Clinical Focus

The Tinnitus Retraining Therapy Trial's Standard of Care Control Condition: Rationale and Description of a Patient-Centered Protocol

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Purpose: The selection and design of control conditions are critical factors in minimizing the influence of unwanted variables in randomized controlled trials (RCTs). This article describes the rationale, design, and content of a standard of care control condition in a Phase III RCT of tinnitus retraining therapy.

Method: Existing tinnitus practices at military hospitals were identified and aligned with the American Speech-Language-Hearing Association's (2006) preferred practice patterns for tinnitus management and counseling

and embedded in a patient-centered protocol to ensure uniformity and treatment fidelity.

Results: For those involved in the design of behavioral RCTs, the article identifies options and methods to consider in the selection and design of control conditions.

Conclusion: For those who provide tinnitus services, the standard of care protocol developed for the tinnitus retraining therapy trial constitutes a patient-centered approach to intervention that can be implemented clinically.

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Tinnitus is the subjective perception of ringing, hissing, or chirping sounds in the absence of actual external sound. For most individuals, tinnitus is transient or occurs at such low levels that it is considered inconsequential. For others, however, the frequency and intensity of the sounds are sufficiently bothersome that professional intervention is warranted (Davis & Rafaie, 2000; Institute of Medicine, 2006; H.-J. Kim et al., 2015).

Unfortunately, as many as 94% of individuals with tinnitus complaints are told that nothing can be done for their condition (Holmes & Padgham, 2009). Although largely untrue, this belief is perpetuated by the fact that there is no actual medical cure for tinnitus. Moreover, systematic reviews of nonmedical tinnitus treatments have revealed equivocal evidence of efficacy (e.g., Dobie, 2002;

Hobson, Chisholm, & El Refaie, 2012; Phillips & McFerran, 2010; Pichora-Fuller et al., 2013). One apparent exception is cognitive behavioral therapy (CBT; Martinez-Devesa, Perera, Theodoulou, & Waddell, 2010), although Cima, Andersson, Schmidt, and Henry (2014) have noted that varying descriptions in the literature make it difficult to define precisely what CBT for tinnitus includes. In general, however, these CBT approaches “address the dysfunctional thought processes, behavioural and emotional responses that maintain aversive reactivity to tinnitus” (Fuller, Cima, et al., 2017, p. 3).

Among audiologists, tinnitus retraining therapy (TRT; Jastreboff & Hazell, 2004, 2008) is one of the more well-known formal approaches to tinnitus intervention. Nonetheless, there has been a lack of prospective studies and randomized trials to evaluate its overall efficacy and to clarify the role of its two components: directive counseling and sound therapy (Dobie, 1999, 2002; Formby & Scherer, 2013; Hoare, Kowalkowski, Kang, & Hall, 2011; Phillips & McFerran, 2010). As with CBT approaches, TRT aims to reduce tinnitus distress and its impact on health-related quality of life. TRT, however, is specifically intended to reduce the impact of tinnitus through a gradual process of habituation. Based on Jastreboff and Hazell's (1993) neurophysiological model, TRT includes tinnitus-specific directive counseling and

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sound therapy to promote habituation to tinnitus, thereby alleviating negative emotional reactions and, ultimately, the impact tinnitus has on the patient's life.

To resolve past shortcomings in research on TRT, a Phase III randomized controlled trial (RCT) of TRT (TRTT; Formby & Scherer, 2013; Scherer et al., 2014) was designed to evaluate the overall efficacy of TRT and establish the contributions of directive counseling and sound therapy. Conducted at six military hospitals, the TRTT incorporated a double-blind sound therapy utilizing placebo-controlled sound generators versus traditional sound generators and included a standard of care (SOC) control condition as a comparator intervention. The SOC was based on existing practices of audiologists at participating centers, which were aligned with practice guidelines for tinnitus management and counseling (American Speech-Language-Hearing Association [ASHA], 2006).

Results of the TRTT (Tinnitus Retraining Therapy Trial Research Group, 2019) indicate significant improvements for the majority of participants in both TRT arms and the SOC control arm, with no significant differences among the treatment arms. Hence, the twofold purpose of describing the SOC protocol is to highlight issues related to developing control conditions for RCTs and to offer a viable patient-centered approach to tinnitus care.

Control Conditions in RCTs

Control conditions are a critical component of clinical trials. Options include no treatment arms; wait list, attention, and placebo conditions; conditions that reflect existing practices; and numerous variations thereof. Not surprisingly, each type of control condition has its own strengths and weaknesses, all of which must be considered to maximize the internal and, ultimately, external validity of the research. No treatment and wait list conditions, although cost-effective and most likely to reveal experimental treatment effects, are prone to several problems, not the least of which is the potential for ethical issues related to withholding treatment. Participants may decline to enroll or, in the interim, may obtain comparable or alternate treatment elsewhere, which may or may not be known to the investigators. With placebo-controlled or attention conditions, in which the intervention has no known treatment effect or is comparable to the experimental treatment in terms of the time and attention provided, participants may develop negative expectations if they suspect or become aware that they are not receiving the experimental intervention. Such expectations can contribute to nonadherence or disenrollment; moreover, there is evidence that negative expectations alone can affect participants' treatment assessments and hence outcome results (Gold et al., 2017; Heppner, Wampold, Owen, Wang, & Thompson, 2016; Mohr et al., 2009). This is an increasingly common problem given the ease with which participants can obtain information about current treatment options and ongoing clinical trials on the Internet.

