). Seven participants wore their own HAs before the study, and 13 did not. The mean duration of tinnitus experience was 11.9 years (range = 0.3–45.0 years; standard deviation = 12.4 years). Participants were provided with HAs free of charge for the duration of the trial. They were given the option to purchase the HAs at the end of the study.

### Inclusion Criteria

Participants were included in the study after meeting the following criteria:

1. Medical clearance prior to treatment;
2. Tinnitus Functional Index (TFI; Meikle et al., 2012) score greater than 38 (chosen to enable us to view a reduction if treatment was successful);
3. Hearing threshold in each ear no more than 70 dB hearing loss (HL) from 250 to 4000 Hz; Thresholds above 70 dB HL at frequencies above 4000 Hz were acceptable;
4. Cognitive, comprehension, and manual dexterity abilities sufficient to administer treatment;
5. No complicated medical issues such as acute/ unstable Meniere’s, chronic otitis media, unilateral hearing loss, and atresia;
6. No significant untreated depressive or anxiety disorders (participants on long-term (> 6 months) psychiatric medications were accepted);
7. No drug, alcohol, ototoxic medications, or substance abuse that would be contraindicative to or interfere with treatment;
8. No pulsatile tinnitus or middle ear tinnitus;
9. No pending compensation case related to tinnitus;
10. Motivated to pursue treatment and actively participate in a 6-month study as judged by the clinician;
11. No loudness hyperacusis (no loudness discomfort levels below 70 dB HL from 500–4000 Hz). No annoyance/fear of sounds or hyperacusis as judged by the clinician (see Tyler, Pienkowski, et al., 2014);
12. Participant must have experienced tinnitus for a period of > 4 months.
13. Not subject to continued excessive noise exposure without effective hearing protection; and
14. Currently not in any active tinnitus treatment regimens.

### Measurements

Data were collected at assessment appointment (baseline) and during return visits. Consistent with the psychological model of tinnitus proposed by Dauman and Tyler (1992), we focused both on measurement of the tinnitus magnitude and on the reactions to the tinnitus. The Tinnitus Handicap Questionnaire (THQ; Kuk, Tyler, Russell, & Jordan, 1990), the Tinnitus Primary Functions Questionnaire (TPFQ; Tyler, Stocking, Secor, & Slattery, 2014), and the TFI (Meikle et al., 2012) were administered as the principal measurement instruments in the study. Participants rated five different visual analog rating scales of 0–10 before starting the treatment. The scales included the following:

- **Tinnitus severity:** “Please evaluate how severe your tinnitus has been over the past two weeks using the scale below.” You can attribute any value between 0 (tinnitus severity is very mild) and 10 (extremely severe tinnitus). Choose the number that best represents your tinnitus severity.

- **Tinnitus awareness:** “Please evaluate how much you were aware of your tinnitus over the past two weeks using the scale below.” You can attribute any value between 0 (not aware at all) and 10 (extremely aware). Choose the number that best represents your tinnitus awareness.
Tinnitus annoyance: “Please evaluate how annoyed you were by your tinnitus over the past two weeks using the scale below.” You can attribute any value between 0 (not annoyed at all) and 10 (extremely annoyed). Choose the number that best represents your tinnitus annoyance.

General level of relaxation: “Please evaluate how relaxed you’ve generally felt over the past two weeks using the scale below.” You can attribute any value between 0 (very relaxed) and 10 (extremely tense). Choose the number that best represents your general level of relaxation.

Sensitivity to loud sounds: “Please evaluate how sensitive you were to loud sounds over the past two weeks using the scale below.” You can attribute any value between 0 (not sensitive) and 10 (extremely sensitive). Choose the number that best represents your sound sensitivity.

Minimum masking levels and loudness discomfort levels were measured pretreatment and posttreatment (see Tyler, 1985, 1992, 2000; for details). The data-logging feature of the HAs was used to review HA use with the patient (Master and Zen programs).

