

The Tinnitus Retraining Therapy Trial: Questions Answered, Questions Raised

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Disclosures

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- Financial disclosures
 - Paid consultant through development, implementation, and execution of the TRTT; protocol monitor for the TRTT through 2017
- Non-financial disclosures
 - None

TRTT Investigators

- Craig Formby – PI, Clinical Director
- Roberta W. Scherer - PI, Data Management Center Director
- Susan Gold – TRT Protocol Monitor, Consultant
- Sue Ann Erdman – SOC Protocol Monitor, Consultant



Design of the Tinnitus Retraining Therapy Trial



What is Tinnitus Retraining Therapy?

TRT is a structured treatment protocol that uses the Jastreboff neurophysiologic model of tinnitus to treat intrusive, often debilitating tinnitus. It has two components:

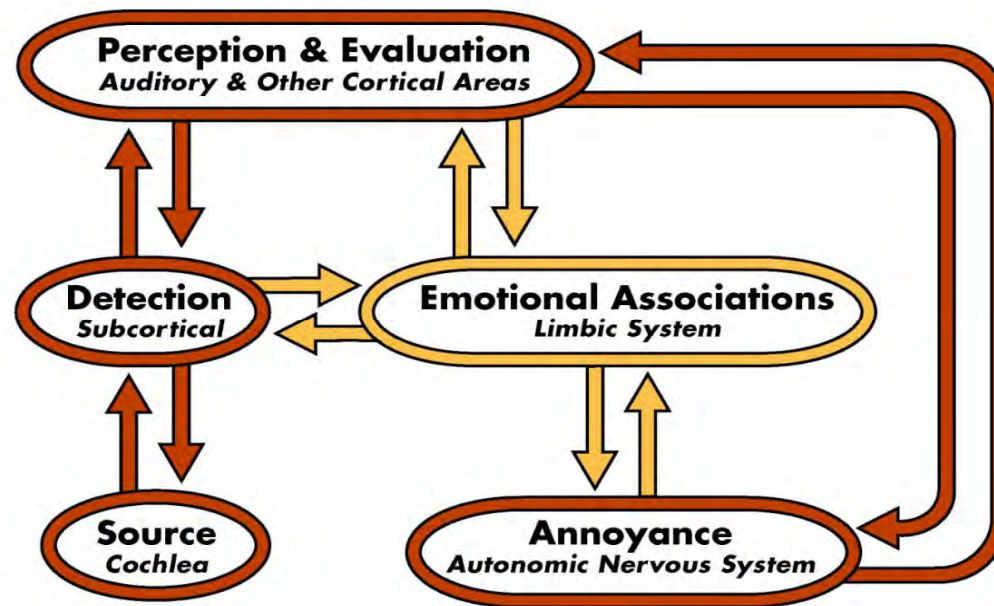
Directive Counseling

initiates habituation of the ***reaction to tinnitus***
(*annoyance*)

Sound Therapy

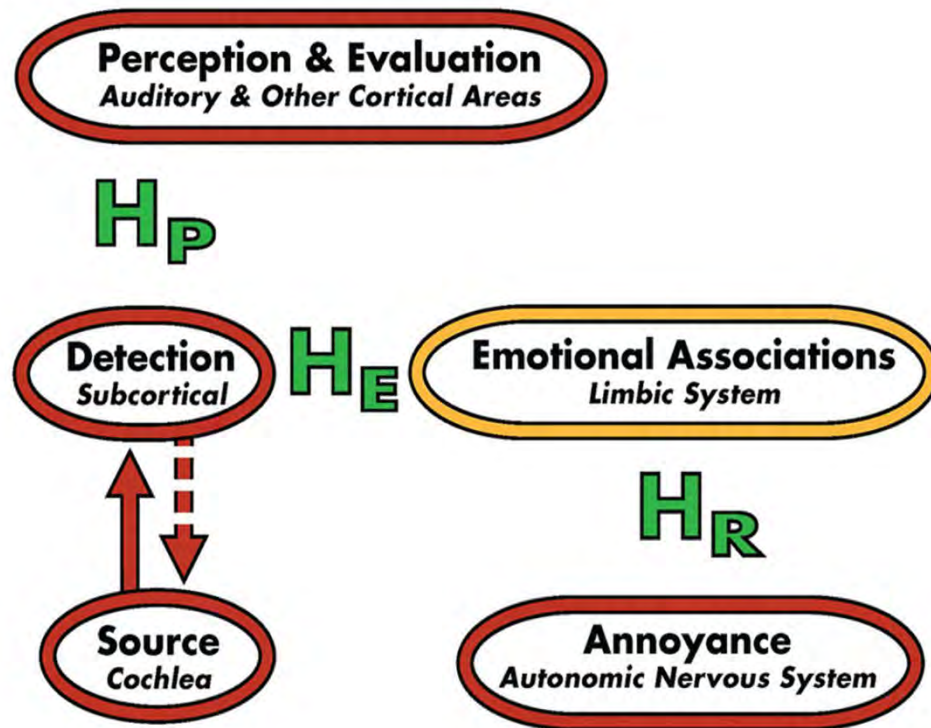
facilitates habituation of the ***perception of tinnitus***
(*awareness*)

Conscious & subconscious neuronal circuits Involved in tinnitus perception



©TRTT (after Jastreboff, 1995)

Full tinnitus habituation following TRT



Neurophysiologic model of tinnitus depicting complete TRT-induced *habituation* of the emotional (HE) and negative (HR) reactions to the tinnitus and its perception (HP).

Why did we conduct an RCT of TRT?