In addition to demonstrating the overall effectiveness of an intervention, RCTs can also serve to elucidate the

role of the intervention's components, its mechanisms of change, and, specifically in Phase III trials, if it is superior or inferior to existing practice. In such trials, the control condition generally consists of a current alternate treatment. Thus, the control group also serves a comparator, and the overall requirements for the condition are necessarily more stringent to permit differences in treatment effects to be observed. Existing practice control conditions that reflect typical clinical practice are generally referred to as *treatment as usual* or as *routine, usual, or standard care*. Those conditions that specifically adhere to an established set of practice guidelines are more commonly referred to as *standard of care*. The use of existing practice control conditions minimizes ethical concerns related to withholding care, but it can still introduce threats to internal validity, that is, the extent to which the outcome of a trial can be attributed to the experimental treatment rather than any alternative factors. Such factors can include the participating clinicians' skill or preference for an approach, the rigor of treatment monitoring across arms, or other issues that affect participants' outcome expectancies or health-promoting attitudes and behaviors. To minimize these potential threats, the existing practice intervention may be modified, standardized, or even enhanced to ensure uniformity, treatment fidelity, and the quality of care (Freedland, Mohr, Davidson, & Schwartz, 2011; Mohr et al., 2009). Modifications of this nature are generally recommended for multicenter projects and for those in which participating clinicians may have allegiance to a particular procedure or intervention or varying degrees of experience, expertise, and motivation. For these very reasons, such modifications were included in formulating the SOC control condition for the TRTT.

Multiple professions, including otology, audiology, and psychology, have been involved in providing assessment and treatment to patients with tinnitus complaints. Not surprisingly, although there is general consensus among professions and their guidelines as to what constitutes appropriate care for tinnitus (Fuller, Haider, et al., 2017), there is no established "best practice" per se (Hoare & Hall, 2011). Consequently, the content of the SOC was based on tinnitus treatment practices at the military health care facilities participating in the TRTT aligned with existing audiology guidelines for the treatment of tinnitus. The development of the SOC protocol included (a) querying clinicians at the sites being considered for participation in the TRTT to identify common practices across clinicians and centers, (b) aligning these practices with established audiology guidelines for tinnitus treatment, and (c) consolidating the results into a standardized format as required for a randomized trial but sufficiently flexible to permit participants' individual tinnitus complaints to be identified and addressed. To minimize threats to internal validity, the SOC was manualized, participating clinicians were trained, and execution of the SOC was monitored via recorded sessions and by clinician and protocol monitor checklists to ensure treatment fidelity as recommended for clinical trials (Bellg et al., 2004; Borrelli, 2011). Training and monitoring

procedures for all treatment arms of the TRTT will be reviewed in a future article on treatment fidelity.

Identifying Content for the SOC Protocol *Procedures/Practices at Military Hospitals*

Military personnel who serve in infantry, armor, and aviation divisions, as well as many other ancillary military specialties, are routinely exposed to hazardous noise. Consequently, audiologists in military hospitals regularly provide services to patients with tinnitus complaints. To obtain an accurate depiction of existing practices at these facilities, we queried audiologists and otolaryngologists at military installations that were being considered for participation in the TRTT. We first questioned clinicians in 2003 as part of the planning process for the TRTT. In 2009, questionnaires were sent to six clinics in conjunction with a resubmission for funding. The questions focused on the kinds of information, reassurances, and recommendations that were provided to patients (see Supplemental Material S1 for examples of questions and responses). The following general categories were identified:

- Describe anatomy and physiology using ear models and medical illustrations.
- Summarize audiologic tests.
- Provide information about tinnitus.
- Provide reassurances about tinnitus.
- Provide recommendations for coping with tinnitus.
- Provide recommendations to minimize noise exposure and other tinnitus triggers.
- Provide both verbal and written materials at the end of the counseling session.

Of the responses received from the participating centers, the area with the most variability involved recommendations related to coping with tinnitus. Audiologists with rehabilitation backgrounds included more in-depth counseling in areas related to the use of environmental sound to minimize tinnitus perception and to the effects of tinnitus on sleep, concentration, and stress.

Professional Guidelines for Tinnitus Treatment by Audiologists

To ensure that the military clinicians' tinnitus practices were appropriate and adequate (i.e., represented "good practice"), we examined clinical guidelines for audiologic management of tinnitus from ASHA (2006) and the American Academy of Audiology (2000). The guidelines from ASHA were more recent and more comprehensive and essentially

included all of the information provided in the American Academy of Audiology guidelines. Consequently, we compared the military audiologists'¹ reported practices to the ASHA guidelines. The tinnitus practice guidelines, as included in ASHA's preferred practice patterns (PPPs) for the practice of audiology, are shown in Table 1.

These general but comprehensive guidelines also provided specific goals for the SOC, which were (a) minimization of tinnitus perception; (b) reduction of negative cognitive, affective, and physical reactions to tinnitus; and (c) improvement of well-being and quality of life. The activities listed under tinnitus management provided guidelines for standardizing the interventions to be provided by all of the audiologists participating at the military centers. During the training phases of the TRTT, discussions with participating audiologists yielded additional options for coping with common tinnitus complaints, which were provided in handouts to the participants (the SOC handouts are available as Supplemental Material S2).