Clinical Procedure

Participants were seen six times over a period of 6 months for this longitudinal study. The study took place in a clinical outpatient, audiological center. The services were provided by an audiologist. The sessions included an assessment appointment, an instructional counseling appointment (see Tyler & Babin, 1986; Tyler & Baker, 1983; which was included in the assessment appointment), a hearing-aid fitting appointment, a Zen program activation appointment, and adjustment-based counseling appointments based on TAT. Further follow-up assessment appointments were scheduled at 3 and 6 months after the beginning of tinnitus treatment.

Visit 1a: Baseline Assessment

The following tasks were completed during the assessment appointment:

(a) TPFQ;
(b) TFI;
(c) THQ;
(d) Tinnitus severity, tinnitus awareness, tinnitus annoyance, general level of relaxation, and loudness hyperacusis were measured using a visual analogue scale (VAS) described earlier;
(e) Pure-tone air conduction (from 250 Hz to 8 kHz) and bone conduction (from 500 Hz to 4 kHz) thresholds;
(f) High-frequency audiometry including high frequencies up to 12500 Hz;
(g) Broadband noise minimal masking level and loudness discomfort levels; and
(h) Review of evaluation and recommendations for the treatment.

Visit 1b: Instructional Counseling

The first counseling session presented information on the prevalence and causes of tinnitus, basic anatomical and

<table>
<thead>
<tr>
<th>Participant No.</th>
<th>Gender</th>
<th>Age (year)</th>
<th>Tinnitus perception</th>
<th>Duration of tinnitus (years)</th>
<th>Location of tinnitus</th>
<th>THQ (0–100)</th>
<th>TFI (0–100)</th>
<th>TPFQ (0–100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td>56</td>
<td>Ringing, cricket-like, pulsating</td>
<td>30.8</td>
<td>Both ears equally</td>
<td>41</td>
<td>47</td>
<td>61</td>
</tr>
<tr>
<td>2</td>
<td>Male</td>
<td>54</td>
<td>Ringing, hissing, steam whistle</td>
<td>14.0</td>
<td>Both ears equally</td>
<td>43</td>
<td>45</td>
<td>40</td>
</tr>
<tr>
<td>3</td>
<td>Male</td>
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<td>Ringing</td>
<td>30.0</td>
<td>Both ears equally</td>
<td>64</td>
<td>76</td>
<td>77</td>
</tr>
<tr>
<td>4</td>
<td>Male</td>
<td>62</td>
<td>Ringing, high-tension wire, buzzing</td>
<td>1.5</td>
<td>Right ear</td>
<td>57</td>
<td>68</td>
<td>64</td>
</tr>
<tr>
<td>5</td>
<td>Male</td>
<td>63</td>
<td>Hissing, cricket-like, high-tension wire</td>
<td>5.0</td>
<td>Head</td>
<td>52</td>
<td>78</td>
<td>68</td>
</tr>
<tr>
<td>6</td>
<td>Male</td>
<td>48</td>
<td>Ringing, whistle</td>
<td>5.5</td>
<td>Both ears equally</td>
<td>70</td>
<td>74</td>
<td>78</td>
</tr>
<tr>
<td>7</td>
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<td>58</td>
<td>Ringing, cricket-like, high-tension wire</td>
<td>3.5</td>
<td>Right ear</td>
<td>63</td>
<td>82</td>
<td>NA</td>
</tr>
<tr>
<td>8</td>
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<td>80</td>
<td>Ringing, hissing, other</td>
<td>30.0</td>
<td>Both ears equally</td>
<td>56</td>
<td>47</td>
<td>61</td>
</tr>
<tr>
<td>9</td>
<td>Male</td>
<td>29</td>
<td>Ringing, sizzling, hissing</td>
<td>2.3</td>
<td>Right ear</td>
<td>27</td>
<td>55</td>
<td>60</td>
</tr>
<tr>
<td>10</td>
<td>Female</td>
<td>56</td>
<td>Ringing, hissing</td>
<td>10.0</td>
<td>Both ears equally</td>
<td>53</td>
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<td>34</td>
</tr>
<tr>
<td>11</td>
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<td>43</td>
<td>Ringing, clicking, hissing</td>
<td>10.5</td>
<td>Right ear</td>
<td>66</td>
<td>55</td>
<td>64</td>
</tr>
<tr>
<td>12</td>
<td>Female</td>
<td>56</td>
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<td>1.0</td>
<td>Head</td>
<td>63</td>
<td>59</td>
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<tr>
<td>13</td>
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<td>57</td>
<td>Ringing, cricket-like</td>
<td>45.0</td>
<td>Both ears equally</td>
<td>48</td>
<td>53</td>
<td>58</td>
</tr>
<tr>
<td>14</td>
<td>Male</td>
<td>66</td>
<td>Hissing</td>
<td>7.8</td>
<td>Both ears equally</td>
<td>56</td>
<td>65</td>
<td>63</td>
</tr>
<tr>
<td>15</td>
<td>Male</td>
<td>58</td>
<td>Ringing, buzzing, other</td>
<td>10.0</td>
<td>Both ears equally</td>
<td>27</td>
<td>43</td>
<td>22</td>
</tr>
<tr>
<td>16</td>
<td>Male</td>
<td>54</td>
<td>Ringing, buzzing, high-tension wire</td>
<td>15.0</td>
<td>Both ears equally</td>
<td>56</td>
<td>72</td>
<td>70</td>
</tr>
<tr>
<td>17</td>
<td>Male</td>
<td>61</td>
<td>Ringing, steam whistle, ocean roar</td>
<td>5.6</td>
<td>Both ears equally</td>
<td>19</td>
<td>39</td>
<td>17</td>
</tr>
<tr>
<td>18</td>
<td>Female</td>
<td>62</td>
<td>High-tension wire, hissing, cricket-like</td>
<td>5.0</td>
<td>Left ear</td>
<td>55</td>
<td>68</td>
<td>75</td>
</tr>
<tr>
<td>19</td>
<td>Male</td>
<td>62</td>
<td>Ringing, high-tension, cricket-like</td>
<td>0.3</td>
<td>Both ears equally</td>
<td>62</td>
<td>72</td>
<td>69</td>
</tr>
<tr>
<td>20</td>
<td>Female</td>
<td>70</td>
<td>Ringing, high-tension wire, other</td>
<td>5.0</td>
<td>Both ears equally</td>
<td>38</td>
<td>69</td>
<td>44</td>
</tr>
</tbody>
</table>

