TINNITUS MANAGEMENT TODAY

LAURA KEARNS AU.D.
SR. CLINICAL EDUCATION SPECIALIST

WIDEX

SPEAKER DISCLOSURE

Relevant Financial Relationships:

- Laura Kearns is an employee of Widex USA and receives financial compensation.

Relevant Nonfinancial Relationships:

- There are no nonfinancial relationships.

25 Million

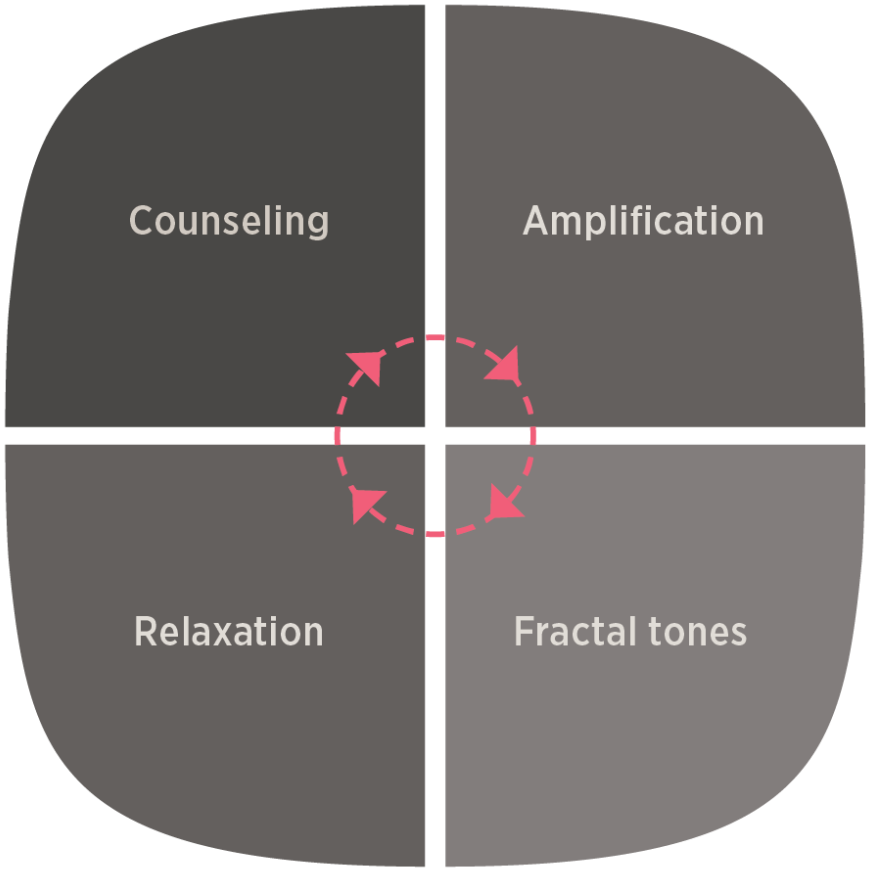
https://www.nidcd.nih.gov/health/tinnitus

37.5 Million

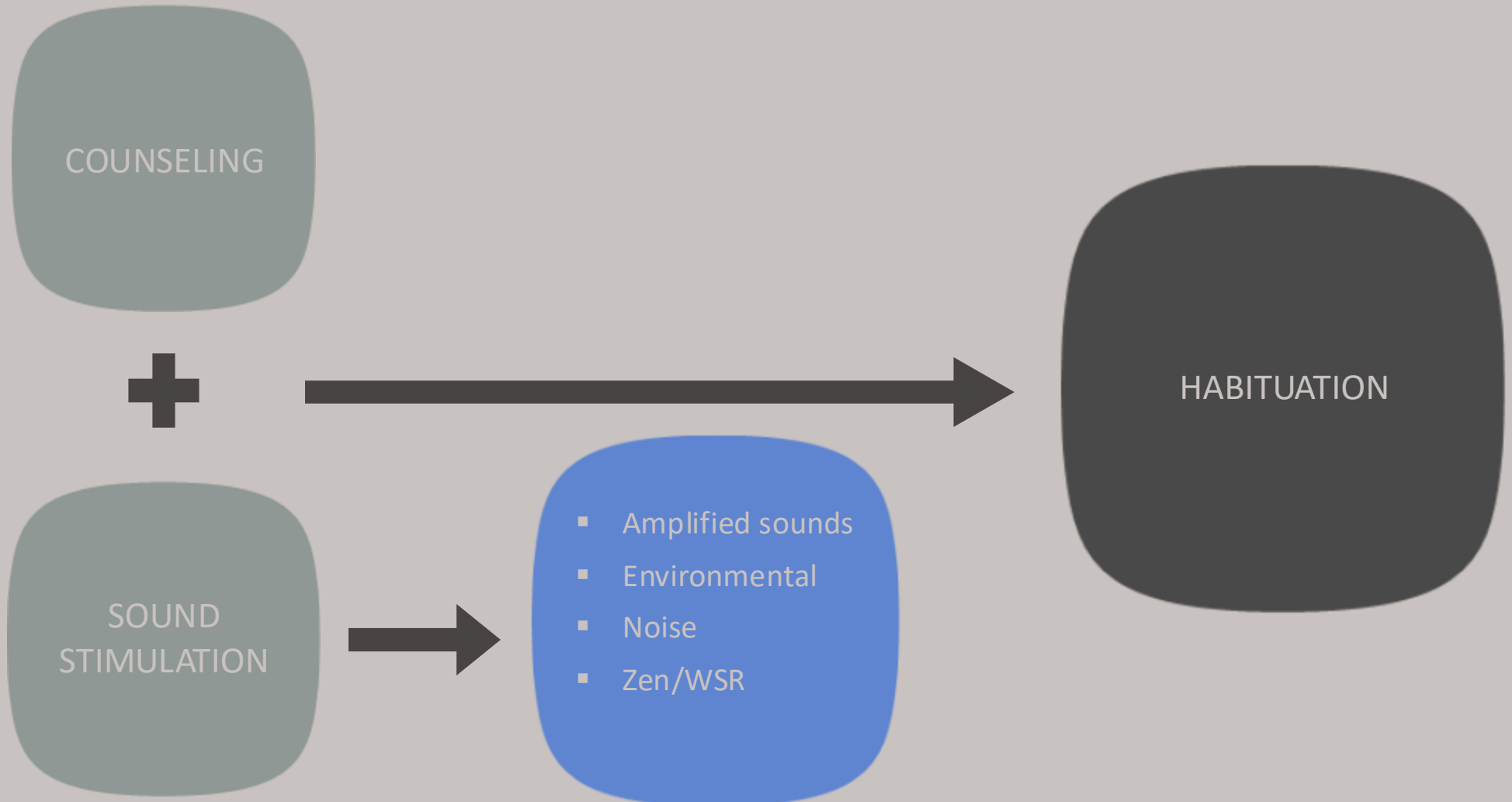
https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing

TINNITUS THERAPY **PROCESS**

COMPONENTS IN TINNITUS MANAGEMENT



PRINCIPLES OF TINNITUS REHABILITATION



WIDEX

HABITUATING TO SOUND

PROMOTING HABITUATION

THE WIDEX APPROACH TO TINNITUS MANAGEMENT

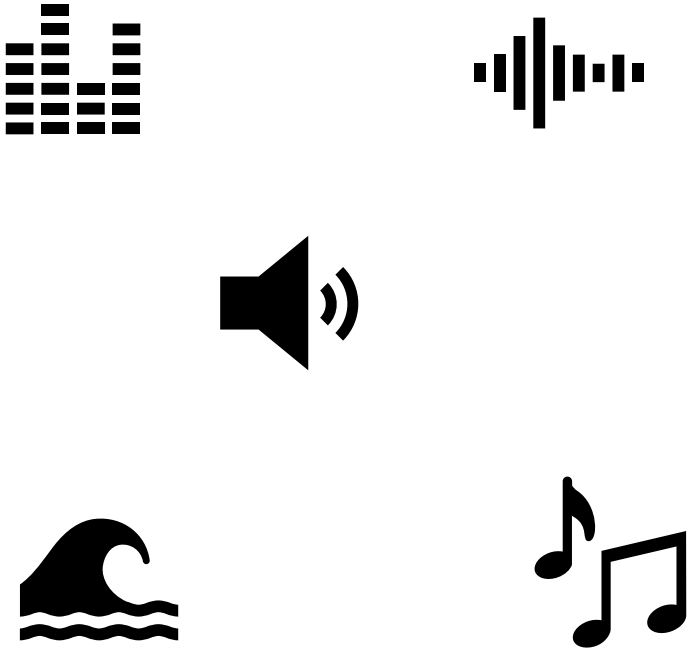
BACKGROUND

- Sound therapy, hearing aids and combination devices are a part of many tinnitus management programs, and together with information and counseling are the primary choice for tinnitus management in audiology departments (Sereda et al.,2018)

- Several studies have shown that sound therapy is an effective method to decrease the tinnitus-related distress, emotional reaction to and awareness of tinnitus (Kuk et al., 2010; Sweetow and Sabes, 2010; Krick et al., 2015; Liu et al., 2021).

TYPES OF SOUND THERAPY

- Sound therapies include:
  - noise shaped according to the audiogram
  - narrowband signals focusing on the frequency of tinnitus
  - notch noise
  - nature sounds
  - music
  - fractal tones



WZT COMPONENTS

WIDEX FRACTAL TECHNOLOGY

WIDEX SOUNDRELAX™ AND WIDEX ZEN

- Calm, continuous, chime-like tones
- Recognizable to the brain like music
- Algorithm-generated—never repeating itself
- Customized based on each individual’s hearing thresholds
- Specially created to facilitate tinnitus habituation and relaxation


WIDEX

BENEFITS OF FRACTAL TONES

Promote passive listening

Facilitate habituation

Reduce the distraction and annoyance of tinnitus

Promote relaxation to reduce stress

RANGE OF PUBLISHED ARTICLES ON ZEN FRACTAL TONES

- Kuk and Peeters (HR, 2008) showed Zen tones relaxed patients
- Sweetow and Hendersen-Sabes (JAAA 2010) showed significant tinnitus reduction on THI
- Kuk et al (HR 2010) reported tinnitus reduction in all survey respondents
- Herzfeld, M. (HR, 2011). Showed a very high (over 90%) success rate using Zen fractal music as a sound therapy tool
- Zubizarreta, A. (Poster AAA, 2012). Very high success rate using HA, fractal music and noise as sound stimulation
- Sekiya et al. (AO, 2013). Shows fractal music as effective in TRT treatment
- Skellgaard et al. (Poster, TRI, 2013): High success rate using counseling, amplification and fractal music in tinnitus management
- Boboshko et al. (Russian ENT magazine, 2014): Fractal music decreased the burden of tinnitus in 90% of the cases.
- Simonetti et al. (Int Arch Otorhinolaryngol, 2018): Fractal tones improve Tinnitus Handicap Inventory scores.

And many more…

WIDEX

PURPOSE

1. Explore the effects of sound therapy on tinnitus-related distress when participants choose a selection of the three sounds they want implemented in a combination device.
2. Explore the relationship between improvement in tinnitus outcome and sound-therapy use, amplification-only use, and total device use time.