As can be seen in Table 1, many components of tinnitus intervention are counseling based. Consequently, we also referred to ASHA's PPPs for counseling in audiology practice (a) to ensure the adequacy and appropriateness of the SOC counseling approach, (b) to confirm that the content was consistent with audiologists' role in counseling, and

Table 1. Preferred practice patterns for the profession of audiology: 13.0 Tinnitus management (American Speech-Language-Hearing Association, 2006).

Clinical indications

Tinnitus management is indicated for individuals who have complaints of tinnitus with or without psychological distress and whose tinnitus cannot be resolved through medical intervention.

Expected outcome(s)

- Tinnitus management minimizes the auditory perception of tinnitus (e.g., ringing, chirping, buzzing).
- Tinnitus management reduces negative cognitive, affective, and physical reactions to tinnitus and improves the patient's well-being and quality of life.

Clinical process

Tinnitus management is based on the patient's complaints, history, audiologic evaluation, and self-assessment and should include family/caregivers.

Tinnitus management may include one or more of the following:

- tinnitus matching to determine the frequency and intensity of the perceived tinnitus;
- evaluation of tolerance problems to determine the presence of hyperacusis;
- counseling regarding the causes, sources, and audiologic significance of tinnitus;
- management of hyperacusis;
- fitting and monitoring the use of tinnitus maskers, hearing aids, or other ear-level sound generators to reduce the perception of tinnitus;
- the use of environmental sounds to aid in the reduction of tinnitus perception;
- identification of factors that may exacerbate tinnitus;
- use of hearing protection in noise;
- counseling to promote adaptive coping behaviors and stress reduction;
- counseling to minimize sleep difficulties related to tinnitus;
- outcome measures to evaluate success of treatment; and/or
- referral to other professionals.

¹The term *military audiologist* is used herein to denote the audiologists practicing at the participating military health care facilities. It should be noted that some were active duty officers whereas others were employed as Department of Defense civilians and may or may not have served as audiologists in the military previously.

(c) to distinguish it from existing CBT tinnitus intervention (see Table 2).

As stated above, ASHA's PPPs specify that tinnitus intervention is based on the individuals' complaints, audiologic evaluation, and self-assessment. Similarly, the counseling PPPs indicate that goals are established based on patients' needs and that goals are modified to facilitate patient's motivation, progress, and engagement in the treatment process. The Preamble to the Audiology PPPs (ASHA, 2006) also points out that decisions regarding treatment goals and

Table 2. Preferred practice patterns for the profession of audiology: 23.0 Counseling (American Speech-Language-Hearing Association, 2006).

Clinical indications

Counseling is indicated for all patients and their family members/caregivers as an integral part of audiologic services.

Expected outcome(s)

- Counseling enhances patients' and their families' understanding of, acceptance of, and adjustment to auditory, vestibular, or related disorders.
- Counseling enhances acceptance of and adjustment to hearing aids and hearing assistive technology systems designed to maximize communication skills.
- Counseling engages patients in the management of their communication problems and enhances the physical and psychosocial well-being and quality of life for individuals with hearing impairment and other auditory disorders.
- Counseling increases awareness of the need for prevention of further damage to auditory, vestibular, or related systems.
- Counseling enhances compliance with treatment recommendations.
- Counseling enhances benefit from and satisfaction with treatment.

Clinical process

- 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 nonauditory effects of hearing impairment and other auditory, vestibular, or related disorders.
- Counseling is individualized for each patient using culturally and linguistically appropriate language.
- Counseling approaches may be cognitive, affective, behavioral, or eclectic in nature based on the patient's specific needs and target goals.
- Counseling should include referral to and consultation with appropriate professionals and nonprofessionals as appropriate.
- Counseling may focus on one or more of the following:
 - evaluation procedures;
 - diagnosis and results of evaluations;
 - treatment options;
 - communication problems experienced secondary to hearing disorders;
 - effects of hearing and balance disorders on psychosocial and behavioral adjustment, including interpersonal relationships, social activities, and occupational options and performance;
 - affective/emotional reactions to auditory, vestibular, or other related disorders;
 - development of problem-solving skills and compensatory behaviors; and/or
 - development and coordination of self-help and support groups.

interventions are often made collaboratively to reflect patients' needs, preferences, and circumstances. These elements of service delivery reflect patient-centered care (PCC), which we consequently adopted as the framework to ensure consistent implementation of the SOC protocol at all of the participating centers.

Structuring the SOC Protocol for Tinnitus Intervention: A Patient-Centered Approach

The effects of individual differences have been well documented in audiologic research. Although audiometric data and self-report measures of problems related to hearing impairment are correlated, over a half century of research has shown that communication difficulties and the psychosocial and behavioral problems that may ensue cannot be predicted from the audiogram (Erdman, 2014). Similarly, reactions to tinnitus vary widely and can be idiosyncratic (Institute of Medicine, 2006; Noble, 2000). This unpredictability is reflected in ASHA's (2006) recommendation that tinnitus intervention be based on individuals' specific needs and complaints. This approach is consistent with Engel's (1977, 1980) biopsychosocial model and its overarching premise that individual differences are responsible not only for the variability in how people are affected by, react to, and cope with disease and disability but also for the discrepancies in benefits derived from treatment. Clinicians who provide tinnitus services recognize the variability in patients' reactions to this auditory disorder, the challenges posed in treatment planning, and the unpredictability of the benefit to be derived from intervention. Addressing the unique needs, concerns, and circumstances of each patient, however, does not readily lend itself to provision of a consistent, uniform treatment protocol as required in clinical trials. To resolve this inherent conflict, we developed a manualized patient-centered protocol that included consistent, comprehensive tinnitus counseling in conjunction with opportunities for participants' individual tinnitus problems to be identified and addressed systematically and appropriately.