Note. Baseline scores on the Tinnitus Handicap Questionnaire (THQ), the Tinnitus Primary Functions Questionnaire (TPFQ), and the Tinnitus Functional Index (TFI) are displayed.
physiological orientation of the auditory system, the relationship between tinnitus and hearing loss, common difficulties associated with tinnitus, overview of the neurophysiologic models of tinnitus, the relationship between tinnitus and stress, and tinnitus habituation.

Visit 2: HA-Fitting Appointment  
(2 Weeks After Initial Counseling)

Amplification device. Participants were fitted with a model from the Widex “Clear-Fusion” HA family (Widex Clear 440 Fusion RIC). They were fitted bilaterally using open fit ear molds. The HA used was a 15-channel, wide-dynamic-range compression HA with a compression threshold as low as 0 dB HL. Among the features were adaptive multichannel directional microphone, adaptive noise reduction, active feedback cancellation, and data logging. The HA also had inter-ear features (Kuk, Peeters, Korhonen, & Lau, 2011b). In addition, the participants got a remote control (RC-DEX) to adjust volume or to change HA programs. Behavioral measurement data were gathered prior to HA fitting during this visit. HAs were programmed according to the default fitting (sensogram and feedback) gain and feature settings (locator with digital pinna, speech enhancer for noise reduction, FbC Supergain, sound soften-ener plus). Appropriate acclimatization levels were used based on the following guidelines and participant feedback.

First-time users. The Master program was set to target with acclimatization Level 2 (according to the Widex software) activated with the goal of setting to target by the end of the trial period.

Experienced users (> 1 year experience). The Master program was set to target (fine-tuning was done if necessary; experienced users chose to participate because of the potential to help with their tinnitus using the new device).