Jastreboff (1999) argued for “evidence by consensus” of TRT’s validity/efficacy. Claimed a meta-analysis would suffice. However,

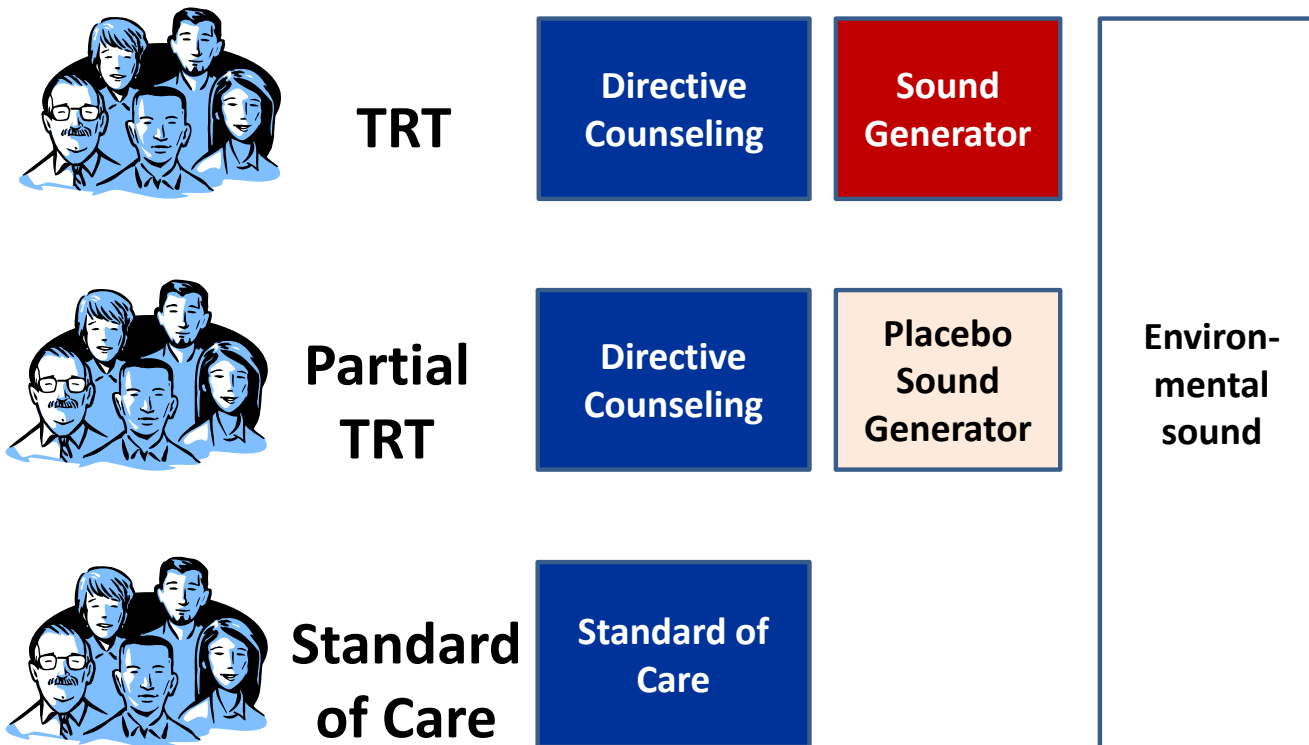
- A Cochrane systematic review only found a single trial
- Other concerns include poor design and equivocal results
- No study isolated the effects of sound therapy and directive counseling
- Persistent questions: Is TRT worth it in terms of time and cost?



Tinnitus Retraining Therapy Trial

- Based on existing equipoise regarding TRT efficacy, the NIDCD funded the Tinnitus Retraining Therapy Trial (TRTT) in 2009.
- The TRTT was a randomized, placebo-controlled, multi-center trial that aimed to test the efficacy of TRT versus standard of care treatment in individuals who have self-perceived debilitating tinnitus and are seen in US military hospitals.

TRTT Treatment Groups



TRTT Clinical Sites



- Wilford Hall Ambulatory Surgical Center, Lackland AFB (TX)
- David Grant Medical Center, Travis AFB (CA)



- Walter Reed National Military Medical Center, Bethesda (MD)



- Naval Medical Hospital Portsmouth (VA)
- Naval Medical Hospital San Diego (CA)
- Naval Hospital Camp Pendleton (CA)

Key Eligibility Criteria

Non-medical

- Active and retired military personnel and dependents
- Age 18 or older
- Able to understand counseling and complete English-language questionnaires
- Willing and able to participate in a research study

Medical

- Continuous, chronic, subjective tinnitus of ≥ 1 year
- Tinnitus Questionnaire (TQ) score ≥ 40 (moderate tinnitus impact)
- Unaided hearing sensitivity bilaterally within audiometric range from normal to mild limits

TRTT Study Visits

- Baseline eligibility Visit
- Randomization visit
- 2 treatment visits
 - Within one month of randomization
 - One month after first treatment visit
- Follow-up visits (3, 6, 12, and 18 months after first treatment visit)

TRTT Outcome Measures

- **Primary Outcome**
 - Change in TQ scores evaluated longitudinally between the baseline visit and the 18-month follow-up visit
- **Other Outcomes**
 - Change evaluated longitudinally in:
 - Tinnitus Functional Index, Tinnitus Handicap Inventory, and 10-point visual analog scale
 - Audiometric measures
 - Beck Depression Inventory
 - Positive and Negative Affect Schedule
 - State/Trait Anxiety Inventory



TRTT as practiced in the TRTT: Directive Counseling

- Didactic educational approach standardized for the TRTT
- Review results of the audiometric/tinnitus/hyperacusis (ATH) evaluation
- Describe anatomy and physiology of auditory system
- Describe how the brain handles auditory input
- Describe how the anatomy, physiology and brain function relate to tinnitus
- Present Jastreboff Neurophysiological Model of Tinnitus
- Encourage avoidance of silence, assigned ST, use of environmental sound
- Describe habituation goals of treatment, encouraging participants not to focus on control of the tinnitus problem