The protocol for the SOC control condition includes elements that are emphasized in widely recognized PCC models, including the Kaiser Permanente four habits model (Frankel & Stein, 1999), Smith's patient-centered interviewing (Fortin, Auguste, Dwamena, Frankel, & Smith, 2012), the patient-centered clinical method (Stewart et al., 2014), and the Calgary–Cambridge observation guides (Kurtz & Silverman, 1996). These essential elements include the following:

- eliciting the patient's story/narrative,
- providing an empathic response to establish mutual validation and trust,
- establishing a therapeutic relationship to facilitate mutual understanding,
- shared/collaborative decision making for treatment goals and strategies, and

- promoting self-efficacy to maximize patients' management of chronic conditions.

Eliciting a narrative and responding empathically are readily observable/measurable clinical processes. The patient–clinician relationship unfolds as a function of mutual validation and the development of trust as described below. The presence, nature, and quality of this relationship can be inferred from the ease with which collaborative engagement ensues and successful information sharing and decision making occur—processes that are also readily observable. Following are descriptions of and the rationale for including these elements in the TRTT's SOC control condition.

Patient Narratives

Patient narratives provide a broad context within which we can understand the impact that disease and disability have on people's lives and the meaning they ascribe to these experiences. At the same time, these stories invariably yield specific and highly relevant details unique to the individual. The use of patient narratives is encouraged because they promote empathy, understanding, and a whole-person approach to care (Charon, 2001; Charon et al., 2016; Greenhalgh & Hurwitz, 1999; Lewis, 2011).

Although the traditional case history continues to be the most common approach to obtaining information from patients in audiology practice, the use of narratives to enhance our understanding of the impact of hearing disorders is increasingly stressed in the literature (e.g., Berg, Canellas, Salbod, & Velayo, 2008; Dauman & Erlandsson, 2012; DiLollo, 2014; DiLollo & Neimeyer, 2014; Erdman, 2014; Erlandsson, Lundin, & Dauman, 2014; Lockey, Jennings, & Shaw, 2010). To obtain an understanding of each participant's specific complaints and circumstances and enable the impact of tinnitus on his or her life to be addressed fully, eliciting a narrative was a critical element of the SOC.

Empathy

The process of hearing, reflecting upon, and understanding a patient's story enables clinicians to respond with empathy. Rogers (1957, 1975) viewed empathic understanding as an element of therapeutic relationships that is essential to treatment success, a belief that is widely supported throughout health care today (e.g., Bayne, Neukrug, Hays, & Britton, 2013; Elliott, Bohart, Watson, & Greenberg, 2011; Riess & Kraft-Todd, 2014; Schrooten & de Jong, 2017; Squier, 1990).

An empathic response from clinicians allows patients to realize that they have been heard and understood; it validates their feelings and experiences. When patients realize that their clinician understands their problems, the clinician, in turn, is validated as a competent, caring professional who understands them and their problems. This mutual validation and the resulting evolution of trust ultimately dictate the extent to which a therapeutic relationship develops. Empathy was included as an essential component of the

SOC because it promotes mutual validation and trust and, hence, the therapeutic relationship.

Therapeutic Relationship

The therapeutic relationship,² the foundation upon which constructive clinical collaboration can proceed, is one of the most salient variables in health care (Tresolini & Pew–Fetzer Task Force, 1994). “This relationship is a medium for the exchange of all forms of information, feelings, and concerns, a factor in the success of therapeutic regimens, and an essential ingredient in the satisfaction of both patient and practitioner. For patients, the relationship with their provider is frequently the most therapeutic aspect of the health care encounter” (p. 9). In counseling, in particular, the therapeutic relationship is crucial. Regardless of the counseling approach, research has consistently demonstrated that it is one of the strongest, most robust predictors of treatment success (Wampold & Imel, 2015). Among the initial tasks to be undertaken within a therapeutic relationship are (a) ascertaining what specific concerns and worries patients have regarding their condition, (b) verifying and clarifying that their perceptions and understanding are accurate, and (c) achieving a mutual understanding of the individual's problems. These goals are achieved through thoughtful reflection and discussion of issues raised in the patient narrative. Undue concern about health conditions often stems from a lack of knowledge or misconceptions that can result in anxiety. Anxiety and a lack of understanding of one's condition inhibit acceptance of the condition and can exacerbate reactions to it. Failure to accept a condition precludes effective coping and overall adjustment, factors that underscore the essential role of information in adjustment counseling (Erdman, 2014). The role of patient education in PCC is especially critical for those with chronic conditions because they will require long-term self-management skills. By enhancing patients' understanding of their condition and clarifying misconceptions they may have, clinicians enable patients to (a) identify specific problems associated with their conditions, (b) recognize the adaptive and maladaptive coping strategies they have used, (c) pinpoint specific goals for intervention, and (d) consider alternate coping strategies. Information from a trusted professional allows patients to acknowledge the impact their condition has had on their lives, thereby preparing them to collaborate in the identification of treatment goals and strategies. The critical nature of this interactive relationship was deemed essential in providing the information and

²In counseling, the term *therapeutic relationship* originated with Carl Rogers and his humanistic approach in person-centered therapy. Similar terms including *working alliance*, *therapeutic alliance*, and *practitioner–patient or clinician–client relationship* appear throughout the health care literature with varying emphases on the nature of the relationship. For the purpose of this article, therapeutic relationship is used to characterize the trusting, engaged, collaborative relationships between patients and their clinicians that are focused on achieving a successful therapeutic outcome.

reassurances required in the SOC and in facilitating collaborative decision making.