Further adjustments to both groups were made as needed such as necessary adjustments to meet Widex criteria of acceptable fit (i.e., predicted thresholds around 20 dB HL up to 2000 Hz and as close to 20 dB HL as possible up to 4000 Hz with adjustment: 40 dB HL acceptable with a severe loss). In addition, gain settings as a function of frequency were examined to verify that soft sounds were audible across frequencies and that loud sounds did not exceed the uncomfortable loudness level and that conversational level sounds were in between soft and loud. Although individuals with loudness, annoyance, fear or pain hyperacusis (Tyler, Pienkowski, et al., 2014), or severe recruitment were excluded from the study, those who reported issues with hearing loud sounds (such as discomfort) but had reasonable loudness discomfort levels were further examined with respect to insertion gain and maximum power output settings. If loudness hyperacusis was recorded during intake, the feedback test was administered after the sensogram was performed. Where loudness hyperacusis was noted, a reduction of insertion gain for loud sounds, was applied. If sound was still judged as “too loud,” the maximum power output was then adjusted as a low maximum power output could lead to poor sound quality (see Kuk, Peeters, Korhonen, & Lau, 2011). Adjustments to the necessary gain parameters were made only if the participant complained that the HAs were too loud. In that case, insertion gain-loud and insertion gain-normal adjustment was sometimes made. Participants had to judge that the sound quality was acceptable.

Visit 3: Zen Programming (2 Weeks After HA Fitting)

This appointment was for participants who still reported a problematic tinnitus (TFI score > 17; chosen arbitrarily). During this visit, participants completed all questionnaires at the start of this visit. The HA data log (“the Sound Diary of the Widex aids”) was examined to ensure compliance. The HA fitting was reviewed, and the need for fine-tuning was adjudged. The acclimatization level was increased for first-time HA users (if possible) in an effort to get participant to target. Zen + was chosen in the program selection and was used as the tinnitus program. Three Zen programs were chosen: Zen (A) was Aqua + mic on, (B) was Aqua + mic on + noise, and (C) was Zen noise + mic on. The volume control option was selected such that the effect of volume control adjustment affected the Zen level only (and not the overall mic + Zen level). It was ensured that the Zen tones were audible but relatively soft (judged by the patient). The volume of the Zen tones was set such that they did not interfere with conversational speech and that the annoyance level of the tinnitus just began to decrease. Participants were instructed to listen to Zen + all day. Participants were instructed to listen to Zen A (Aqua) during all their activities. Zen Aqua + noise (B) or Zen noise (C) could be used if participants did not like to listen to Zen (A) or if they were very bothered by their tinnitus. The Master program was recommended in listening situations in which hearing and communication were essential for the participants with significant hearing loss. Participants were reminded that Zen + should be used for passive listening (i.e., as a sound background only). They were instructed not to focus their attention in trying to analyze the sound. They were asked to use a “set and forget” approach with the Zen, avoiding adjustments in volume level or Zen settings as much as possible.

Visit 4a: First Adjustment-Based Counseling  
(2 Weeks After Zen Programming)

This appointment was for participants who still had a problematic tinnitus. This visit included an abbreviated component of TAT, including some cognitive behavioral therapy and acceptance and relaxation strategies. Participants completed all questionnaires at the start of this visit. Fine-tuning of Zen + was provided, if necessary. Participants were administered relaxation exercises based on individual needs and preferences. Participants used Zen, silence, or any other background sound when performing the exercises. One or more of three techniques (progressive muscle relaxation, deep breathing, or guided imagery) were used. Adjustment-based counseling was initiated. It was explained that the overall objective of the treatment was to ensure that the tinnitus did not negatively affect the participant’s quality of life. Participants’ perspectives on
their tinnitus were also explored. TAT was administered to identify unwanted thoughts and behaviors hindering natural habituation, to challenge their validity, and to help the participant replace the negative thoughts with alternative and logical thoughts and behaviors.

**Visit 4b: Additional Adjustment-Based Counseling**

Additional sessions for TAT were available if desired by participants as long as TFI was > 17. There were only three participants whose TFI was close to or below 18 after TAT: TFI for Participant 1 dropped to 12, Participant 12 dropped to 18, and Participant 15 dropped to 8. Only one additional session was provided.