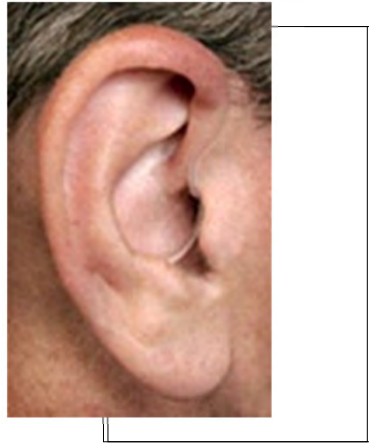
TRTT Sound Therapy

Sound generators provided by General Hearing Instruments



❖ Conventional Sound Therapy

- Behind-the-ear/in-the-ear devices
- Generates low-level (seashell-like) noise
- Volume set at/ just below “mixing point”



❖ Placebo Sound Therapy

- Similar to above, but...
- Noise begins to fade after 40 minutes
- Noise undetectable after additional 30 minutes
- Resets upon removal from behind ear
- Operation enables double-blind ST

Standard of Care in the TRTT



“Current practices” as control conditions

- Conditions that reflect typical clinical practice
 - Treatment as usual
 - Routine/usual
 - Standard care**
- Conditions that specifically adhere to a set of practice guidelines to provide consistency and treatment fidelity:
 - Standard of care**

(Freedland, Mohr, Davidson, & Schwartz, 2011; Mohr et al., 2009)



Developing TRTT's Standard of Care

- ❖ Identified current practices:
 - Surveyed military sites to identify typical practice

- ❖ Aligned military tinnitus practices with “best practices:
 - Used ASHA's Preferred Practice Patterns (2006) to ensure consistent tinnitus intervention and to obtain a generic goal.

- ❖ Identified SOC treatment goal:
 - Reduce negative cognitive, affective, physical, and behavioral reactions to tinnitus and improve the individual's well-being and quality of life (ASHA, 2006)



Developing TRTT's Standard of Care (cont.)

- ❖ Aligned with ASHA's PPPs for counseling to:
 - confirm consistency with audiologists' counseling role and responsibilities
 - distinguish it from existing CBT tinnitus interventions
- ❖ Implemented patient/person centered framework specifying:
 - intervention is based on patients' *complaints*
 - goals are designed and modified to facilitate motivation, progress, and *engagement* in the treatment process
 - *decisions* regarding treatment goals and interventions are made *collaboratively* to *reflect patients' needs, preferences, and circumstances*

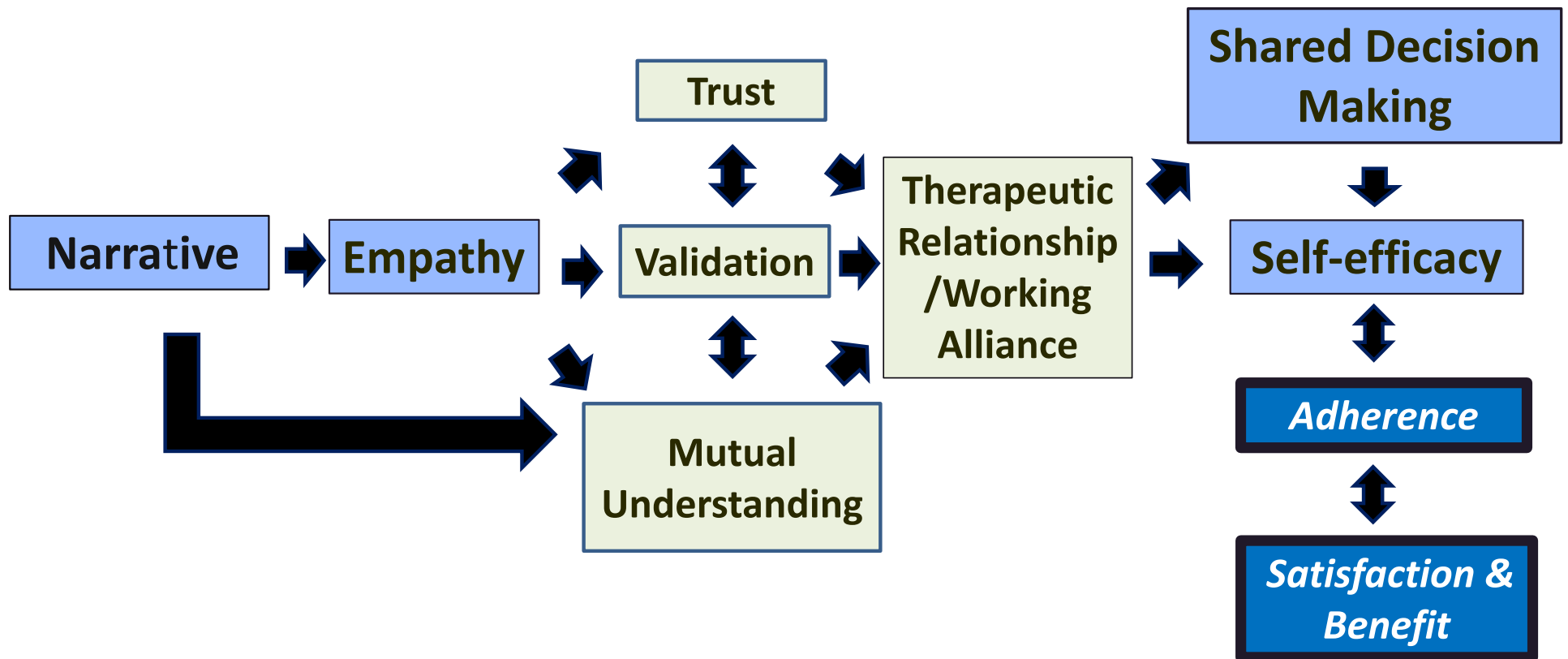


Essential steps in the SOC patient-centered process

- Eliciting the patient's story/narrative
- Responding empathically to establish mutual validation and trust
- Establishing a therapeutic relationship to facilitate mutual understanding
- Shared/collaborative decision making for treatment goals and strategies
- Promoting patients' self-efficacy to facilitate management of tinnitus



Patient-centered SOC protocol



(Erdman, 2014)



The patient's story/narrative

- When a patient shares a story with you, you become involved in a relationship.
- Patients' stories tell us what it means to live with an illness or a disability.
- Listening and responding sensitively to patients' stories provides opportunities for empathic care and greater clinical effectiveness.