Lelic D, Caporali S, Parker D, Nielsen J and Balling LW (2024) Impact of a combination sound therapy on tinnitus distress: an exploratory one-year longitudinal study. Front. Audiol. Otol. 2:1322596. doi: 10.3389/fauot.2024.1322596

frontiers | Frontiers in Audiology and Otology

TYPE Original Research
PUBLISHED 05 March 2024
DOI 10.3389/fauot.2024.1322596

Check for updates

OPEN ACCESS

EDITED BY
Alicja Natalia Malicka,
La Trobe University, Australia

REVIEWED BY
Michelle Loeliger,
La Trobe University, Australia
Emma Stapleton,
The University of Manchester, United Kingdom

*CORRESPONDENCE
Dina Lelic
dina.lelic@wsa.com

RECEIVED 16 October 2023
ACCEPTED 14 February 2024
PUBLISHED 05 March 2024

CITATION
Lelic D, Caporali S, Parker D, Nielsen J and Balling LW (2024) Impact of a combination sound therapy on tinnitus distress: an exploratory one-year longitudinal study. *Front. Audiol. Otol.* 2:1322596. doi: 10.3389/fauot.2024.1322596

Impact of a combination sound therapy on tinnitus distress: an exploratory one-year longitudinal study

Dina Lelic*, Sueli Caporali, Daniel Parker, Jakob Nielsen and Laura Winther Balling

WS Audiology, Lynge, Denmark

Introduction: Combination devices offering both amplification and sound therapy are commonly used in tinnitus management. However, there is insufficient evidence supporting the relationship between sound therapy and tinnitus outcomes. The aim of this study was to explore longitudinal effects of sound therapy on tinnitus-related distress using a combination device.

Method: Twenty participants with mild to moderate tinnitus related distress were fitted with combination devices that included three sound-therapy programs. The sound-therapy programs were selected by the participants from the available sounds offered in the combination device. The sounds comprised fractal music, nature sounds and combinations of the two. Participants were asked to wear the devices for 12 months and to complete questionnaires related to tinnitus distress at baseline and 1, 2, 4, 6, and 12 months after starting the treatment. Additionally, at 2, 4, 6, and 12 months, the device log data capturing information about amplification and sound-therapy use were collected.

Results: Tinnitus handicap inventory (THI), tinnitus functional index (TFI), tinnitus awareness and annoyance decreased following the device fitting. This improvement plateaued at 4 months. The degrees of improvement in THI, TFI and tinnitus annoyance were correlated with daily hours of sound-therapy use but not with daily hours of amplification-only or total device use.

Conclusions: A combination sound therapy consisting of therapy sounds, amplification as needed, and counseling was associated with a reduction in tinnitus-related distress. A future randomized controlled trial should be conducted to allow for detangling the effect of sound therapy from effects of amplification, counseling, placebo, and time itself, and to investigate the predictors of sound-therapy benefit and use.

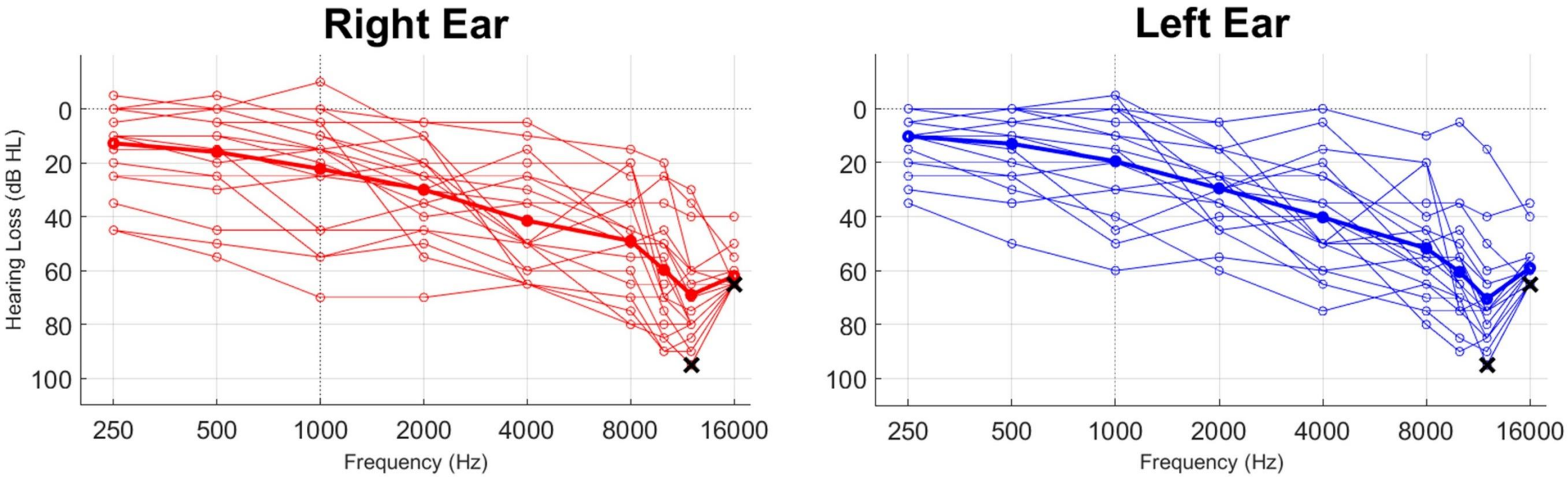
KEYWORDS

tinnitus, sound therapy, fractal tones, amplification, combination device

Introduction

Tinnitus refers to perception of noise without any external stimuli (Baguley, 2002). It affects ~10–15% of adults (Gallus et al., 2015; McCormack et al., 2016; Biswas et al., 2022), with about 20% of the affected population experiencing symptoms that negatively affect quality of life (Jastreboff and Hazell, 1993; Davis et al., 2000; Sereda et al., 2018). The most common problems associated with tinnitus are stress, concentration difficulties, insomnia, and decreased speech discrimination (Axelsson and Sandh, 1985). The available evidence indicates that various tinnitus management programs offer distinct advantages.

PARTICIPANTS



Twenty participants, four with normal hearing and 16 with various degrees of hearing loss

Participants signed up for the study with tinnitus, and not hearing loss, as the primary complaint.

The inclusion criteria were: 18 years of age, chronic tinnitus (6 months+), THI score between 18 and 70, and willingness to commit to the required tasks and study duration.

STUDY FLOW

Before study

Participants recruited based on screening questionnaire and THI between 14 and 74

Visits 1-3 at study start

1. Audiometry and UCL
2. HA fitting with three SoundRelax options
3. Baseline questionnaires, one informational counseling session

2 weeks

Follow-up via telephone

1 month

Questionnaires

2 months

Questionnaires and HA log

4 months

Questionnaires and HA log

6 &12 months

Questionnaires, HA log data, UCL measurements

VISUAL ANALOG SCALE QUESTIONNAIRE

Question	VAS Scale		
How aware have you been of your tinnitus in the past week?	Not at all (0)	⟷	Very (10)
How bothered by your tinnitus have you been in the past week?	Not at all (0)	⟷	Very (10)
How strong/high in volume has your tinnitus been in the past week?	Very weak (0)	⟷	Extremely strong (10)
How relaxed have you felt in the past week?	Very (0)	⟷	Not at all (10)
How has your ability to concentrate been in the past week?	Very easy (0)	⟷	Very difficult (10)
How has your mood been this past week?	Very good (0)	⟷	Very bad (10)

Supplementary Table 1. The VAS questions and scales. The questions are translated from Danish.

VAS questionnaire assessing relaxation, concentration, mood and tinnitus over the past week.

WIDEX

STUDY FLOW

Before study

Participants recruited based on screening questionnaire and THI between 14 and 74

Visits 1-3 at study start

1. Audiometry and UCL
2. HA fitting with three SoundRelax options
3. Baseline questionnaires, one informational counseling session

2 weeks

Follow-up via telephone

1 month

Questionnaires

2 months

Questionnaires and HA log

4 months

Questionnaires and HA log

6 &12 months

Questionnaires, HA log data, UCL measurements

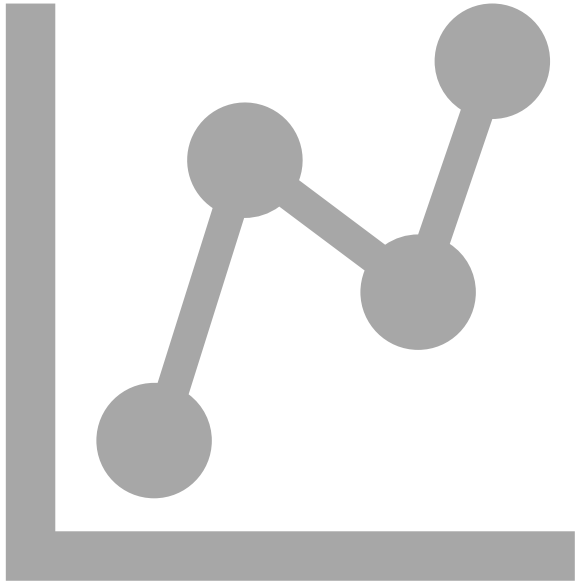
RESULTS

Sixteen participants successfully completed the 1-year trial.

Four participants dropped out after the 2 month follow-up.

Results reported:

1. Sound ratings and preferences
2. Device use in real life
3. Long-term effects on tinnitus outcomes
4. Relationship between tinnitus outcomes and device use