Collaborative/Shared Decision Making

Shared decision making (SDM) is the collaborative work that occurs in the care process. SDM models described in the literature (e.g., Barry & Edgman-Levitan, 2012; Charles, Gafni, & Whelan, 1997, 1999; Edwards & Elwyn, 2009; Elwyn et al., 2012; Fraenkel & McGraw, 2007; Makoul & Clayman, 2006) focus on the following:

- encouraging patient participation;
- exploring the patient's values, preferences, concerns, lifestyle, and expectations;
- valuing the patient's responsibility and rights to an active role in decisions;
- explaining scientific information, current best practices, and available options to patients;
- discussing pros and cons, risks, and benefits of treatment options;
- identifying and agreeing on target problems and desirable, achievable goals; and
- verifying that treatment options are feasible and doable.

Inherent in SDM models is an understanding of the different roles and responsibilities that clinicians and patients have. The clinician is the expert with respect to best practices, existing alternatives, and the pros and cons of these options for a given patient. The patient is an expert on his or her own values, needs, concerns, priorities, lifestyle, and abilities. The collaborative melding of this information enables those involved to reach agreement on desirable treatment goals and the treatment options that patients can best incorporate or adopt into their lives to achieve those goals. SDM was included as an essential ingredient in the SOC to ensure identification of acceptable and appropriate tinnitus interventions for each individual.

Promoting Self-Efficacy

The promotion of self-efficacy was a key component of the SOC to enhance successful use of tinnitus coping strategies. The concept of self-efficacy beliefs may be best summarized by the refrain in Piper's (1930) perennial childhood classic, *The Little Engine That Could*: "I think I can, I think I can!" Self-efficacy, the belief that one is capable of organizing and executing certain behaviors or reaching certain goals (Bandura, 1977, 1997), is a strong predictor of behavior change and ultimately determines whether or not a new behavior will be initiated, how much effort will be expended in doing so, and how long the behavior will be sustained. These issues are critical in adopting behaviors needed for successful self-management of chronic health conditions (Bandura, 2004, 2005). The likelihood that patients will adhere to recommended treatment strategies depends not only on their ability and motivation to do so but also on their

belief that they can do so. Collaborative decision making regarding treatment options must take patients' perceived and actual abilities into account to ensure that new adaptive strategies will be adopted and utilized. Ultimately, this involves promoting patients' self-efficacy. Self-efficacy beliefs can be promoted in a variety of ways, including mastery experiences that entail enactment or practice; vicarious experiences such as videos, role playing, or observing peers; verbal persuasion including reassurance, encouragement, and positive feedback; and psychological/affective reactions that result from successful attempts or failure. Inasmuch as self-efficacy beliefs are predictive of behavior change and success, promoting these beliefs is a critical component of interventions designed to engage patients in self-management of their conditions. The true essence of PCC requires combining and tailoring goals and learning approaches to meet each person's needs, abilities, and lifestyle. Hence, to promote adaptive coping behaviors as outlined in ASHA's PPPs, the promotion of self-efficacy beliefs was a critical ingredient of the SOC.

The overall PCC process contributes to basic differences between the SOC protocol and the traditional TRT approach, as shown in Table 3. Unlike TRT's didactic, directive counseling approach that is based on Jastreboff's neurophysiological model (Jastreboff & Hazell, 2004, 2008), the SOC protocol is an interactive, facilitative intervention that focuses on each individual's specific tinnitus complaints.

The TRTT Patient-Centered SOC Protocol

The SOC control condition that aligned the military audiologists' usual tinnitus practices with ASHA's (2006) tinnitus and counseling preferred practices was conducted as a systematic, patient-centered process. Depending on the individual participant's questions and needs, the protocol typically required 1.5–2.5 hours to complete. The duration of this session was consistent with the counseling portion of the other TRTT treatment arms. Clinicians participating in the TRTT received extensive training for all elements of the trial and demonstrated the requisite knowledge and skill in these areas prior to treating actual participants (Scherer et al., 2014). To be certified to provide treatment, each clinician first conducted the protocol with surrogates in recorded sessions that were reviewed and evaluated by the protocol monitor. Subsequent recorded sessions were then randomly reviewed to ensure treatment fidelity. Checklists were

Table 3. Differences between the tinnitus retraining therapy (TRT) and standard of care (SOC) protocols in the TRT trial.

TRT	SOC
Theory driven	Patient driven
Jastreboff's model	Current practice/ASHA guidelines
Directive	Facilitative
Didactic/top-down	Interactive/horizontal
Complex concepts	Adapted content
Sound therapy devices	Environmental sound

Note. ASHA = American Speech-Language-Hearing Association.

completed for each participant by the clinician and by the protocol monitor to demonstrate adherence to the protocol. The SOC protocol is described below.

After an initial greeting, the audiologist elicited the participant's tinnitus story or narrative with the following verbiage:

Our goal is to make it possible for you to cope with tinnitus so it does not have negative effects on your well-being and your life. To do that, it is important that I understand how your tinnitus affects you every day and how you feel about it. So, please, tell me about your tinnitus.

