

Developing the protocol for the standard-of-care treatment arm of the Tinnitus Retraining Therapy Trial

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Tinnitus epidemiology

- Tinnitus affects over 50 million Americans (about 15% of the U.S. population)
- Tinnitus prevalence 10-14% ¹
- 2% of persons with tinnitus are severely debilitated, requiring professional help – about 1 million Americans ²

¹Davis A, Rafaie E. Epidemiology of Tinnitus. In R. Tyler (ed), Tinnitus Handbook (p.1-23). San Diego, CA. Singular Press.

²Dobie RA. A review of randomized clinical trials in tinnitus. *Laryngoscope*. 1999. 109: 1202-11; Jastreboff PJ, Jastreboff MM. Tinnitus Retraining Therapy (TRT) as a method for treatment of tinnitus and hyperacusis patients. *Am J Acad Audiol* 2000. 11:162-77.



Tinnitus Retraining Therapy

- **Directive or educational counseling**
 - Detailed review of the anatomy, physiology of auditory system and brain function and how these relate to tinnitus
 - Presents neurophysiological model of tinnitus
- **Sound therapy**
 - Achieved through sound generators
 - Reduces the discrepancy between environmental sound and the tinnitus sound

Tinnitus Retraining Therapy Trial

The TRTT is a randomized, placebo-controlled, multi-center trial that will be conducted in military hospitals to test the efficacy of Tinnitus Retraining Therapy (TRT) versus the Standard of Care (SOC) treatment in individuals who have self-perceived debilitating tinnitus .

Treatment groups include:

- Full TRT
- Partial TRT, using placebo sound generators
- SOC



3 steps to develop the SOC treatment

1. Find out how military clinics usually treat individuals with severe tinnitus.
2. Review the pertinent guidelines to see what is good practice.
3. Develop a structured, standardized format to ensure consistent, uniform procedures across participating clinical sites.

Clinical center surveys

- Two phases
 - 2003, 12 audiologists, 2 physicians in 6 clinics
 - 2009, 5 audiologists, 1 physician in 6 clinics
- Survey asked about the “usual and preferred practice”
- Included questions on:
 - Setting for treatment
 - Amount of detail for description of audiological tests, anatomy and physiology
 - Reassurances
 - Recommendations
 - Materials given to patient

How often do you tell the patient the following? (2003)

Statement	<u>Rarely</u>	<u>Sometimes</u>	<u>Almost always</u>
Tinnitus is non-health threatening	3	5	5
Tinnitus has no impact on hearing	4	6	3
Tinnitus has no impact on new or additional hearing loss	5	6	2
Tinnitus is not caused by or evidence of a tumor	10	1	2
Tinnitus is a common condition	0	5	7
Your tinnitus may go away	5	5	2
Your tinnitus may get worse or fluctuate	3	5	4
Most people learn to ignore their tinnitus	3	6	3
You have to learn to live with your tinnitus	9	3	1

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Reassurances and recommendations that the majority of clinicians provided were incorporated into the protocol



AMERICAN
SPEECH-LANGUAGE-
HEARING
ASSOCIATION

ASHA Preferred Practice Patterns

- Counseling goals are established based on **assessment of patient's needs.**
- Counseling goals and approaches are modified to **facilitate patients' motivation, progress, and engagement** in the management of auditory and non-auditory effects of hearing impairment and other auditory, vestibular, or related disorders.
- Counseling approaches may be cognitive, affective, behavioral, or eclectic in nature based on the **patient's specific needs and target goals.**

(ASHA, PPPs, 2006)