Why elicit narratives?

Patient's stories ...

- are intrinsically therapeutic or palliative
- allow patients' perceptions and understanding to be verified/clarified
- help set a patient-centered agenda
- encourage a whole-person approach to care
- encourage empathy
- promote mutual understanding
- often indicate additional therapeutic options
- encourage mutual reflection

(Greenhalgh and Hurwitz, 1999)



Empathy: The ❤️ of PPC



- Empathy communicates concern and understanding.
- Empathy promotes mutual validation, the foundation for a trusting therapeutic relationship.
- Patients who realize that you
 - understand their problems,
 - understand how those problems make them feel, and
 - understand how the problems affect their well-being and quality of life... will trust you.
- Trust is associated with better adherence.
- Empathy enhances our treatment efforts

Validation is a two-way street



- When patients feel heard and understood, they are validated.
- When you understand their problems, you are validated as a competent, caring professional.

To achieve a mutual understanding: Clarify & Verify



- Evaluate patients' understanding of their condition, hearing mechanism, and hearing test results
- Verify that they understand the problems
- Clarify misconceptions or doubts about the implications of their condition

Tinnitus: What it is and isn't

- Tinnitus refers to sounds that you hear that do not originate outside your body.
- It may be a ringing, buzzing, hissing, or chirping sound.
- Tinnitus results from nerve activity in the inner ear.
- It can be caused by noise, some medications, disease, head trauma, and stress.
- Tinnitus may or may not be associated with hearing loss.
- It will *not* damage your hearing.
- Tinnitus is *not* a health threatening condition.
- There is no proven medical treatment for tinnitus.
- It may get worse, may stay the same, or it may go away.

Tinnitus: Noticing it and ignoring it

- Almost everyone notices tinnitus from time to time.
- People with hearing loss may notice it more because they hear less sound around them.
- Tinnitus is very common among those who have been exposed to very loud noise.
- Most people who have tinnitus aren't bothered by it.
- Focusing on tinnitus can make it more noticeable.
- Many people learn to ignore their tinnitus.
- You can learn to ignore tinnitus.
- Other sounds in the environment make it easier to ignore tinnitus.

The therapeutic relationship.



“... is among the most salient variables in health care

- Critical medium for the exchange of information, feelings, and concerns
- For patients, the relationship with their provider is frequently the most therapeutic aspect of the health care encounter.”

(Tresolini and the Pew Fetzter Task Force,1994)



Shared Decision Making: The Pinnacle of PCC

- Encourage patient participation
- Explore patient's values, preferences, concerns, lifestyle, and expectations
- Value patient's responsibility and rights to an active role in decisions
- Explain healthcare problem, current best practices, and available options
- Discuss pros and cons, risks and benefits of treatment options
- Identify and agree on target problems and desirable, achievable goals
- Verify that treatment options are feasible and doable.

"Nothing about me without me."

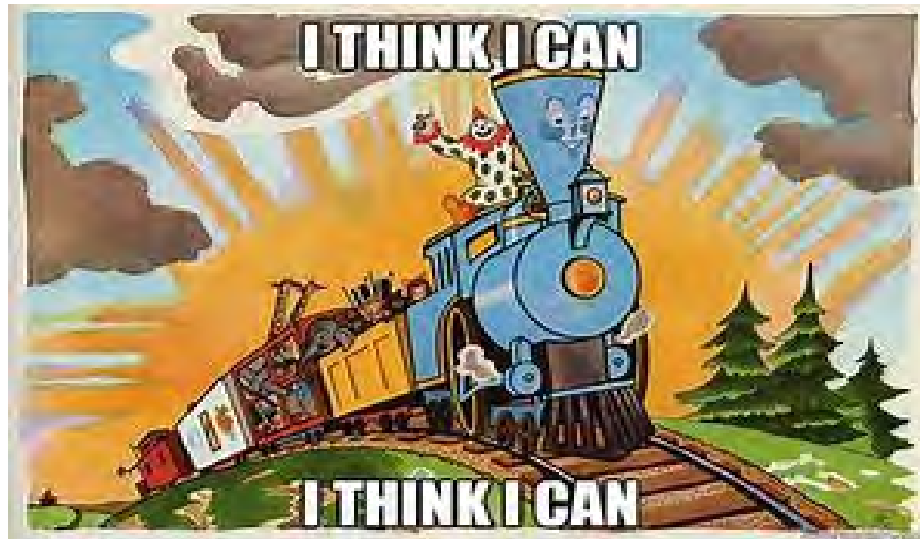




Shared Knowledge/Mutual Understanding

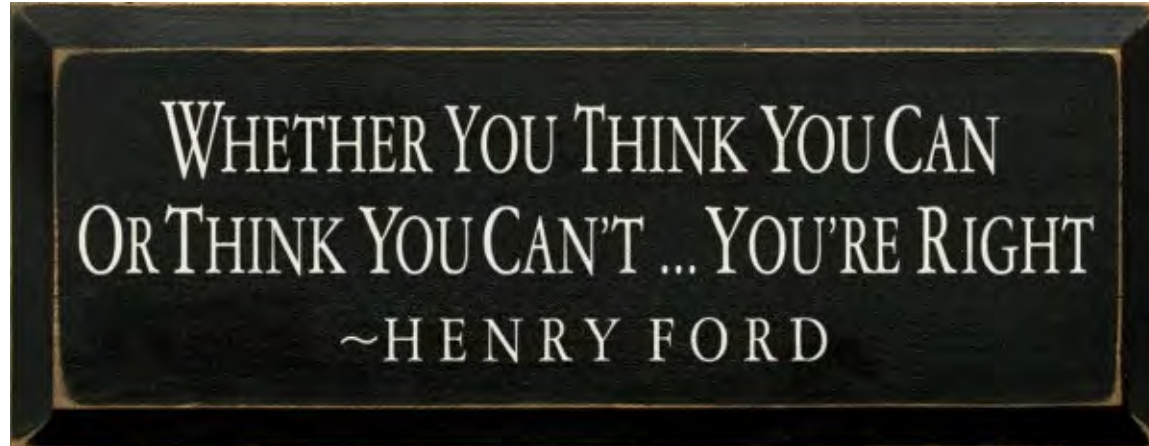
- Do patients have sufficient knowledge to make decisions?
 - Preferences may not be accurate if they are based on misinformation
- Do clinicians have sufficient knowledge about the patient as a person to identify appropriate options?
 - Treatment “recommendation” may be doomed without this insight.
- Are decision aids neutral in nature or are disclosures indicated?
 - Minimize reliance on commercial publication; prepare your own balanced sources of information.
- Some patients prefer to have clinician make decisions.
 - Guide them toward a decision they can own.