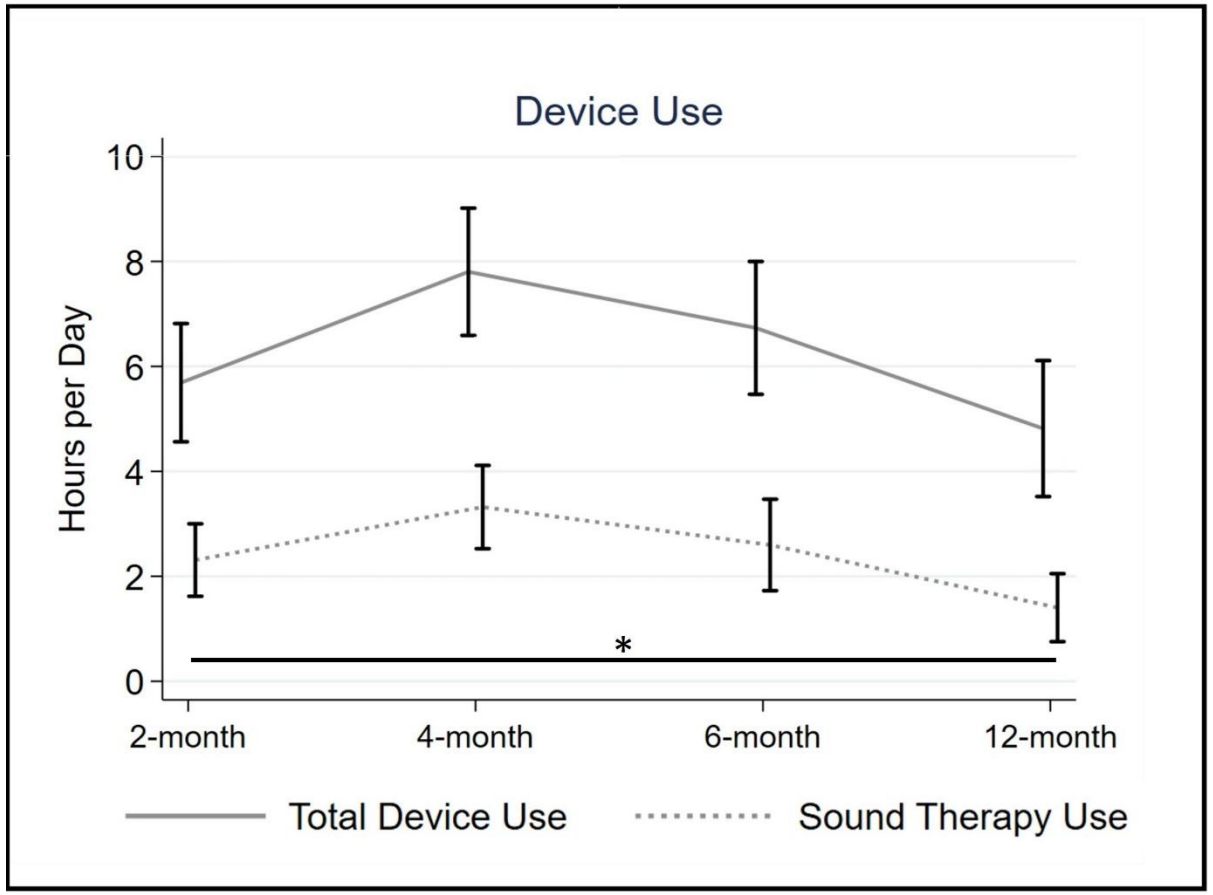


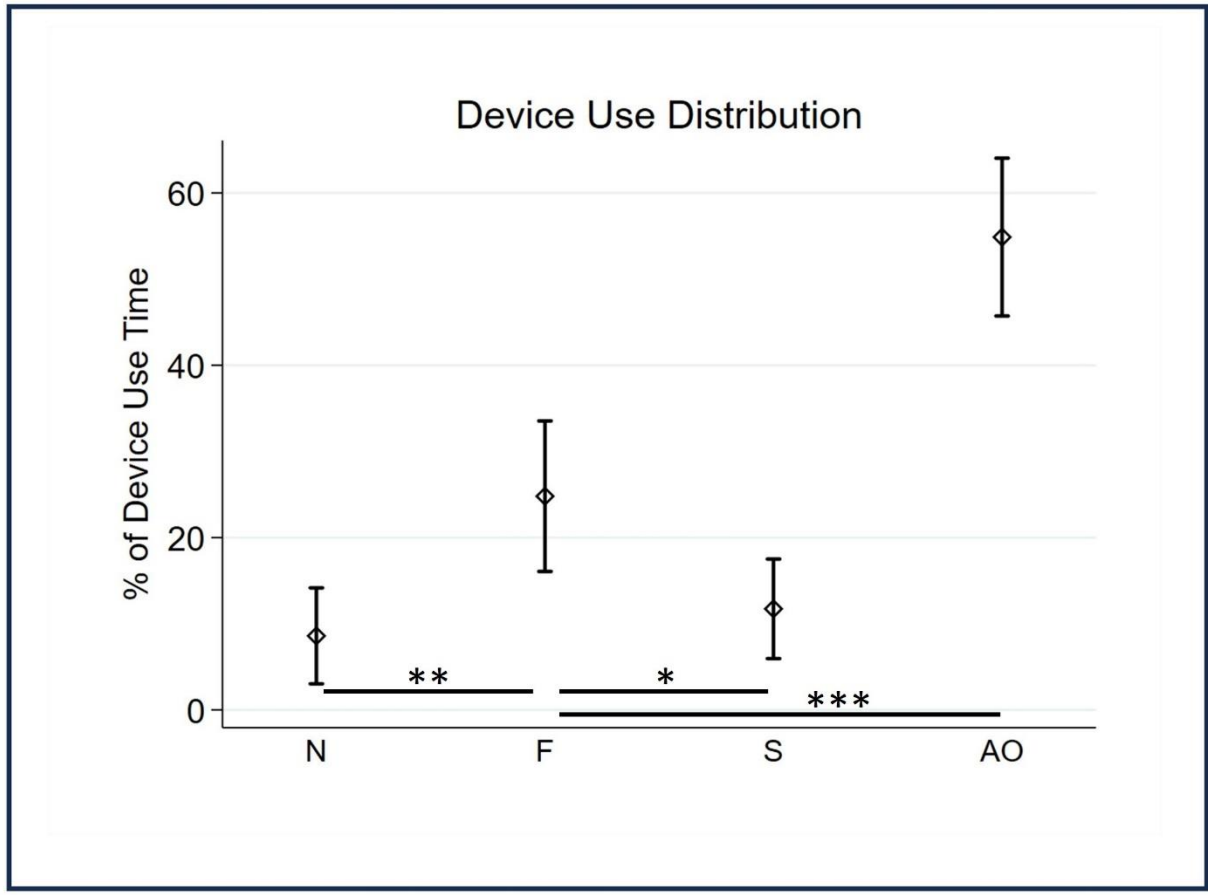
SOUND RATINGS AND PREFERENCES

- Participants preferred sounds:
  - fractal - 42% of cases (chosen at least once by twelve participants)
  - soundscapes - 36% of cases (chosen at least once by thirteen participants)
  - Nature sounds - 22% of cases (chosen at least once by nine participants)

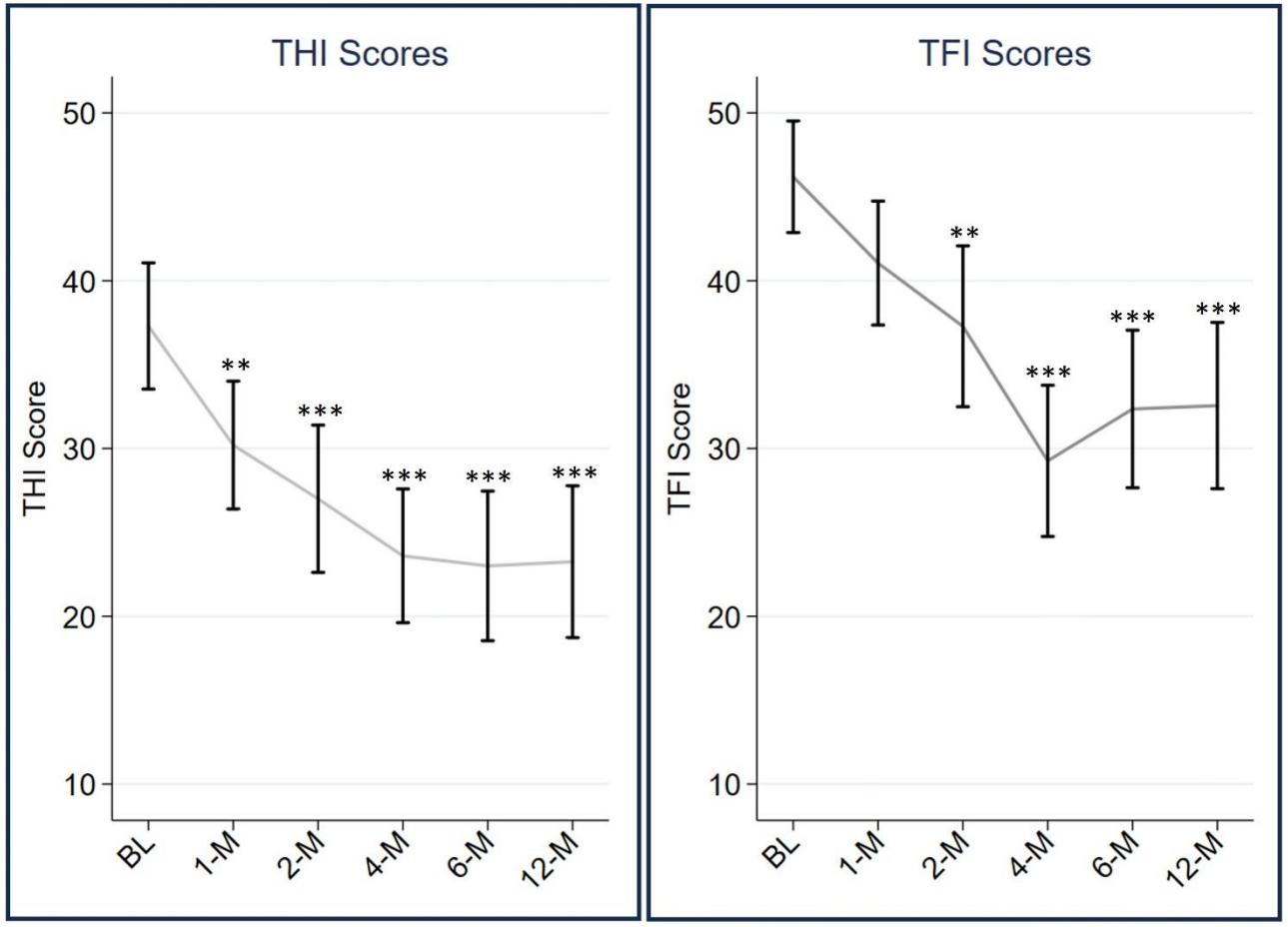
- Ratings:
- Ratings for the three preferred sounds at Visit 2 were 7.7 ± 1.0 for liking and 7.5 ± 1.4 for relaxation.
- Sound preferences varied between participants and the most common reasons given for preferences were that the sound was relaxing, calming, comfortable or distracted from tinnitus.

DEVICE USE IN REAL LIFE





LONG-TERM EFFECTS ON TINNITUS OUTCOMES



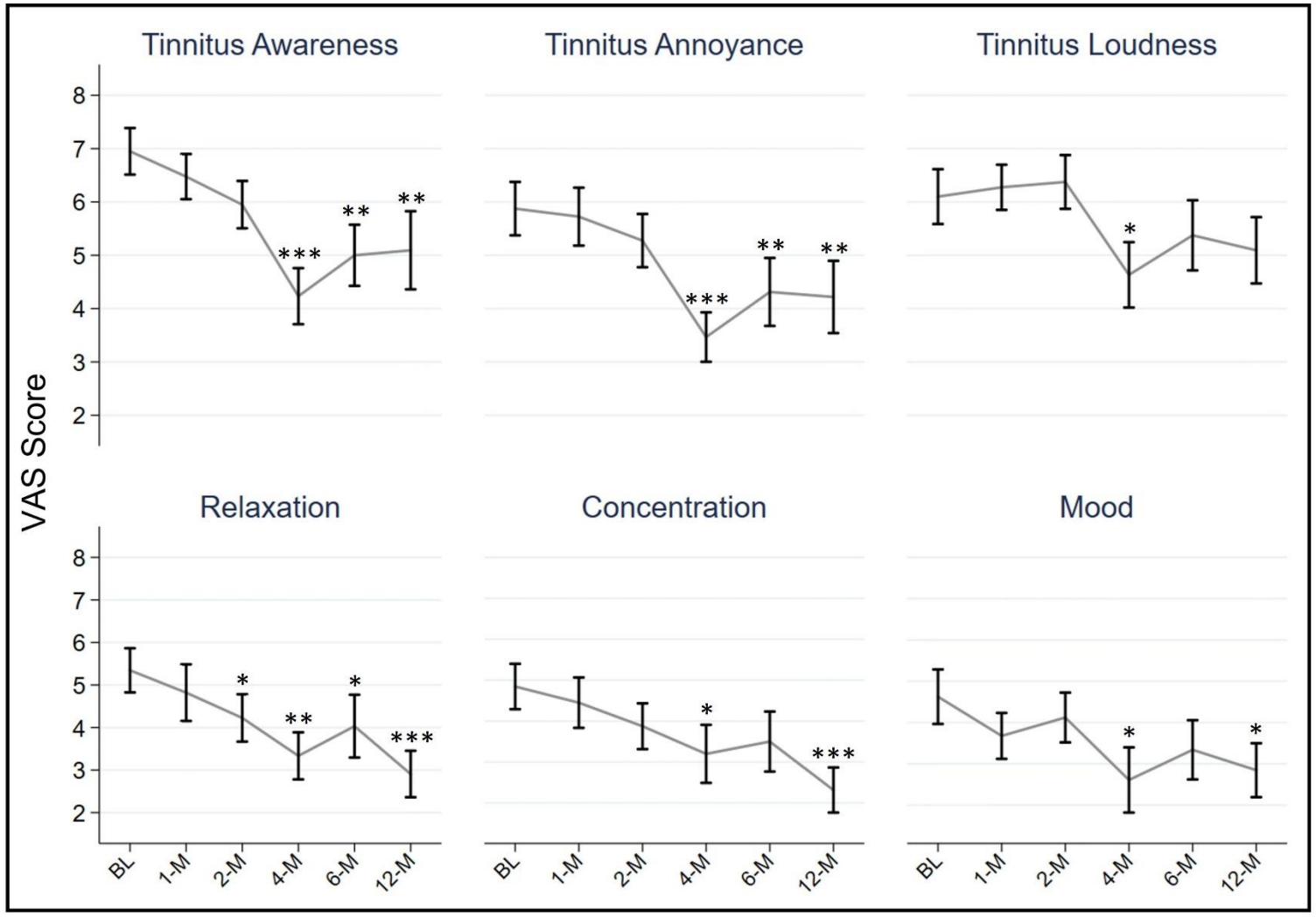
THI and TFI scores at baseline and the five follow-ups.