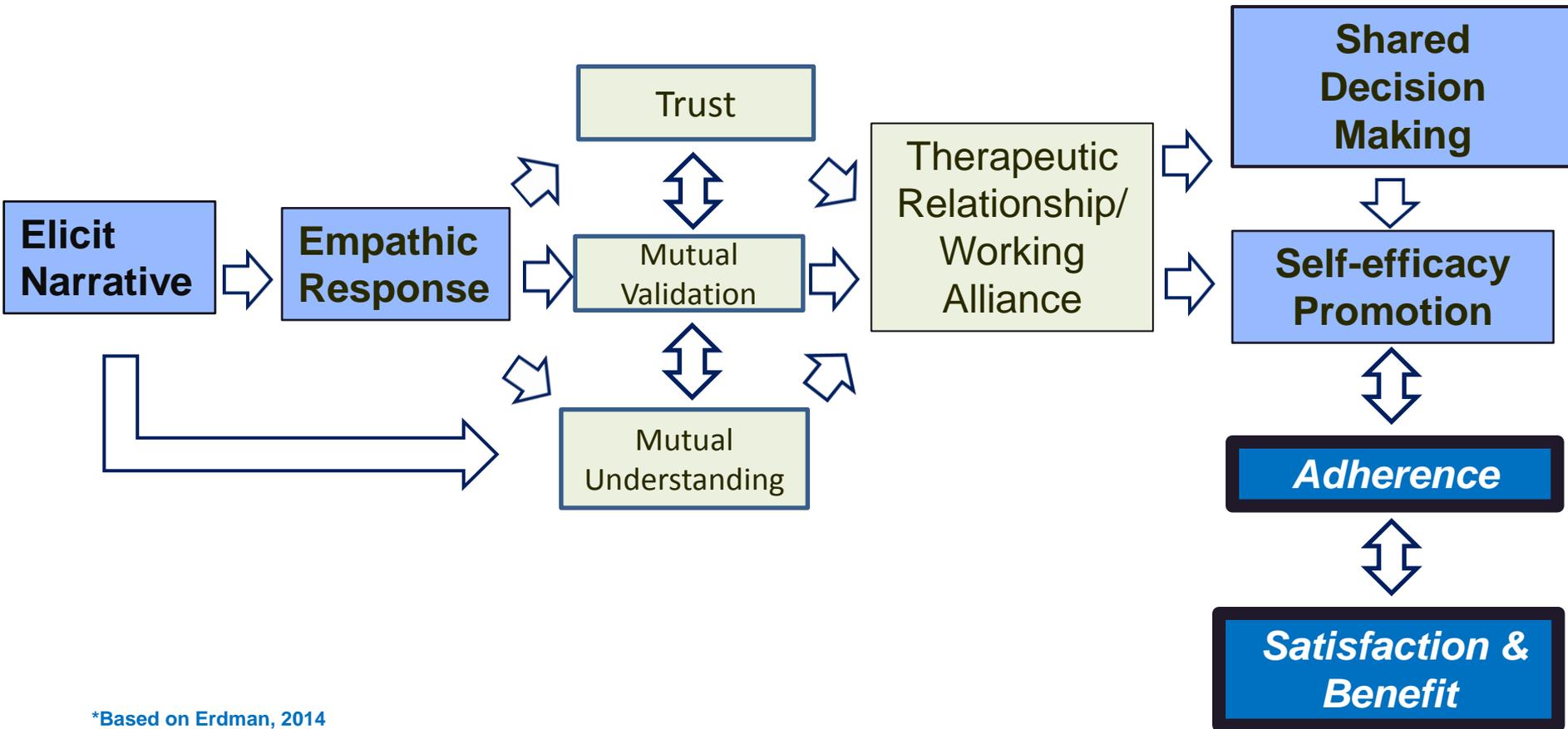
Person-centered approach

- States that warmth, empathy, trust, respect and unconditional positive regard:
 - Are personal attributes that the effective counselor presents to the client
 - Defines the working alliance in counseling
- Contributors to concept of person-centered approach
 - Rogers C – developed idea of person centered approach
 - Engel GL – incorporated the idea of psychiatric treatment for medical conditions in The Need for a New Medical Model: A Challenge for Biomedicine” (1977)
 - Bandura A: developed the idea of self-efficacy - “believing in yourself to take action”

TRTT Standard of Care Outline

- Approach may be educational, behavioral, or eclectic in nature ***based on the patient's needs***
- Goal is to facilitate motivation, progress, engagement
- Elicit patient narrative, summarizing key points
- Discuss hearing mechanism, tinnitus, and audiological exam
- Describe strategies to deal with problems related to:
 - Sleep
 - Stress
 - Concentration
- Describe use of environmental sound
- Set goals based on assessment of patient's needs

Patient Centered Standard of Care for the TRTT



*Based on Erdman, 2014

Aids used in SOC counseling session



3-D ear model



Standard of care scripts

Handout materials

1. Key Points about Tinnitus – what it is and what it isn't; noticing and ignoring it
2. Sleep tips
3. Relaxation tips
4. Concentration tips
5. List of environmental sound devices
6. List of website resources

Limitations of the current Standard of Care treatment

- Not really “usual” care, but probably more care than what each clinic usually provides
- Some military audiologists were not comfortable with “counseling” and an “empathetic” approach
- Some military audiologists still wanted to make treatment recommendations instead of working together with the study participant

Strengths of the current Standard of Care treatment

- Common practices across military sites are incorporated into the study protocol
- The patient–centered approach follows current best practice guidelines
- Consistent approach that still allows each participant’s needs to be identified and addressed.

Conclusions

- Developed a standard of care that incorporated both current guidelines and current practice in the participating clinical centers
- Person centered approach allowed for a structured, but flexible approach for each study participant

Acknowledgements

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National Institute on Deafness and
Other Communication Disorders

Improving the lives of people who have communication disorders