What is self-efficacy?

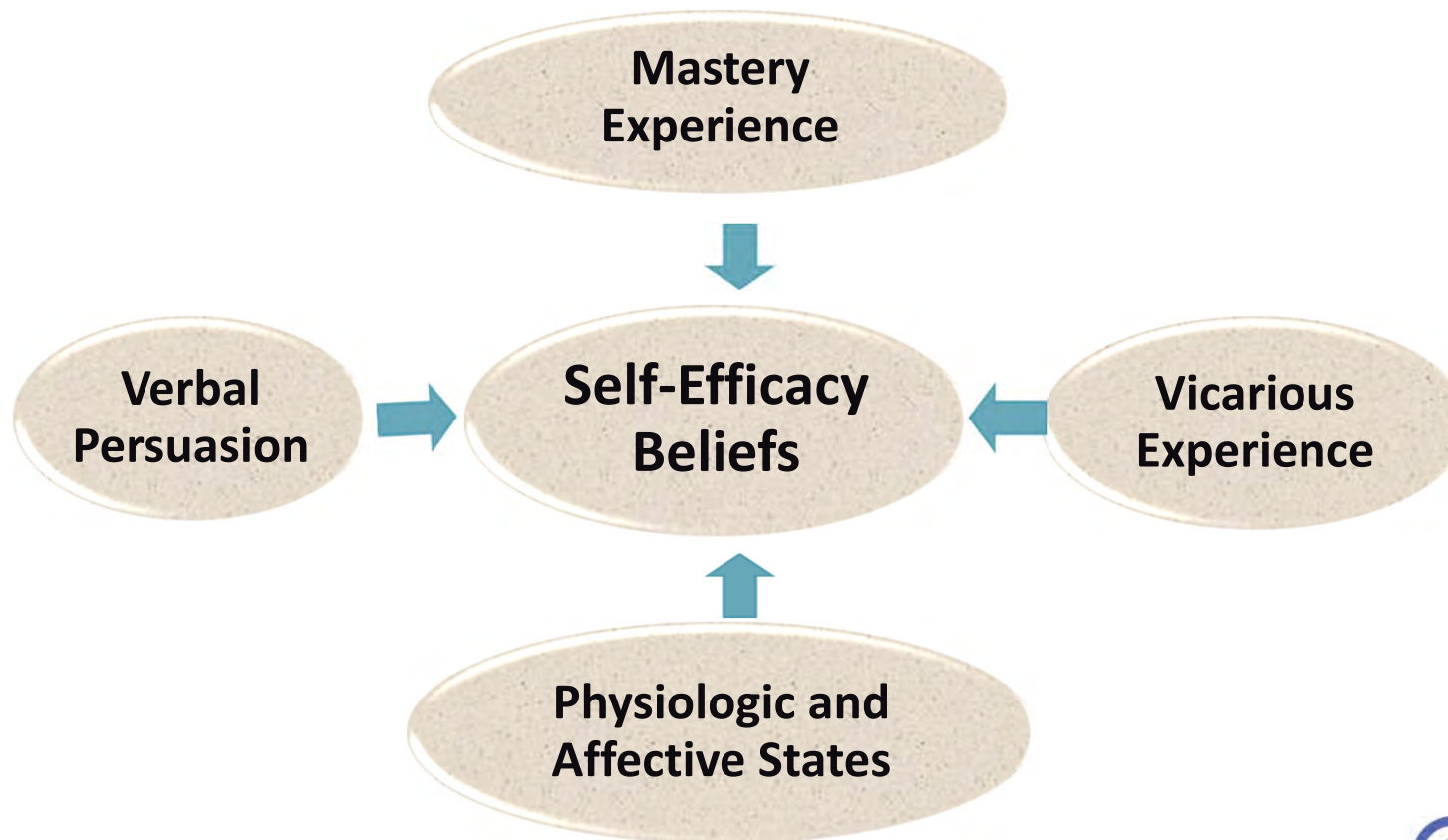


Psychologist Albert Bandura defines self-efficacy as the belief that one is capable of organizing and executing certain behaviors or reaching certain goals.

Why is self-efficacy important?