The goal of eliciting the tinnitus narrative was to identify the ways in which and the extent to which tinnitus has impacted the person's life. This information enabled the clinician to respond empathically to the person's experiences and reactions, promoted mutual understanding, and initiated identification of issues that warranted intervention. When an individual was withdrawn or reticent, additional questions or statements such as "Tell me more about that" or "What is that like for you?" were suggested to encourage participants to be more forthcoming and to prompt a more extensive description of their reactions to tinnitus problems.

To respond empathically, clinicians were instructed to summarize the key cognitive and affective aspects of the participant's narrative to validate the experience and to communicate understanding. For example:

- From what you are saying, I can tell that tinnitus has been interfering in some important aspects of your life... (identify situations) and that you feel (identify emotions cited, e.g., depressed, stressed) as a result.
- I can see that tinnitus has been very troubling for you and causes you a great deal of stress.
- Sounds like not being able to sleep has been really frustrating and aggravating for you.

Empathic responses often result in confirmation and/or clarification of one's statements and may also lead to additional revelations, thoughts, and feelings. After appropriate discussion of any additional issues, the audiologists were instructed to summarize the problem areas that were identified and to inquire if there were any other issues or problems the participants wanted to share or thought the clinician should know. Upon completion of this discussion, the focus was shifted to providing information to facilitate understanding of tinnitus problems. Statements such as the following were used to make this transition:

After we have talked a little about your tinnitus and tinnitus in general, I want to discuss these situations with you and how you have been coping with them because there are other devices and strategies you can consider that can also be helpful.

The next portion of the SOC protocol involved verifying that participants had an accurate and realistic understanding of tinnitus and what it may or may not portend.

To initiate this discussion, the audiologist asked participants, "Do you worry about your tinnitus?" To affirmative responses, a follow-up question included, "What worries you about it?" Following appropriate discussion of the participant's specific concerns, the audiologist continued with:

People often have misconceptions about tinnitus that make it more worrisome, so I'd like to review some facts with you to make sure you don't have any unnecessary concerns that could make your tinnitus even more stressful.

Participants were then given handouts summarizing basic information about tinnitus that was reviewed with them (see Tables 4 and 5).

Information in these handouts included topics that the military audiologists had indicated is typically provided at their clinics. The purpose of reviewing this information was to verify that participants had an accurate understanding of tinnitus and to clarify any doubts or misconceptions regarding the implications of tinnitus.

The discussion of tinnitus was followed by basic information on the hearing mechanism and types of hearing loss. Clinicians were encouraged to adjust the details and depth of these discussions to participants' current understanding of their hearing, their interest level, their grasp of information, and any questions they may have had. Emphasis was placed on maintaining participants' interest, facilitating comprehension, and adjusting the discussion accordingly. A review of the individual patient's audiologic, tinnitus, and hyperacusis evaluations followed. The specificity of these topics was also discretionary based on the participant's level of interest and comprehension. After confirming that there were no questions regarding this information, the discussion returned to the specific tinnitus problems that the patient had identified.

The collaborative decision-making process entailed

- having participants focus on their specific tinnitus problems and prioritizing which ones they wished to address;
- reviewing information/handouts³ on devices and strategies that could be useful in these situations;
- reviewing the potential pros and cons of the devices and strategies; and
- determining which options seemed most acceptable or appropriate given each individual's personal needs, preferences, and situations.

To enable participants who did not immediately identify a preferable option for a device or strategy or who appeared reluctant to decide, the protocol encouraged engagement by posing questions such as "Is this something you think would work for you?" or "How easy would it be for you to

³As noted earlier, handouts that were provided to participants in the TRTT's SOC are included in Supplemental Material S1 for interested readers.

Table 4. Tinnitus handout—Key points about Tinnitus I: 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 may go away.

do this?” The selection of strategies that participants thought could be readily and willingly incorporated into their daily routines optimized the likelihood that they would be successfully utilized, which would naturally promote self-efficacy. Emphasis was also placed on the extent to which and ways in which participants may already have coped effectively with tinnitus. Continued and more frequent use of those strategies was encouraged. By doing so, the audiologist provided a foundation upon which to enhance these beliefs and introduce effective use of additional new strategies. Demonstrations and actual practice of new strategies were included to ensure success.

Our review of existing practices at the participating centers revealed considerable variations in the extent to which and ways in which strategies for coping with tinnitus complaints had been emphasized. For the purposes of the SOC, we consolidated ideas from all of the clinicians and ASHA' PPPs (2006) to provide treatment options to be presented for the most common tinnitus problems during the collaborative/shared decision-making process. Consistent with the literature, the most common complaints of patients with tinnitus at the military sites included stress and tinnitus interference with sleep and concentration. To ensure consistent intervention, the SOC protocol included specific strategies to deal with these most common complaints.

Environmental Sound

The use of environmental sound was recommended to all participants in the SOC arm to minimize tinnitus

Table 5. Tinnitus handout—Key points about Tinnitus II: Noticing it and ignoring it.

- Almost everyone notices tinnitus from time to time.
- People with hearing loss may notice tinnitus 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.
- Having other sound in the environment makes it easier to ignore tinnitus.

perception. The protocol emphasized the interaction between noticing tinnitus and how bothersome it is as follows:

- Using environmental sound is the most important thing you can do to make sure that tinnitus is not as noticeable or as bothersome.
- There are many devices available that you can use to accomplish this.
- It is important to find sources of environmental sound for the situations that have been problems for you because your tinnitus will be less noticeable and it will be less bothersome.
- And, when it is less bothersome, you will start noticing it less often too.
- Select sounds that you find enjoyable or relaxing and soothing.