Lower scores indicate better ratings. The error bars indicate standard errors of the mean.

Significant improvements at follow-up visits relative to baseline are denoted by asterisks (**P < 0.01; ***P < 0.001).

BL, baseline; 1-M, 1-month follow-up; 2-M, 2-month follow-up; 4-M, 4-month follow-up; 6-M, 6-month follow; 12-M, 12-month follow-up.

LONG-TERM EFFECTS ON TINNITUS OUTCOMES



THI and TFI scores at baseline and the five follow-ups. Lower scores indicate better ratings. The error bars indicate standard errors of the mean.

Significant improvements at follow-up visits relative to baseline are denoted by asterisks (*P < 0.05; **P < 0.01; ***P < 0.001).

BL, baseline; 1-M, 1-month follow-up; 2-M, 2-month follow-up; 4-M, 4-month follow-up; 6-M, 6-month follow; 12-M, 12-month follow-up.

RELATIONSHIP BETWEEN TINNITUS OUTCOMES AND DEVICE USE

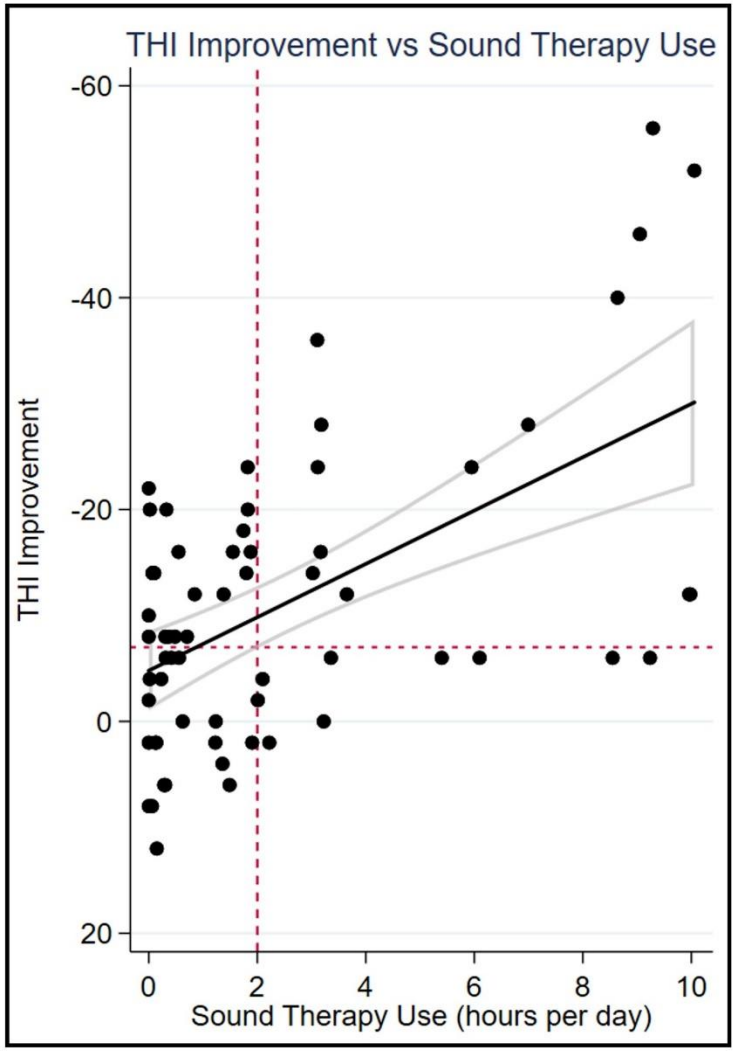
Improvement in	Sound-therapy use	Amplification-only use	Total device use
THI	**ρ = −0.54***	ρ = 0.08	ρ = −0.05
TFI	**ρ = −0.69****	ρ = −0.18	ρ = −0.46
Hyperacusis	ρ = −0.32	ρ = 0.10	ρ = −0.01
Tinnitus awareness	ρ = −0.34	ρ = 0.02	ρ = −0.19
Tinnitus annoyance	**ρ = −0.51***	ρ = 0.06	ρ = −0.17
Tinnitus loudness	ρ = −0.23	ρ = 0.22	ρ = 0.04
Relaxation	ρ = −0.45	ρ = 0.02	ρ = −0.22
Concentration	ρ = −0.30	ρ = −0.27	ρ = −0.29
Mood	ρ = −0.26	ρ = −0.20	ρ = −0.21

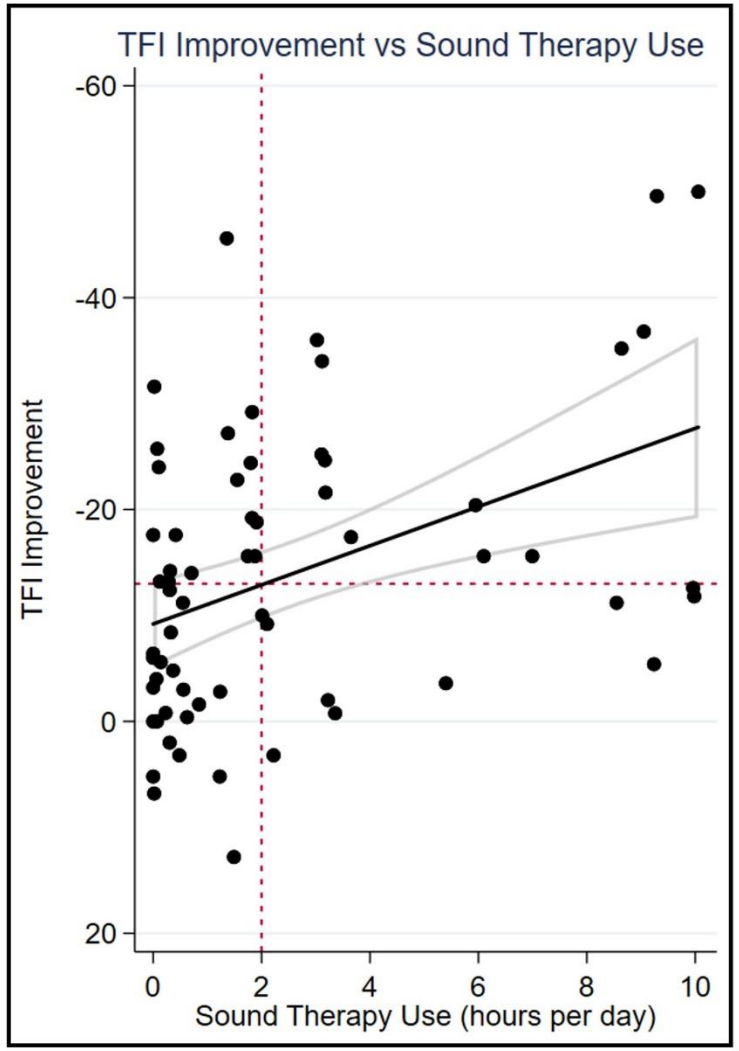
Improvements in THI, TFI and tinnitus annoyance were correlated with sound-therapy use but not with amplification only use or total device use

Significant correlations are depicted in bold and with one asterisk (*) representing $P < 0.05$ and two asterisks (**) representing $P < 0.01$.

WIDEX

RELATIONSHIP BETWEEN TINNITUS OUTCOMES AND DEVICE USE





Scatter plot of THI improvement (left) and TFI improvement (right) vs. sound-therapy use. Datapoints from all measurement points (2, 4, 6, and 12months) are plotted.

The black diagonal lines are the lines of best fit and the areas outlined by gray lines depict the 95% confidence intervals of the lines of best fit.

The horizontal dashed lines denote the clinically meaningful improvement of seven points in THI and 13 points in TFI.

The vertical dashed lines denote the instructed minimum 2 h per day listening time.

KEY FINDINGS

1. The results of the current study indicate that a combination device together with counseling is effective for treatment of tinnitus.

2. The effects of the combination device in this study are already evident after 1 month of treatment but peak at 4 months.

3. The experienced improvements in THI, TFI and tinnitus annoyance are associated with sound therapy use but not with amplification-only or total device use time.

Lelic D, Caporali S, Parker D, Nielsen J and Balling LW (2024) Impact of a combination sound therapy on tinnitus distress: an exploratory one-year longitudinal study. Front. Audiol. Otol. 2:1322596. doi: 10.3389/fauot.2024.1322596

CLINICAL IMPLICATIONS

This explorative study showed that sound therapy implemented in a combination device together with instructional counseling can be an effective method to manage tinnitus-related distress.

However, it is important that the sound therapy is accompanied by information-based counseling and that the user chooses the sound they prefer and like from a variety of available sounds.

Lelic D, Caporali S, Parker D, Nielsen J and Balling LW (2024) Impact of a combination sound therapy on tinnitus distress: an exploratory one-year longitudinal study. Front. Audiol. Otol. 2:1322596. doi: 10.3389/fauot.2024.1322596

LET ME ASK YOU SOMETHING…

77% of people experience stress that affects their physical health

(American Psychological Association, 2022)

Source: https://www.apa.org/news/press/releases/2022/10/multiple-stressors-no-function:

Common effects of stress

On your body | On your mood | On your behavior

Source: mayoclinic.org

Common effects of stress

On your body	On your mood	On your behavior
Headache	Anxiety	Overeating or undereating
Muscle tension or pain	Restlessness	Angry outbursts
Chest pain	Lack of motivation or focus	Drug or alcohol misuse
Fatigue	Feeling overwhelmed	Tobacco use
Stomach upset	Irritability or anger	Social withdrawal
Sleep problems	Sadness or depression	Exercising less often

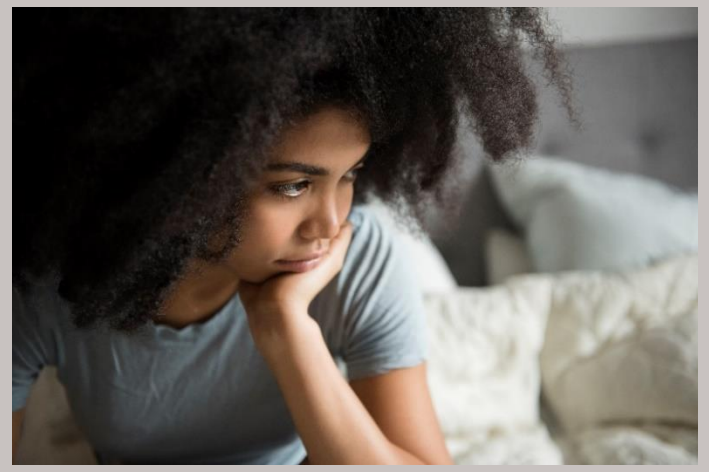
Source: mayoclinic.org

WIDEX

Emotional and physical factors including stress have been linked to the onset and worsening of tinnitus