**Visit 5: 3 Months Posttreatment**

Visit 5 was the first follow-up visit. Participants completed all questionnaires at the start of this visit.

**Visit 6: 6 Months Posttreatment**

Visit 6 was the second follow-up visit. Participants completed all questionnaires at the start of this visit. Progress was reviewed, and any questions that arose after the last appointment were addressed.

**Results**

We first provide background data on individuals before showing results for averages and individuals. Figure 1 summarizes the audiograms of individual participants (averaged both ears). There were two participants (4, 11) with asymmetrical hearing loss, whose pure-tone average (PTA; averaged 500 Hz, 1000 Hz, and 2000 Hz) difference between the two ears was greater than 10 dB HL. The other 18 participants had symmetrical hearing loss. The solid black line represents the mean audiogram of all participants. Twelve participants had normal low-frequency hearing (PTA < 25 dB HL) but with high-frequency loss either in one or both ears, five participants had mild hearing loss (25 dB HL < PTA ≤ 40 dB HL), and three participants had moderate hearing loss (40 dB HL < PTA ≤ 55 dB HL). One participant (#20) had a predominately low-frequency hearing loss.

Data were treated with parametric analyses based on TFI scores being treated as real numbers (thus parametric; e.g., Fackrell, Hall, Barry, & Hoare, 2016; Meikle et al., 2012; Sweetow, Kuk, & Caprioli, 2015). Using nonparametric analysis would have implied that the magnitude of TFI change was not as important as it should be; however, in the Fackrell et al. (2016) study, the magnitude of TFI change was important to determine the smallest detectable change and to test its reliability. We treated the VAS, TPFQ, and THQ data as real numbers similar to the Fackrell et al. (2016) study, in which they verified the performance of TFI with these two measures.

We used repeated-measures analysis of variance (ANOVA) after testing the assumption of equality of variances of the differences between treatment levels. If this assumption was violated, we applied the Greenhouse–Geisser correction for determining the significance level. The normality for each data set in TFI, VAS, THQ, and TPFQ was tested with the Shapiro–Wilk test. The results showed that the majority of data sets were normally distributed (15 of 20), and any violation of equality of variances between visits was treated with the Greenhouse–Geisser correction before any significant difference was determined.

**Tinnitus Severity Ratings**

Figure 2 shows the average VAS subscale ratings across time. The labels at the horizontal axis represent the
result of a treatment component. Therefore, IC represents the effect of informational counseling, HA refers to the VAS ratings after HAs were fitted and worn for 2 weeks, and so on. Only small changes were observed following informational counseling. Improvements were noted following the provision of HAs, Zen, and TAT. Results were stable at the follow-up visits.

Figure 3 shows the tinnitus severity ratings at each visit for each individual participant. The mean response is shown in the solid black line: 7.9 (SD = 1.4), 8.1 (SD = 0.8), 7.0 (SD = 1.6), 6.2 (SD = 1.9), 5.0 (SD = 2.4), and 4.3 (SD = 2.5) for Visit 1, Visit 2, Visit 3, Visit 4, Visit 5, and Visit 6, respectively. There were large individual differences. On average, the greatest benefits were observed following the HA, Zen, and the TAT.

A one-way repeated-measures ANOVA was conducted on the tinnitus severity ratings with time of obtaining data as a within-subject variable (informational counseling, HA fitting, Zen fitting, TAT-based counseling, follow-up at Visit 5, follow-up at Visit 6). The results show that time is significant, $F(5, 90) = 18.89$, $p < .001$, $\eta^2 = 0.51$, power = 0.99. Post hoc analysis with Bonferroni adjustment for multiple comparisons was used to find out which times were significantly improved over the previous ones. Table 2 shows the $p$ value when comparing the tinnitus severity ratings obtained at two different times. Significant $p$ values (i.e., tinnitus improvements over time) are marked with an asterisk in Table 2.