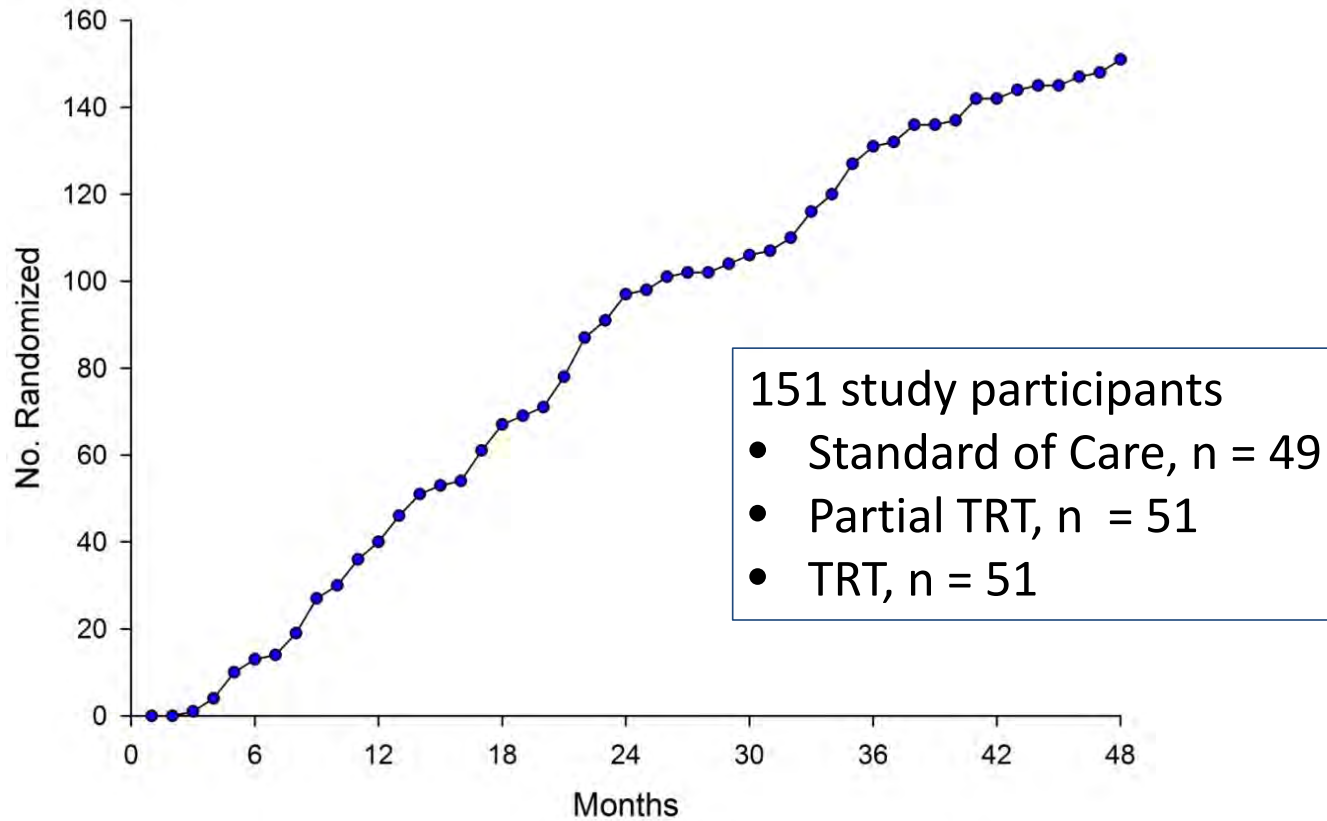
How are self-efficacy beliefs influenced?