It is common for tinnitus to start at times of high stress

It is also common for existing tinnitus to worsen during periods of high stress



This leads to a ‘vicious cycle’ as each contributes to worsening the other

WIDEX SOUNDRELAX™


WIDEX ZEN™
2008

WIDEX ZEN THERAPY (WZT)

2012


WIDEX SOUNDRELAX™
2022

WIDEX SOUNDRELAX – EXPANDING OPTIONS

Widex SoundRelax applies the benefits of fractal generated sounds to the fields of relaxation and concentration, opening up the benefits of fractal tones to help more people achieve well-being

WIDEX SOUNDRELAX	**SOUNDS FOR WELL-BEING & TINNITUS MANAGEMENT**

WELL-BEING	SOUNDSCAPES	PURESOUND
New Opportunities with: Well-being Relaxation Concentration	NEW Fractal tones + Modulated Wave-like sounds Expanding the Zen library	New program base Available for both Zen and SoundRelax

MUSIC REDUCES STRESS AND HELPS RELAX

Studies show that:

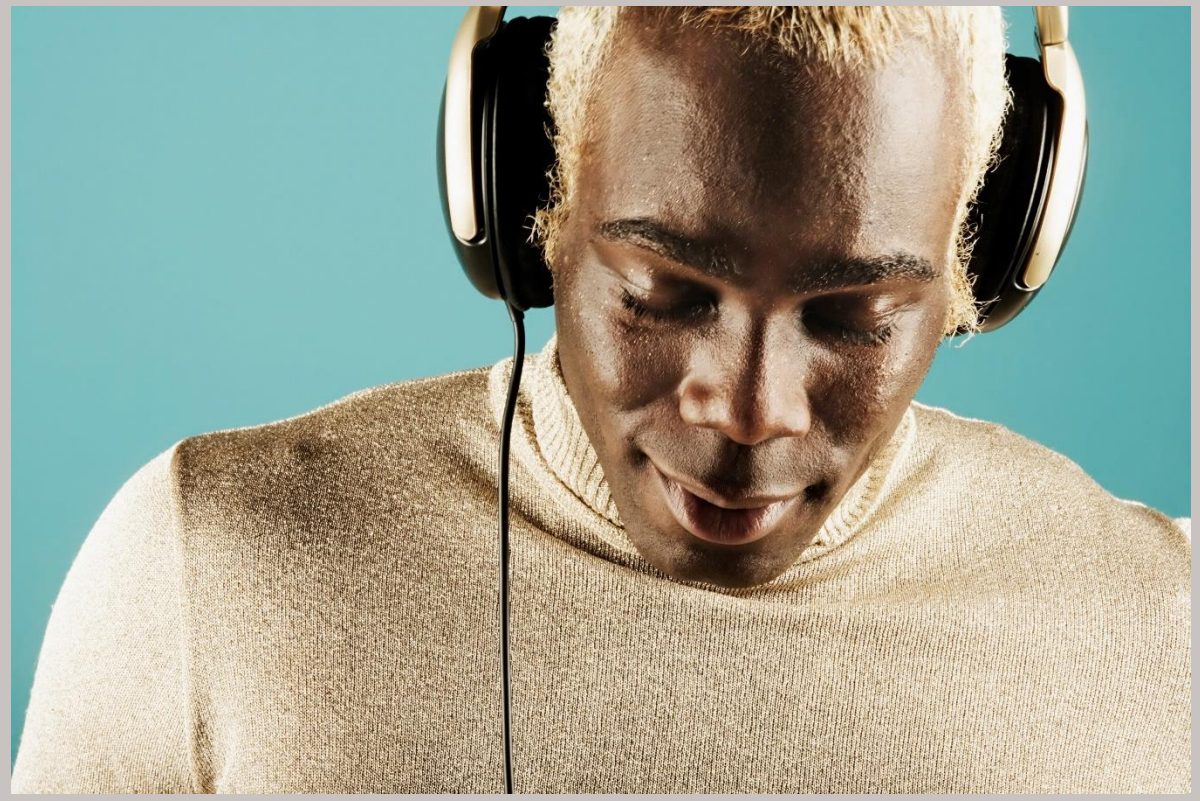
- Listening to music can help older people to **reduce depression** level

- **Valuable effect** of music therapy on anxiety and depression in patients with mild to moderate Alzheimer's disease

- **Profound effects** were found when 'relaxation' was stated as the reason for music listening:
  - **decreases** in subjective stress levels
  - **lower cortisol** concentrations

WIDEX

SO I JUST TELL MY PATIENTS WITH TINNITUS TO LISTEN TO MUSIC AND THEY'RE GOOD?



WIDEX SOUNDRELAX STYLES OVERVIEW

	DEFAULT PITCH			DYNAMIC RANGE		DEFAULT TEMPO			TIMBRE				DEFAULT WAVES	
FRACTAL STYLE	LOW	MEDIUM	HIGH	RESTRICTED	BROAD	SLOW	MEDIUM	FAST	CLEAR	SOFT/ PURE	FLUTES	ORGANIC	ON	OFF
SUMMER	●			●			●					●	●	
BREEZE	●			●		●				●				●
SPRING ǂ			●	●			●			●			●	
WINTER		●			●		●		●					●
BLOSSOM		●			●		●				●		●	
FALL		●		●			●					●		

*The noise soundscapes do not include tones and are therefore not represented in the table

ǂ Not dichotic

LARGE VARIETY OF SOUNDSCAPES TO CHOOSE FROM CATERS TO MANY USERS

WIDEX

ARE HEARING AIDS THE ANSWER TO REDUCING STRESS AND IMPROVING WELL-BEING?

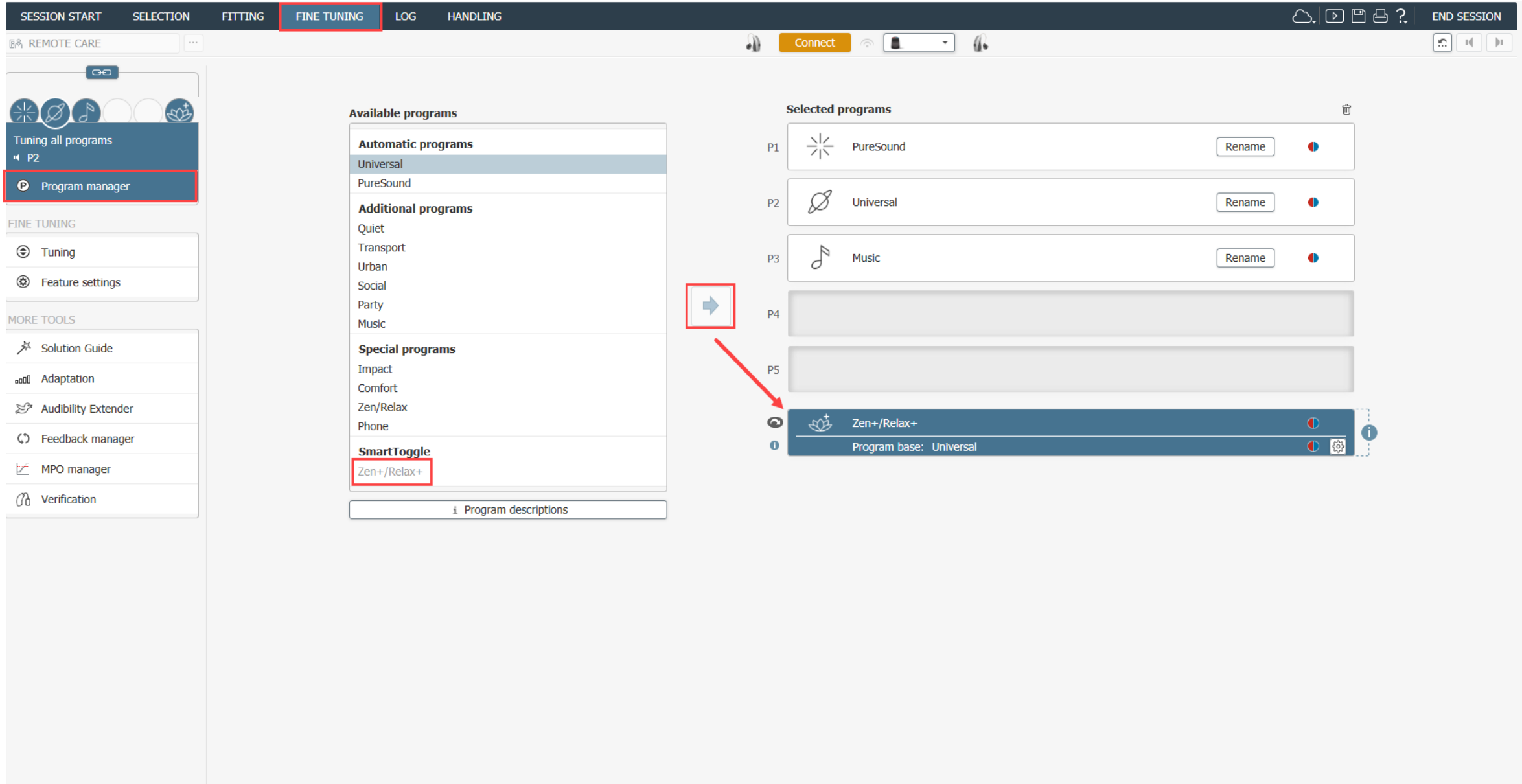
Goal:

Evaluate the potential of Widex SoundRelax to support hearing aid users' relaxation, concentration, and well-being for those with and without tinnitus.

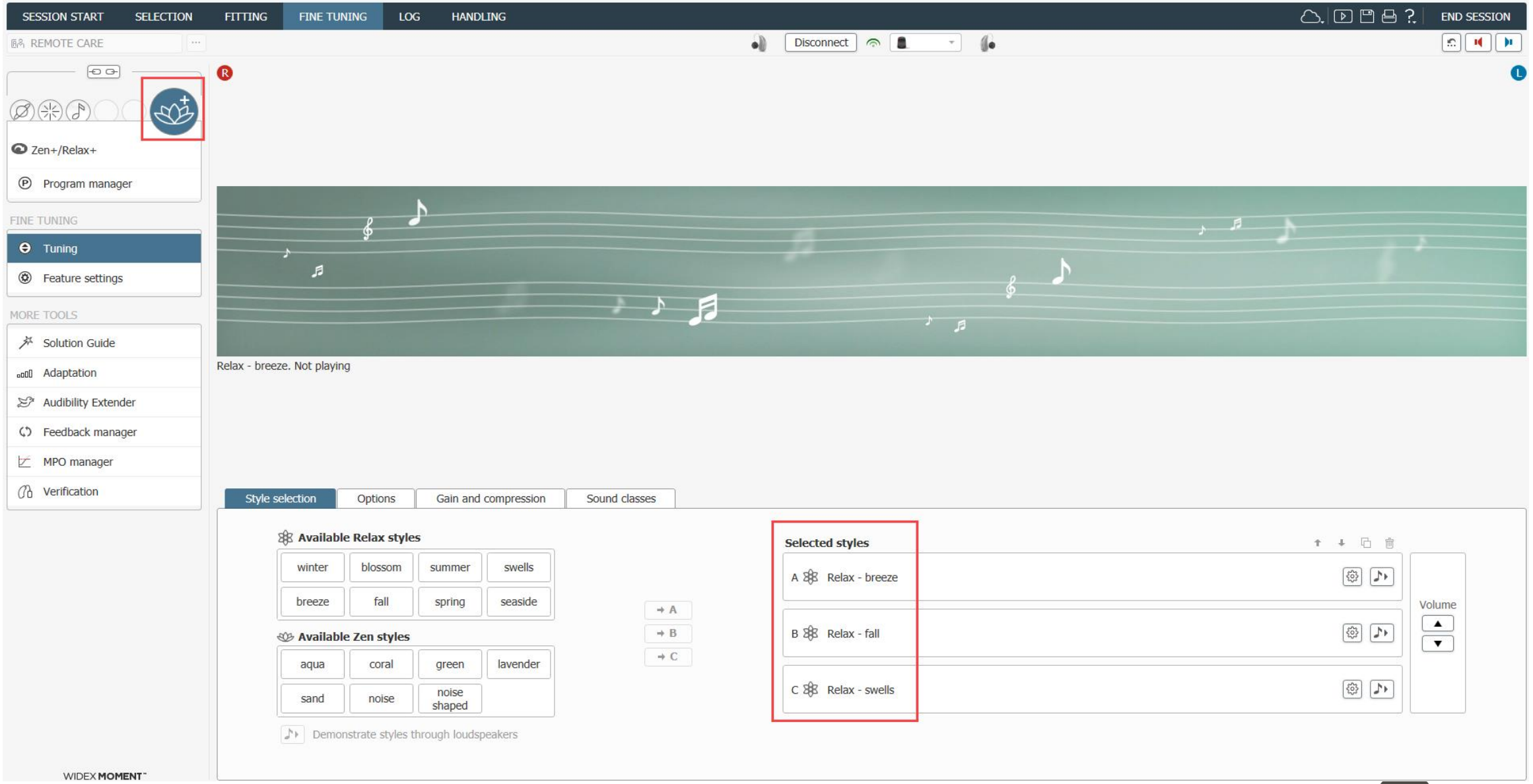
Outcome:

Relaxing sounds in a hearing aid may not stand alone in combating stress, but both the background research and the study results reported in this article confirm the potential of Widex SoundRelax to help users relax and experience a sense of well-being.

Balling, Laura Winther, Caporali, Sueli, Parker, Daniel, Jeppesen, Anne Mette & Helmink, Dana. 2022. "Are Hearing Aids the Answer to Reducing Stress and Improving Well-Being?" *Hearing Review* 29(8), pp. 24-27.

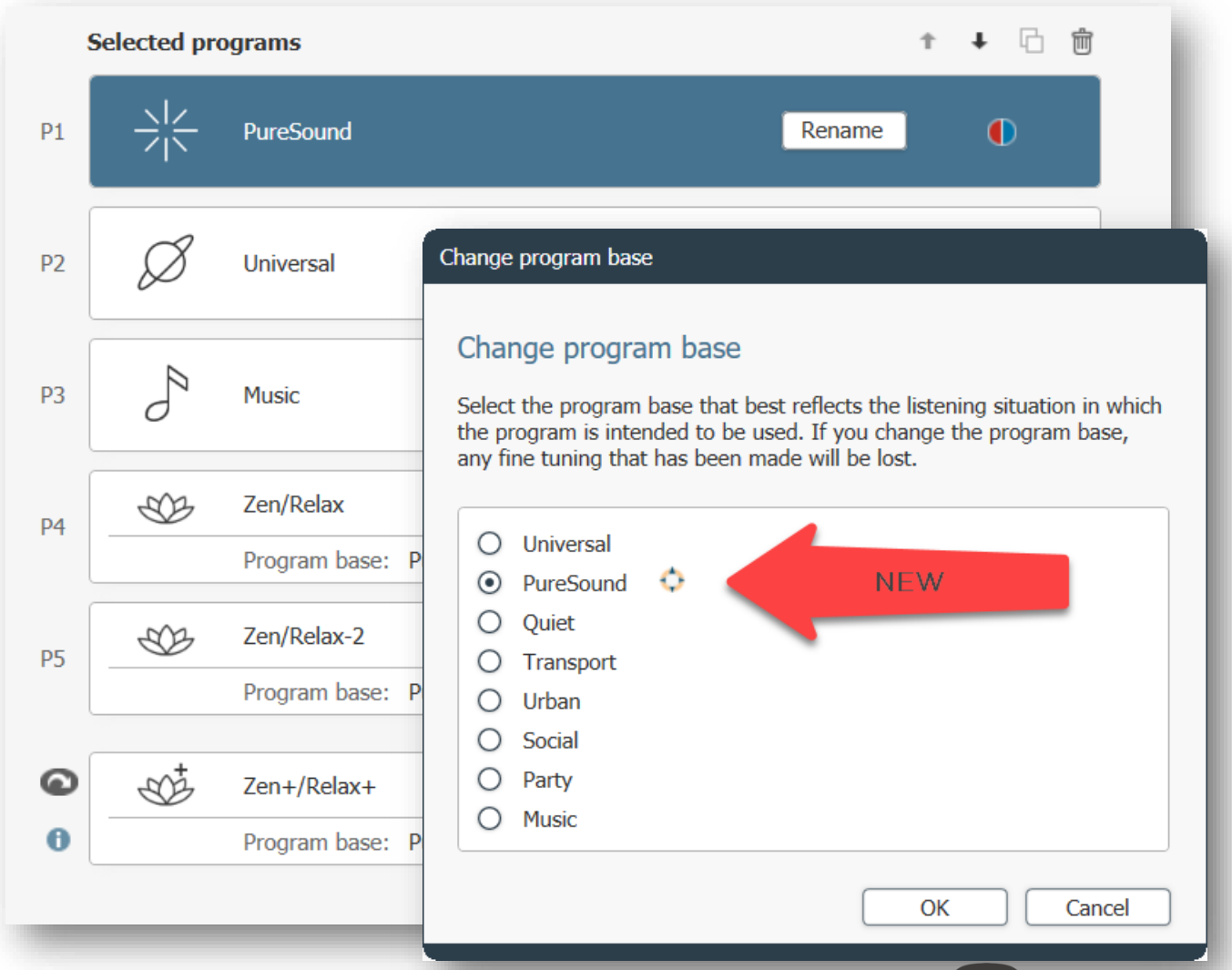

SESSION START
SELECTION
FITTING
FINE TUNING
LOG
HANDLING
END SESSION
REMOTE CARE
Connect
Tuning all programs
P2
Program manager
FINE TUNING
Tuning
Feature settings
MORE TOOLS
Solution Guide
Adaptation
Audibility Extender
Feedback manager
MPO manager
Verification
Available programs
Automatic programs
Universal
PureSound
Additional programs
Quiet
Transport
Urban
Social
Party
Music
Special programs
Impact
Comfort
Zen/Relax
Phone
SmartToggle
Zen+/Relax+
Program descriptions
Selected programs
P1
PureSound
Rename
P2
Universal
Rename
P3
Music
Rename
P4
P5
Zen+/Relax+
Program base: Universal

WIDEX SOUNDRELAX: EASY TO PROVIDE RELIEF

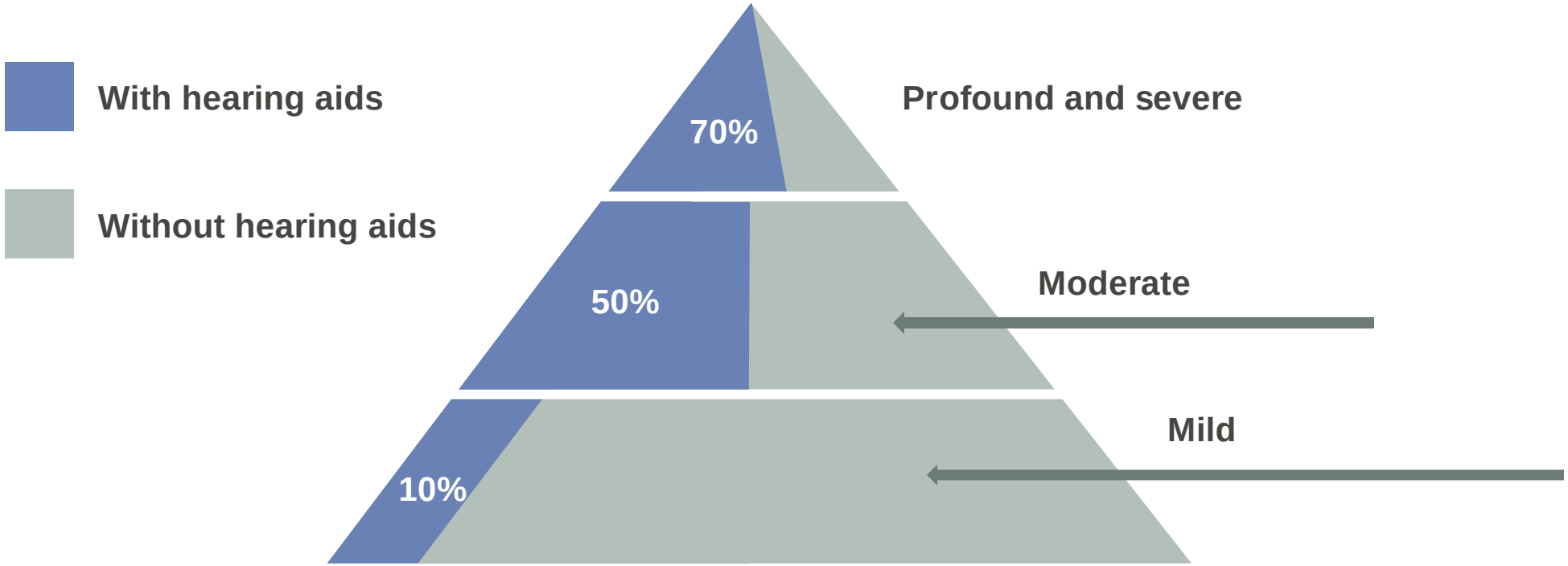


WIDEX SOUNDRELAX IN COMPASS GPS

- PureSound can be selected as the program base



CREATING NEW OPPORTUNITIES



Source: Hearing Review; Karl Strom. Sound Quality as a Tipping Point for the Younger, Milder Hearing Loss Market Sep 2, 2020