Tinnitus Questionnaires

Figure 4 shows the average data for the three tinnitus questionnaires. Similar results were observed for all three questionnaires (data were collected at all times for the THQ and TPFQ), with the largest changes observed followed Zen and TAT. The mean values of TFI for Visit 1 to Visit 6, respectively, are 61.3 (SD = 12.8), 59.6 (SD = 14.4), 52.3 (SD = 19.3), 44.1 (SD = 19.6), 34.5 (SD = 21.1), and 35.3 (SD = 22.1). The mean values of THQ for Visit 1, Visit 5, and Visit 6, respectively, are 50.7 (SD = 14.2), 37.7 (SD = 23), and 33.3 (SD = 20.7). The mean values of TPFQ for Visit 1, Visit 3, Visit 4, Visit 5, and Visit 6, respectively, are

---

Table 2. The $p$ values for the differences of tinnitus severity ratings obtained at two different times.

<table>
<thead>
<tr>
<th>Visit</th>
<th>Visit 2 (HA)</th>
<th>Visit 3 (ZEN)</th>
<th>Visit 4 (TAT)</th>
<th>Visit 5 (FU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1 (IC)</td>
<td>.2428</td>
<td>.0465</td>
<td>.0036*</td>
<td>.0001*</td>
</tr>
<tr>
<td>Visit 2 (HA)</td>
<td>.0036*</td>
<td>.0001*</td>
<td>.0004*</td>
<td>.0014*</td>
</tr>
<tr>
<td>Visit 3 (ZEN)</td>
<td>.0001*</td>
<td>.0000*</td>
<td>.0002*</td>
<td>.0016*</td>
</tr>
</tbody>
</table>

Note. Significant differences are marked with an asterisk ($p < .008$).

---

Figure 3. Tinnitus severity ratings for individual participants across time. The solid black line represents mean tinnitus severity ratings for all participants. IC = informational counseling; HA = hearing aid fitting; ZEN = Zen fitting; TAT = tinnitus activities treatment-based counseling; FU = follow-up.

Figure 4. Average performance over time for the Tinnitus Handicap Questionnaire (THQ), Tinnitus Primary Functions Questionnaire (TPFQ), and Tinnitus Functional Index (TFI). IC = informational counseling; HA = hearing aid fitting; ZEN = Zen fitting; TAT = tinnitus activities treatment-based counseling; FU = follow-up.
57.7 (SD = 17.9), 54.1 (SD = 20.1), 43.7 (SD = 21.1), 32.1 (SD = 24.3), and 32.2 (SD = 25.7).

**TFI Scores of Individual Participants**

Figure 5 shows the TFI score obtained at different times for individual participants. The 3-month (Visit 5) and 6-month (Visit 6) data points were not available for Participant 18 as she dropped out of the study.

The mean TFI score of all participants in Figure 5 (solid black line) was 61 points at Visits 1a/b (baseline/informational counseling). The TFI score at HA fitting (Visit 2) was similar to the TFI score at informational counseling (Visit 1). The TFI score dropped from 61 points at informational counseling (Visit 1) to 52 points at the Zen fitting (Visit 3). There was a further average drop of nine points at the TAT-based counseling (Visit 4) as compared with the Zen fitting (Visit 3). There was a drop of nine points in the follow-up Visit 5 compared with the TAT-based counseling (Visit 4). A total drop of 26 points was noted when compared with informational counseling (Visit 1). The score at the second follow-up (Visit 6) was similar to the score at Visit 5. This reflects that performance stabilized after Visit 5.