TRTT Trial Results



TRTT study population

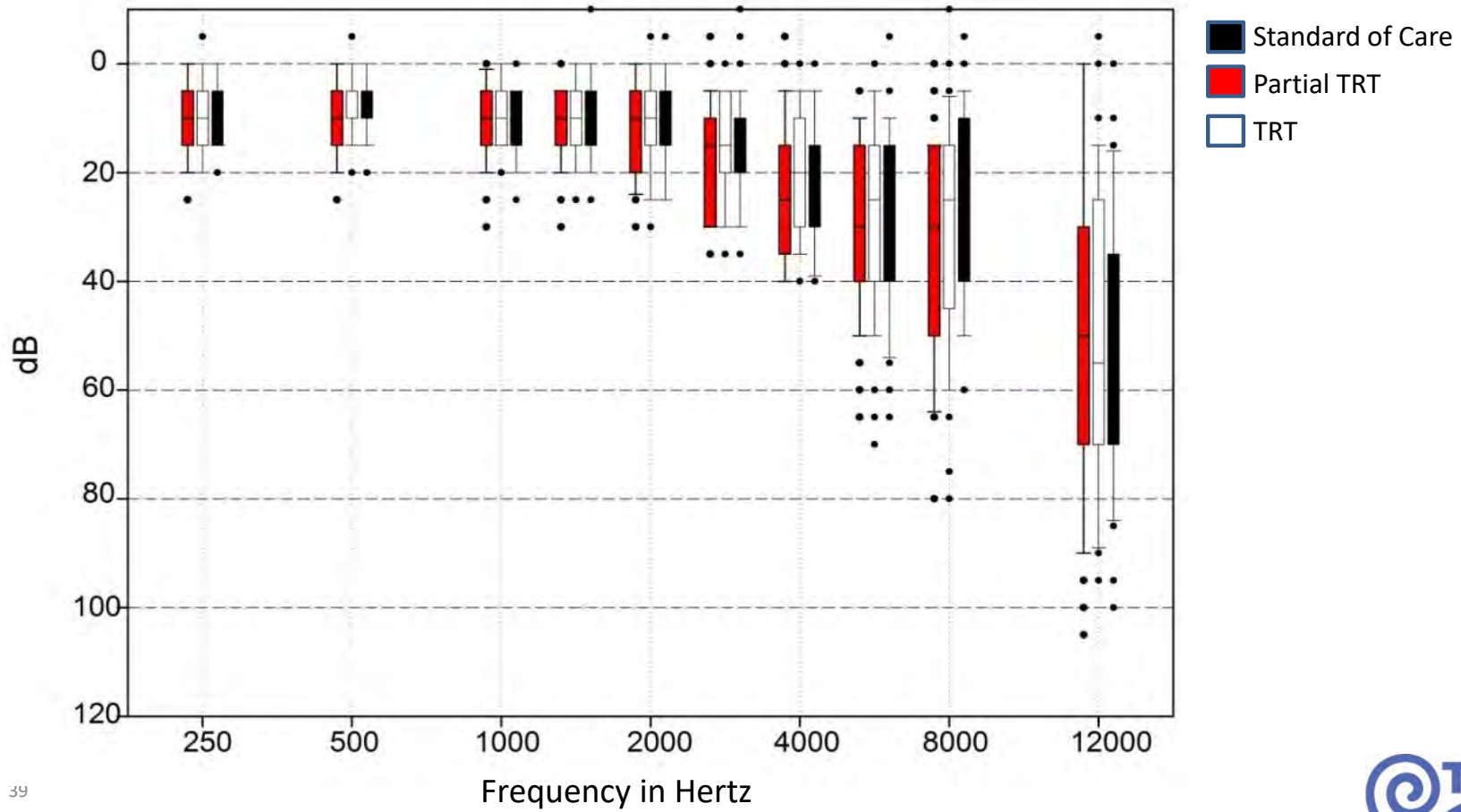


Demographic Characteristics

Characteristic	Standard of Care	Partial TRT	TRT
N	49	51	51
Age, mean (S.D.)	49.9 (10.0)	50.9 (11.2)	51.1 (12.6)
Male sex,%	73.5	72.6	66.7
Race/ethnicity,%			
White	71.4	76.5	70.6
Black/African-American	14.3	11.8	9.8
Other	4.1	7.8	5.9
Hispanic/Latino	10.2	9.8	13.7
Marital status,%			
Married/with partner	83.7	80.4	76.5
Without partner	16.3	19.6	21.6



Baseline Audiograms



Baseline Tinnitus Characteristics

Characteristic	Standard of care	Partial TRT	TRT
N	49	51	51
Tinnitus duration	%	%	%
Tinnitus a problem < 2 years	12.2	21.6	23.6
Tinnitus a problem 2 to 5 years	40.8	33.3	29.4
Tinnitus a problem > 5 years	44.9	43.1	47.1
Type of sound			
Tonal	95.9	92.2	92.2
Low frequency noise	2.0	3.9	7.8
High frequency noise	0	2.0	0
Other (crickets, clicking, other)	0	2.0	0

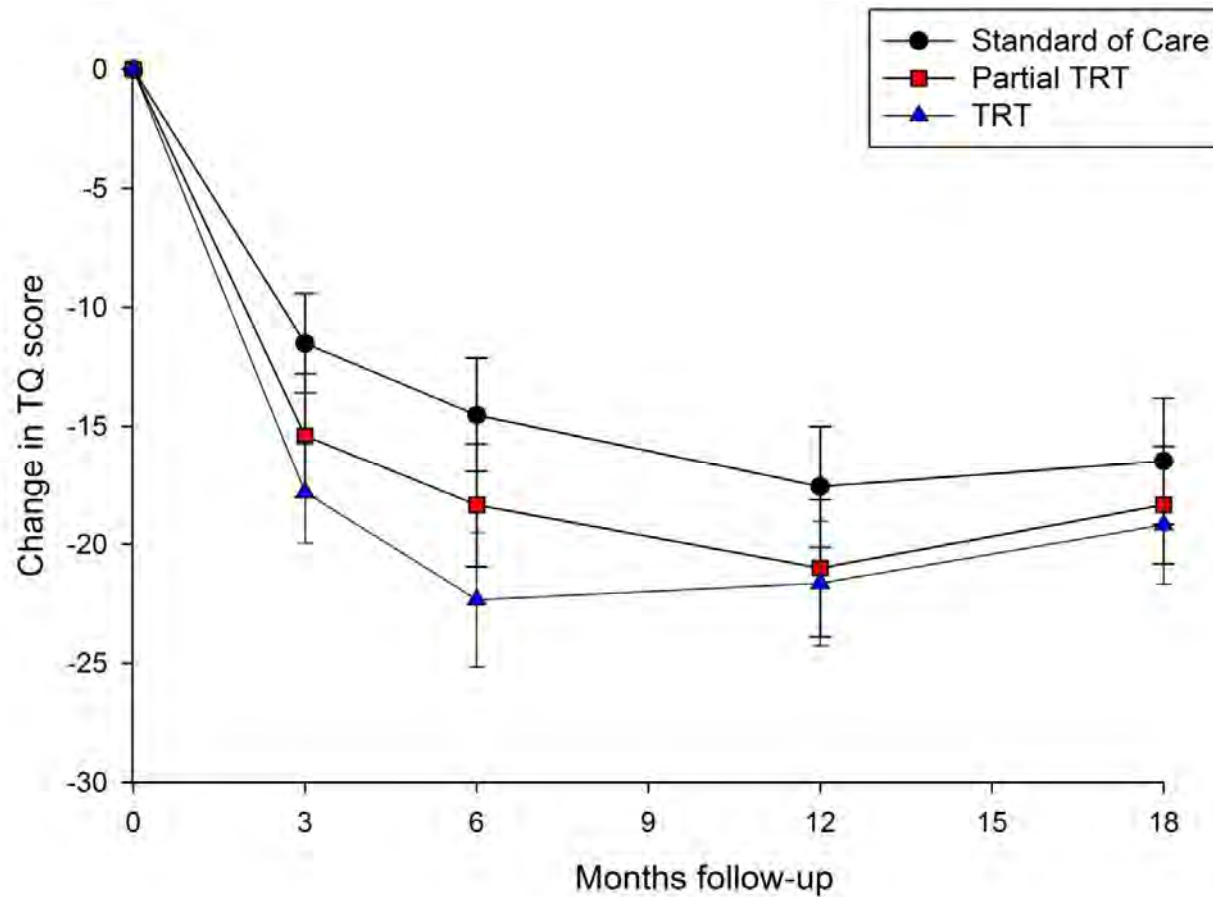
Baseline Tinnitus Distress

Instrument	Standard of care	Partial TRT	TRT
	49	51	51
Tinnitus Questionnaire mean (SD)	54.6 (11.2)	54.4 (11.5)	56.4 (11.9)
10 point VAS scale mean (SD)	6.7 (1.9)	6.5 (1.8)	6.4 (1.8)