Participants were provided with information on a range of environmental sound sources ranging from everyday appliances such as portable fans or radios, to white noise generators and miniature water fountains, to apps and CDs. Purchasing/ordering information was included for specialized devices.

Stress Reduction

The SOC protocol included specific areas of emphasis for participants who indicated that tinnitus was a source of stress. These included the following:

- Having other sounds in the environment makes tinnitus less noticeable. This makes tinnitus easier to ignore and, therefore, less stressful.
- It is important to find ways to reduce stress, not only because tinnitus can be stressful but also because, for some people, stress appears to aggravate tinnitus.
- Medical personnel, educators, and counselors recommend a variety of ways to reduce stress: Deep breathing, progressive muscle relaxation, and visual imagery are very effective techniques. Yoga, tai chi, and meditation are other options that involve more time but are also very effective.

These options were reviewed, and clinicians demonstrated deep breathing, progressive muscle relaxation, and guided imagery exercises for participants who were not familiar with these techniques. Participants were asked to identify methods they deemed most suitable for their lifestyle and were encouraged to engage in these strategies and any other feasible stress reduction methods on a regular basis. The use of these strategies and relaxing background sound was emphasized because of the synergistic effects of stress and tinnitus perception.

Sleep Aids

Participants were informed that sleep is a very common issue for individuals with tinnitus but that there are many

options for alleviating this problem. Other factors that affect sleep were also covered. Areas of emphasis included the following:

- Improving sleep habits is important because lack of sleep increases stress, fatigue, and irritability, plus it negatively affects overall health.
- Environmental variables such as noise, light, and temperature and irregular schedules, jetlag, medications, caffeine, nicotine, and alcohol can disrupt sleep, as can stress and other emotions.
- A routine sleep schedule with consistent times for going to bed and getting up every day is advocated to encourage 8 hr of sleep.
- Exercise should be encouraged during daytime but discouraged immediately prior to bedtime. Daytime naps should be avoided, as should stressful activities, caffeine, alcohol, large meals, and spicy foods close to bedtime.
- Sleeping conditions should be optimized, with distractions (TV, computer, food/drink) removed, comfortable bedding used, bedroom darkened, and cool temperatures (between 58°F and 68°F) recommended.
- Soothing background noise (e.g., music, nature sounds, or broadband noise) often is conducive to sleep. Pillow speakers preclude bothering a partner.
- Progressive relaxation exercises and visual imagery should be encouraged if needed to help fall asleep.

Although not all of the audiologists had routinely, included such recommendations in their tinnitus practice prior to participating in the TRTT, all recognized the importance of sleep hygiene and enthusiastically supported inclusion of these recommendations in the SOC. A handout on sleep tips from the Mayo Clinic was provided to the participants.

Concentration

Also included in the SOC protocol were recommendations for helping individuals cope with difficulties concentrating due to tinnitus interference. Adding low-level environmental sound to minimize tinnitus perception was routinely suggested. The following points were emphasized to promote effective ways of dealing with concentration problems.

- Inability to concentrate affects memory, performance, and productivity.
- Inability to concentrate causes stress and irritability.
- In addition to tinnitus, other factors that can affect concentration include noise, temperature, distractions, lighting, hunger, fatigue, health, boredom, stress, and depression.

The following strategies were also reviewed:

- Work in shorter spans and/or take breaks.
- Control or optimize external/environmental conditions to maximize comfort.

- Establish a designated “worry time.”
- Use an internal “Stop!” command to minimize distracting thoughts and refocus attention.
- Practice attention shifting to illustrate that focusing on tinnitus increases how noticeable it is and that focusing on other sounds makes it possible to ignore tinnitus.

To learn this last strategy, participants were actively engaged in an attention-shifting exercise during their counseling sessions. Clinicians identified or created a sound in the environment (e.g., nail or pencil tapping on a desk) and instructed the participants to shift their attention from their tinnitus to the sound to demonstrate the ease with which attention can be shifted.

The SOC protocol concluded with a review of the problem areas identified by each participant and the decisions that were made regarding treatment goals and strategies. The treatment recommendations constituted a summary of the interactive counseling session and a mutual understanding of the participant’s concerns, needs, and ability and willingness to engage in the identified treatment options. A written outline of the recommendations was provided to each participant based on the summary discussion. The following general recommendations that applied to all participants were also provided:

- Avoid loud noises. If exposure to noise is unavoidable, properly fitted earplugs and/or other hearing protection should be used.
- Avoid excessive caffeine, alcohol, aspirin, and other substances that may trigger or exacerbate tinnitus.

A follow-up appointment was scheduled for a month later, during which a narrative regarding the person’s progress and feedback regarding the effectiveness of the coping strategies adopted was obtained and reviewed, and treatment options were modified appropriately as needed.

Clinical Considerations

By aligning military audiologists’ existing tinnitus practices with ASHA’s (2006) preferred practice guidelines for tinnitus and counseling and embedding these practices in a structured patient-centered protocol, the TRTT SOC met the criteria stipulated by National Institutes of Health for the purposes of RCTs and the recommendations for standardized control interventions in behavioral investigations (Freedland et al., 2011; Mohr et al., 2009). As those authors indicated, development of a SOC protocol for RCTs can require modification or enhancement of existing practices to ensure uniformity, treatment fidelity, and the quality of care from multiple clinicians across multiple sites.