A one-way repeated-measures ANOVA was conducted on the TFI scores with time of obtaining data as a within-subject variable (informational counseling, HA fitting, Zen fitting, TAT-based counseling, follow-up at Visit 5, follow-up at Visit 6). The results show that time is significant, $F(5, 90) = 17.39, p < .001, \eta^2 = 0.49$, power = 0.99. For post hoc analysis, Table 3 shows the $p$ value when comparing the TFI scores obtained at two different times. Significant $p$ values (i.e., tinnitus improvements over time) are marked with an asterisk in Table 3. TFI scores at informational counseling (Visit 1) and HA fitting (Visit 2) were not significantly different, $p > .008$. This finding suggests that the counseling instruction alone may not be sufficient in improving tinnitus. TFI scores at informational counseling (Visit 1) and HA fitting (Visit 2) were significantly higher than those scores at the other four subsequent times, $p < .008$. Comparing HA fitting (Visit 2) with Zen fitting (Visit 3) showed a significant drop in scores, indicating the benefit of amplification in improving tinnitus. Performance was significantly different between Zen fitting (Visit 3) and TAT-based counseling (Visit 4), $p < .008$. This finding suggests the benefit of Zen in its initial trial for 2 weeks. Scores at the two follow-up visits were significantly lower than that at Zen fitting (Visit 3). After TAT-based counseling (Visit 4), the TFI scores did not improve significantly as measured in the subsequent two follow-up visits. Performances at the two follow-up visits were not significantly different.

**Figure 5.** Tinnitus Functional Index (TFI) scores of individual participants across different visits. The solid black line represents mean TFI scores of all participants. IC = informational counseling; HA = hearing aid fitting; ZEN = Zen fitting; TAT = tinnitus activities treatment–based counseling; FU = follow-up.

**Table 3.** The $p$ values for the differences of TFI (all items) obtained at two different times.

<table>
<thead>
<tr>
<th></th>
<th>Visit 1 (Baseline, IC)</th>
<th>Visit 2 (HA)</th>
<th>Visit 3 (ZEN)</th>
<th>Visit 4 (TAT)</th>
<th>Visit 5 (FU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 2 (HA)</td>
<td>.3587</td>
<td></td>
<td>.0049*</td>
<td>.0078*</td>
<td></td>
</tr>
<tr>
<td>Visit 3 (ZEN)</td>
<td>.0003*</td>
<td>.0002*</td>
<td>.0049*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visit 4 (TAT)</td>
<td>.0001*</td>
<td>.0001*</td>
<td>.0013*</td>
<td>.0155</td>
<td>.0238</td>
</tr>
<tr>
<td>Visit 5 (FU)</td>
<td>.0001*</td>
<td>.0002*</td>
<td>.0013*</td>
<td>.0238</td>
<td>.6521</td>
</tr>
</tbody>
</table>

*Note.* Significant differences are marked with an asterisk ($p < .008$). IC = informational counseling; HA = hearing aid fitting; ZEN = Zen fitting; TAT = tinnitus activities treatment–based counseling; FU = follow-up.

**TPFQ Scores of Individual Participants**

Figure 6 shows the TPFQ scores obtained at different times for individual participants.

The mean TPFQ scores of all participants are displayed in Figure 6 (solid black line). The baseline TPFQ score was 38 points, which dropped slightly to 54 points after HA use and dropped further to 44 points after Zen use. The final TPFQ at 3 months and 6 months was 32.

A one-way repeated-measures ANOVA was conducted on the TPFQ scores with time of obtaining data as a within-subject variable (Visit 1, Visit 3, Visit 4, Visit 5, Visit 6). The results show that time is significant, $F(4, 60) = 13.67, p < .001, \eta^2 = 0.47$, power = 0.99. For post hoc analysis, Table 4 shows the $p$ values for comparisons between TPFQ scores obtained at two different times. Significant $p$ values (i.e., tinnitus improvements over time) are marked with an asterisk in Table 4. Visit 5 shows significant improvement in tinnitus over all other visits except Visit 5. Visit 5 shows significant improvement in tinnitus over the baseline, Zen use, and TAT treatment ($p < .012$). Visit 4 shows significant improvement in tinnitus over the baseline and Zen use ($p < .012$). This indicates the benefit of Zen use for the first 2 weeks.
Discussion

The aim of the present study was to explore the effect of the Zen therapy in alleviating tinnitus. The relative contributions of different components of the Zen therapy were studied using behavioral tinnitus measures including questionnaires and rating scales. Mean changes were observed after each visit on tinnitus questionnaires (THQ, TPFQ, TFI) as well as rating scales (VAS) and are discussed below. Benefits were retained at follow-up visits.