TRTT results in a nutshell

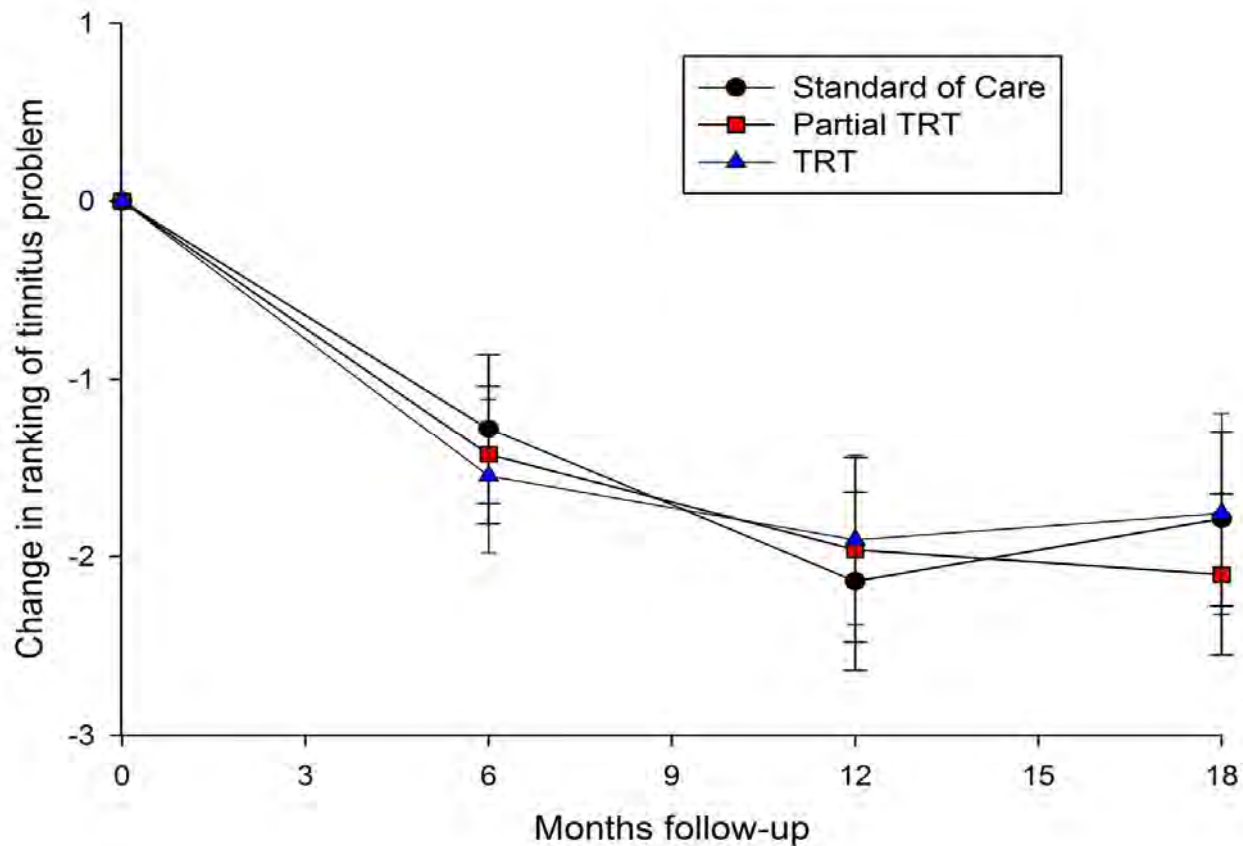


Change in TQ scores by visit and treatment group



All significantly different from baseline values at $p < 0.0001$

Change in tinnitus problem using TRT Interview visual analogue scale



All significantly different from baseline values at $p < 0.0001$



TRTT Conclusions

- All three treatment groups – TRT, Partial TRT and Standard of Care showed improvement as measured by a significant decrease in the TQ score from baseline to 18 months.
- There was no difference between treatment groups in change in TQ measured longitudinally.
- The same pattern of improvement was verified across all other measures of tinnitus distress including the TFI, THI, and VAS.

Clinical Implications

Perplexing questions about the results?

- If both treatments are effective, what are the differences and similarities between them?
- Which treatment should be used under what circumstances?
- Are there differences in either cost or time to administer either?
- In general, does any counseling provide a sufficient intervention for tinnitus distress?
- Is avoidance of silence, i.e., use of environmental sound, sufficient to alleviate the effects of tinnitus?

Similarities between TRT and SOC protocols

- Time spent per counseling session
 - 87% of SoC session were more than one hour vs 88% for TRT sessions, with 4% vs 13% more than 2 hours
- Number of visits
- Review of anatomy & physiology of the auditory system
- Review of audiologic/tinnitus evaluation results
- Encourage use of sound in environment



Differences between TRT vs SOC protocols

TRT	SoC
Theory driven	Patient driven
Based on Jastreboff's model	Current practice and ASHA
Didactic	Interactive problem focused
Detailed, structured descriptions of habituation	Facilitative
Possibly challenging concepts explained at comprehension level of patient	Adapted to comprehension/interest
Highly directive	Flexible
Detailed scripted process	Based on patient's symptoms
Sound therapy uses SGs	Environmental sound
Cost and compliance with ST	No significant additional cost



Possible clinical trends...

Preliminary analyses of psychological variables suggest a possible association of high trait anxiety with improved TQ scores in the TRT groups. Questions:

- Does providing sound generators have a mitigating effect on tinnitus distress that is associated with trait anxiety?
- Is TRT more effective in alleviating high anxiety?

Is PCC a reasonable, cost- and time-effective treatment?

Participating clinicians' observations:

1. The PCC-SOC results appear to be at least as good as TRT from a clinical perspective.
2. Flexible/individualized treatment options with a whole person perspective
3. Subjects appear to show better retention/understanding of tinnitus concepts over time

Facilitative-interactive approach in SOC may be easier for **SOME** clinicians and patients

- Focuses on enhancing patients' comprehension and interest level
- Engages and empowers
- Provides understanding, support, and encouragement



TRT may be easier for **SOME** clinicians and patients

- Uses standardized comprehensive protocol, including diagnostic, educational and treatment components.
- May be more effective for those patients who “need to know” everything possible about their tinnitus. For them...



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