WIDEX

Artificial

Hollow

Echo

Like a Microphone

Boomy

Funny

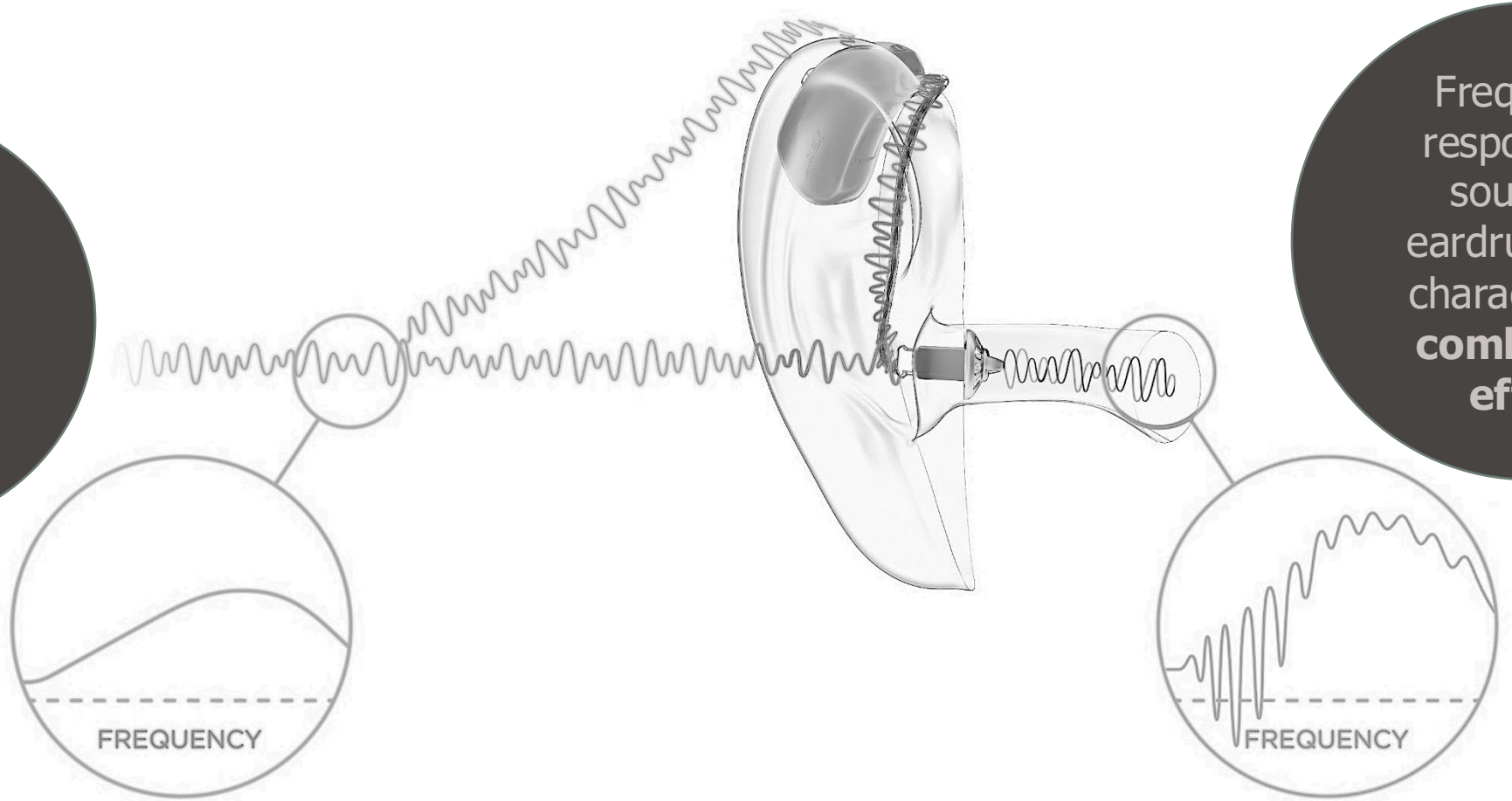
Tinny

Weird

LONGER DELAY = COMB FILTER DISTORTION

RESPECT ALL SOUNDS

Smooth frequency response of the original sound signal

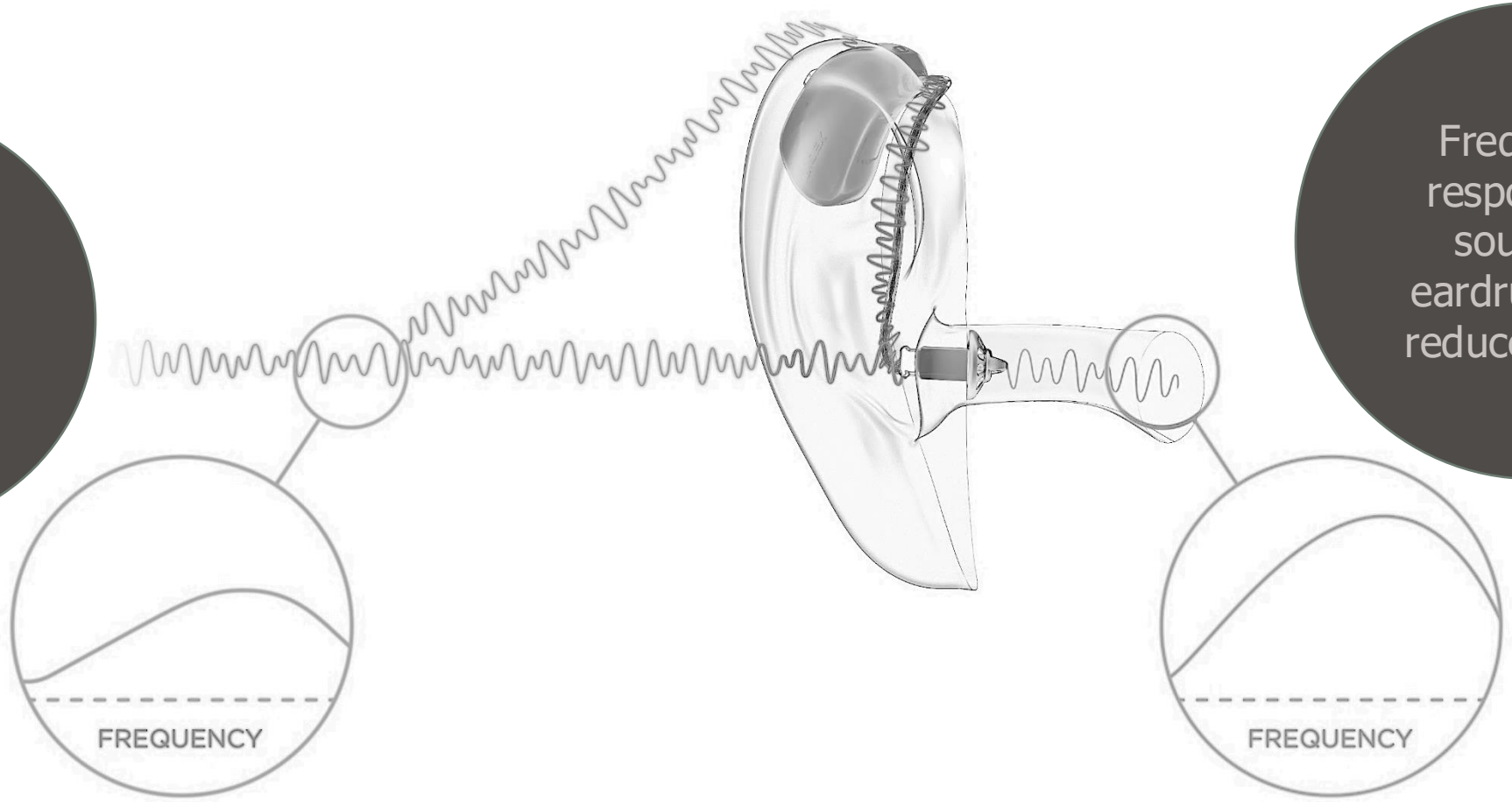


Frequency response of sound at eardrum with characteristic **comb filter effect**