For TFI, the smallest score required to detect a true change—termed as the “smallest detectable change”—is a global score (i.e., all items) of at least 22.4 points (Fackrell et al., 2016). In the present study, 13 of 19 (68%) participants reported a tinnitus improvement important to them, and they reported a change greater than 22.4; thus, a majority of our subjects reported a tinnitus improvement important to them.

The overall improvement/confined improvement of mean scores following informational counseling should not imply that informational counseling was not helpful. The effect of informational counseling on tinnitus scores depends on the attributes of the participant and the information provided at the session, as well as their expectations from the session. Another factor is the amount of time allocated for such an informational counseling approach. Typically, some form of a progressive management strategy is applied (Tyler et al., 1989) after the emotional severity of the effects of tinnitus is determined. The need for HAs and/or sound therapy may also be determined at this session.

Of course, there have been brief counseling protocols proposed for individuals with tinnitus (e.g., Tyler et al., 1989; Tyler & Babin, 1993). Tyler and Erlandsson (2003) referred to three levels of patient needs: curious, concerned, and distressed. The informational counseling sessions can be tailored according to patient needs. Self-help books can also be a helpful resource at such sessions (e.g., Henry & Wilson, 2001b; Tyler, 2008). The large improvement following Zen does indicate that this is a good option as a sound therapy. Individual preferences of the sound type and quality are critical, but clearly the Zen approach here should be a viable option for many tinnitus patients.

We also noted improvements following TAT. A shortened version of TAT was used, and larger improvements may be expected with the individually tailored, interactive strategies focused on the four primary functions influenced by tinnitus: thoughts and emotions, hearing, sleep, and concentration.

In this study, we attempted to demonstrate sequential effects in a typical clinical situation. As such, the sequential study design used here may mean that any measurement point in time might be a cumulative effect of all (or one) particular stage of the treatment. It is important to note that a study with a control group on the use of the Zen tones has been previously conducted in people with mild hearing loss (Sweetow et al., 2015). Participants were not blinded. They were aware of the sequence of steps from the start of the study. This might have influenced their expectations and rating at any point in time.

The protocol we followed (Widex Zen Treatment protocol) in the present study is similar to the one adopted in obtaining TFI scores in the Sweetow et al. (2015) study. Their mean difference of TFI between 6 months and baseline was 21.0 ($SD = 13.4$). Power analysis based on their results suggests a sample size of at least six in order to get a power of test $> 0.8$ at the .05 significance level. Thus, our sample size of 20 participants should yield sufficient power.

Finally, we wish to note that larger effects may have been observed with different measurement tools. The interval scale of 0–10 allows participants to choose only among 11 points. We noted floor effects and ceiling effects. Better resolution can be obtained by using a scale from 0–100. This results in participants choosing 0, 5, 10, 15, and so on, allowing for 21 points (see Tyler, Noble, & Coelho, 2006; Tyler, Oleson, Noble, Coelho, & Ji, 2007).

Conclusions

We carefully followed several participants through a typical clinical routine of tinnitus therapy using the

| Table 4. The $p$ values for comparisons between Tinnitus Primary Functions Questionnaire scores (all items) obtained at two different times. |
|---|---|---|---|---|
| | Visit 1 (baseline, IC) | Visit 3 (ZEN) | Visit 4 (TAT) | Visit 5 (FU) |
| Visit 3 (ZEN) | .384 | | | |
| Visit 4 (TAT) | .003* | .004* | | |
| Visit 5 (FU) | .000* | .000* | .002* | |
| Visit 6 (FU) | .000* | .001* | .004* | .443 |

Note. Significant differences are marked with an asterisk ($p < .01$). IC = informational counseling; ZEN = Zen fitting; TAT = tinnitus activities treatment–based counseling; FU = follow-up.
Zen tinnitus therapy. The following observations were noted:

- Many participants benefited from this systematic treatment of counseling, HAs, Zen, and TAT.
- Large improvements were made following HA and Zen.
- Improvements were made following an abbreviated form of TAT.
- Individual differences in benefit were large.
- The benefits observed were maintained 6 months following the TAT session.

Acknowledgments

This study was partially funded by Widex.

References