ELIMINATE DELAY = ELIMINATE DISTORTION

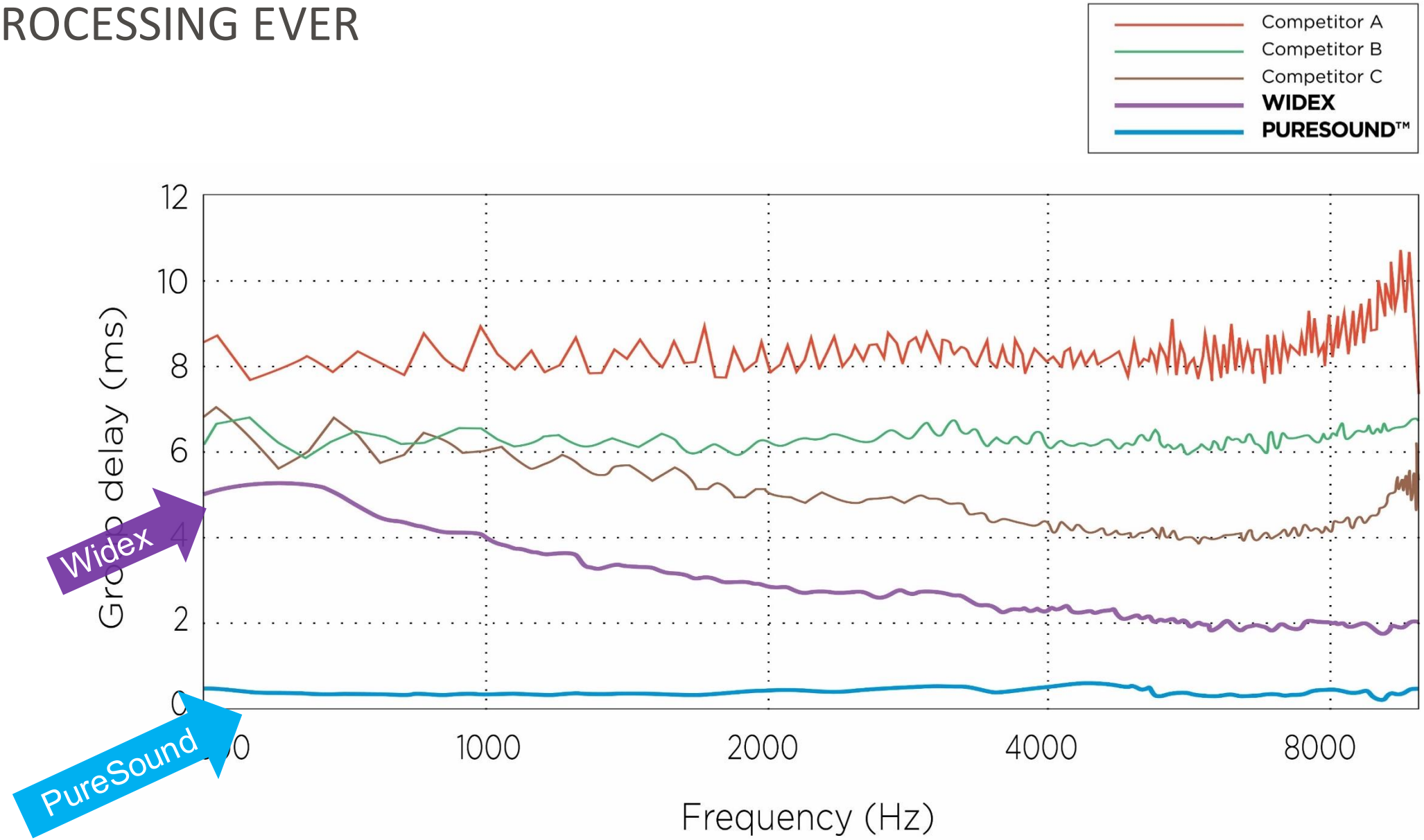
RESPECT ALL SOUNDS

Smooth frequency response of the original sound signal



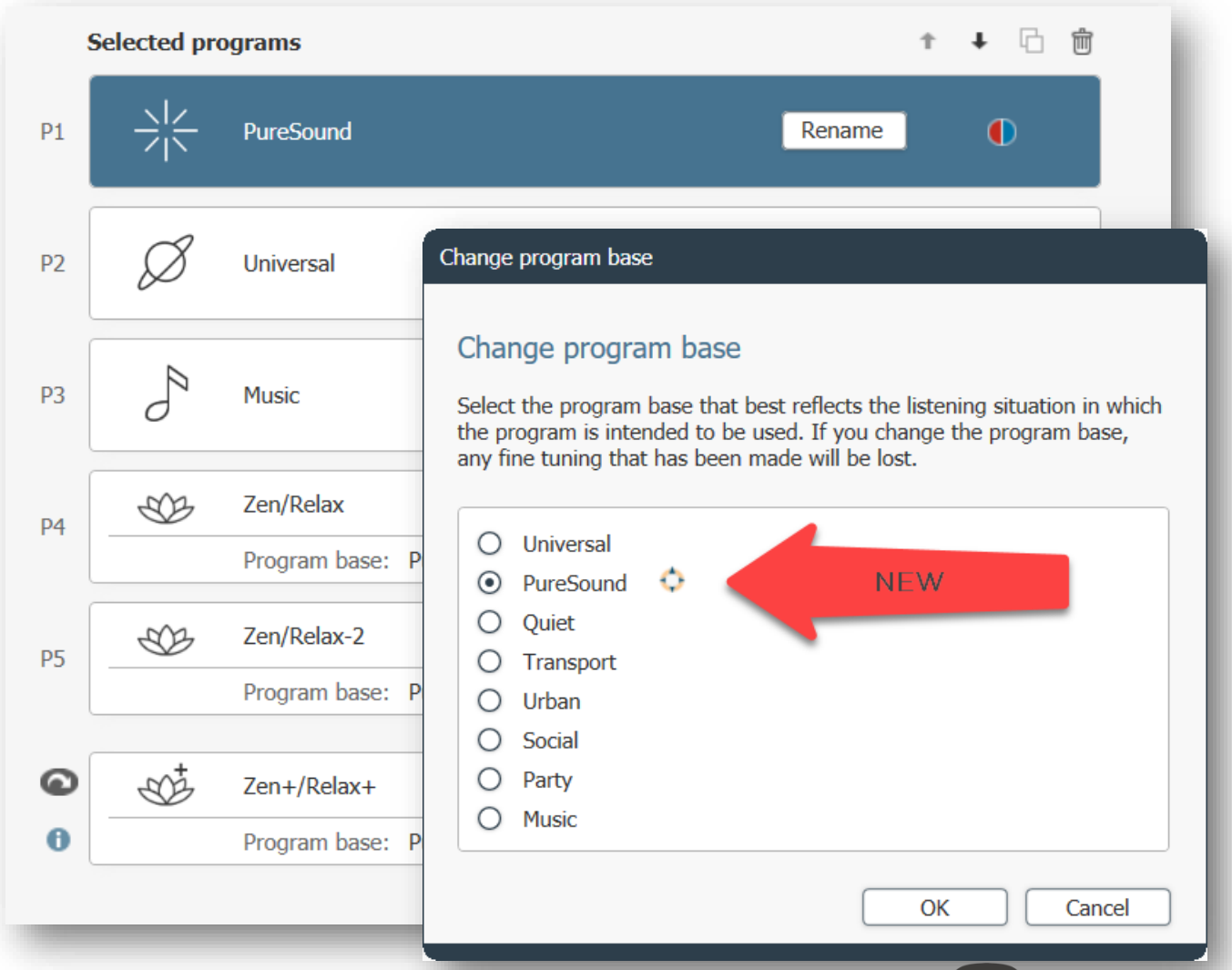
Frequency response of sound at eardrum with reduced delay

THE FASTEST DIGITAL HEARING AID PROCESSING EVER



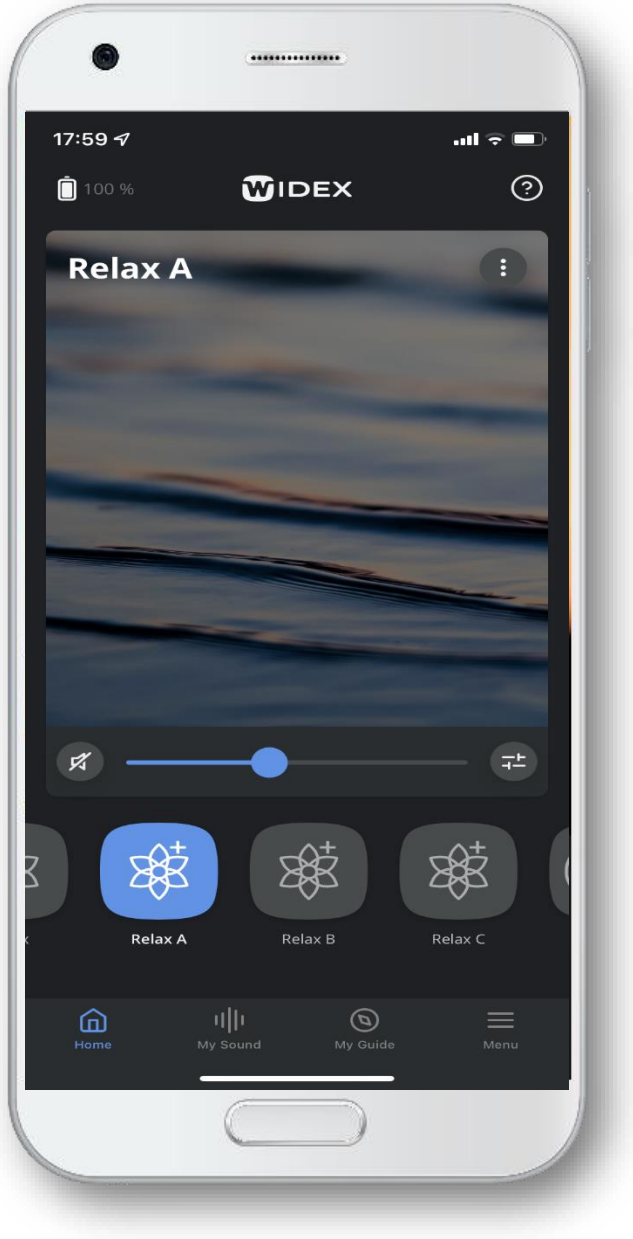
WIDEX SOUNDRELAX IN COMPASS GPS

- PureSound can be selected as the program base



WIDEX SOUNDRELAX IN MOMENT APP

- User-driven option for relaxation and concentration via the MOMENT app
- Relaxation and sound stimulation when and where it is needed
- For tinnitus and non-tinnitus applications



WIDEX ZEN TINNITUS APP - RELAXATION TOOLS AT THEIR FINGERTIPS

Relaxing sounds

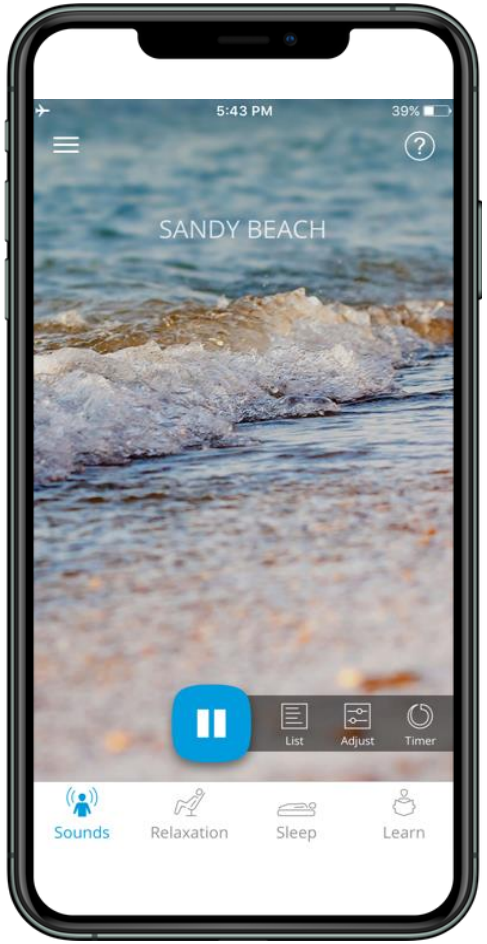
- List of several nature sounds that can be streamed or played through the phone

Guided relaxation exercises

- Deep breathing
- Progressive muscle relaxation
- Guided imagery

Sleep exercise

- Dr. Robert Sweetow



INTRODUCTION TO WIDEX ZEN THERAPY(DBR117)

1 INTAKE PROCESS
LEARNING ABOUT THE PERSON WITH TINNITUS

Before you begin to incorporate the components of Widex Zen Therapy, you need to understand the medical history, needs, and expectations of the person with tinnitus, so that you can individualize the therapy. The first step in this process is to administer the intake questionnaires and complete an audiological evaluation.

ASSESSMENT PROCESS	DESCRIPTION
WZT Intake Questionnaire	**Collects information on:** • Tinnitus & medical history • Previous treatments • Lifestyle • Reaction to tinnitus
Subjective Tinnitus Scales • Tinnitus Functional Index (TFI) • Tinnitus Handicap Inventory (THI)	**Designed to:** • Establish a baseline score • Identify how tinnitus is affecting the person's quality of life • Track progress
Audiological Evaluation	**Measures:** • Audiometry • Potential causes of tinnitus
Initial Interview	Dialogue with patient, to ensure that you have all of the information you need to create a treatment plan.

For your convenience, Widex has developed an intake questionnaire that can be used to gather this information. You can also get copies of the subjective tinnitus scales from your local Widex sales representative.

A medical consultation is always recommended to rule out any significant medical conditions.

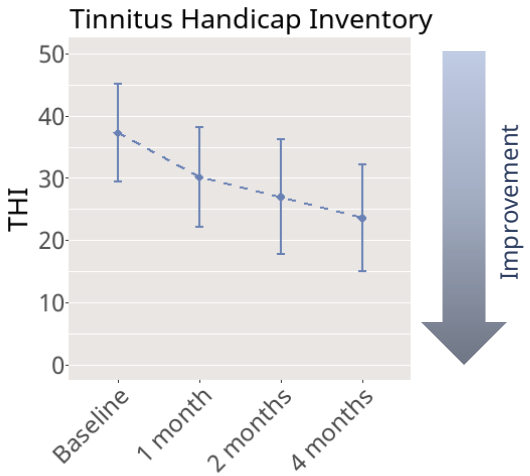
The following red flags indicate a need for immediate referral, preferably to an otolaryngologist
- Sudden hearing loss
- Unexplained unilateral hearing loss
- Pulsatile tinnitus
- Tinnitus accompanied by dizziness or vertigo
- Tinnitus with conductive hearing loss previously not diagnosed
- Depression, anxiety, or uncontrolled and extreme stress

WIDEX

WIDEX ZEN THERAPY MANUAL – DBR116

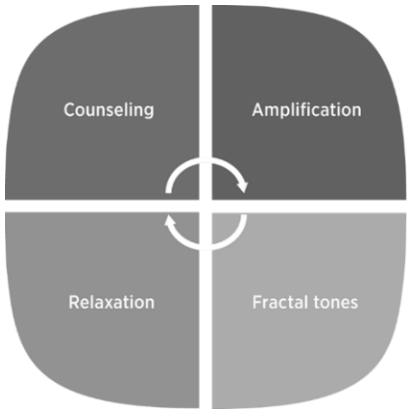
WIDEX

WIDEX SOUNDRELAX FOR WEARERS WITH TINNITUS…



Demonstrate the value of prescriptive hearing care:

Widex SoundRelax delivers a SIGNIFICANT improvement in tinnitus severity within the critical first month of treatment

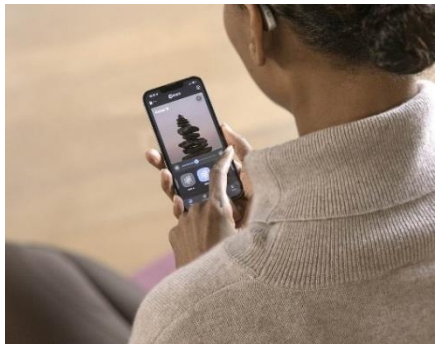


Confidence in evidence-based recommendations:

Widex SoundRelax fractal sounds show the same positive effects on tinnitus that have been repeatedly proven for Zen.

80%

of participants experienced a reduction of tinnitus severity



Choose a practical tinnitus solution for you and your patients:

Widex SoundRelax options are EASY to apply while providing a truly PERSONALIZED solution.

Balling, Laura Winther, Caporali, Sueli, Parker, Daniel, Jeppesen, Anne Mette & Helmink, Dana. 2023. "Expanding Options for Effective Tinnitus Management" *Hearing Review* 30(2).

SCAN QR CODE FOR SURVEY- LAURA KEARNS

THANK YOU!

SCAN ME

Laura Kearns, AuD

Sr. Clinical Educational Specialist

Laura.Kearns@widexsound.com

502-965-0077