The military audiologists had considerable experience and expertise in tinnitus practice, and although not all of the clinicians had been utilizing all of the tinnitus practices ultimately included in the SOC prior to the TRTT, they were familiar with the rationale for and utility of these

practices and embraced including them in the SOC. Many subsequently report that they now routinely include these practices when working with patients with tinnitus.

The patient-oriented framework adopted for use in the SOC constituted a somewhat different approach to practice for several of the military audiologists. Many audiologists have a diagnostic focus that mirrors the traditional medical model in which the disease or disability is focal rather than the impact of the condition on the person. The PCC approach was considered appropriate for the SOC tinnitus protocol because (a) PCC itself is now considered “best practice” throughout health care, particularly for chronic conditions (McMillan et al., 2013; Rathert, Wyrwich, & Boren, 2012), and (b) PCC’s systematic approach to identifying and meeting the individual needs of patients is consistent with the patient-oriented components of the clinical processes in ASHA’s PPPs (ASHA, 2006).

The tendency for audiologists to adhere to the traditional medical model was apparent during training to conduct the SOC. In practice sessions, clinicians often reverted to a case history approach when eliciting a narrative and focused specifically on tinnitus (e.g., onset, characteristics) rather than on its impact. Case histories provide an ailment-oriented set of details, which limits the extent to which clinicians can connect with patients on a more human level and capitalize on the valuable insights that narratives provide. Clinicians were reminded that (a) the medical/audiologic history is already in the person’s records and (b) the purpose of the narrative is to gain an understanding of what it means for that person to live with tinnitus—an understanding that is crucial to managing the condition. These prompts helped clinicians remember that the focus of PCC is the impact tinnitus had on participants’ lives.

Clinicians are often under the impression that the narrative approach takes longer than a traditional case history. Research has shown, however, that eliciting a narrative typically takes only a minute longer (Margalit, Glick, Benbassat, & Cohen, 2004) and, importantly, that it results in greater patient satisfaction (Epstein et al., 2003). The broader context and specific details inherent in patients’ narratives often include invaluable insight into affective, cognitive, and behavioral factors that ultimately affect outcomes because they so frequently influence adherence to treatment. Analyses of tinnitus narratives obtained by psychologists have provided insight into the different meanings patients ascribe to their tinnitus experience (Dauman & Erlandsson, 2012; Erlandsson et al., 2014). Also, the dynamic appraisal that narratives provide has revealed the intraindividual variability of tinnitus (Dauman, Erlandsson, Lundlin, & Dauman, 2015). These findings support the use of narratives in tinnitus management to promote attention to the individual and his or her unique needs.

Also consistent with a diagnostic/medical model approach to intervention, some of the audiologists in the TRTT experienced difficulty responding empathically during the SOC training. Audiologists who had experience in audiologic rehabilitation or who were comfortable in a counseling role had little or no difficulty with this required

component of the protocol. Interestingly, a sizeable number of the military audiologists participating in the TRTT were not familiar with Carl Rogers—an indication that counseling is underemphasized in audiology curriculum and that, in all likelihood, empathy is largely ignored. Ironically, empathy is continuously emphasized in training for medical students and practicing physicians (e.g., Batt-Rawden, Chisolm, Anton, & Flickinger, 2013; Lam, Kolomiro, & Alamparambil, 2011; Riess, 2015; Stepien & Baernstein, 2006). Teaching clinicians how to respond empathically often includes reflective writing (DasGupta & Charon, 2004), reflective group thinking (Ramesh, 2012), role-playing (Lim, Moriarty, & Huthwaite, 2011), and mindfulness (Beckman et al., 2012; Greason & Cashwell, 2009). The SOC training included information about the main components of empathy:

- an affective component that consists of accurate emotional attunement,
- a cognitive component that represents an accurate perspective of the individual’s experience and what it means to them, and
- a behavioral component that consists of mindful listening and verbally and/or nonverbally offering sensitive understanding of the cognitive and affective elements of the patient’s story.

Additional SOC training included reflective group thinking and role-playing. Mindfulness concepts were included on an individual basis when additional emphasis was needed.

Because empathic care is associated with patient satisfaction and adherence to treatment recommendations (e.g., DiMatteo, Haskard-Zolnieriek, & Martin, 2012; Hojat, 2016; S. S. Kim, Kaplowitz, & Johnston, 2004; Pollak et al., 2011), its function and importance are increasingly emphasized throughout health care. Clinicians, however, frequently miss opportunities to respond empathically (Hsu et al., 2012), and this was also evident throughout training for the SOC. Such missed opportunities may be the result of the following:

- failing to recognize patients’ distress,
- viewing routine clinical problems as commonplace and nonserious,
- focusing on fixing the problem rather than acknowledging the impact it has on the individual,
- minimizing or discounting problems in an attempt to make the person feel better, or
- not knowing what to say or do in response to patients’ experiences or concerns.

Having clinicians reflect on how they would feel in the patient’s position is an effective way to facilitate the emotional responsiveness needed in clinical empathy. The belief that emotional and psychosocial needs are not important clinical issues or that one is not a counselor can inhibit the extent to which clinicians respond empathically to patients (Coulehan et al., 2001; Hsu et al., 2012; Suchman,

Markakis, Beckman, & Frankel, 1997). We specifically included ASHA's audiology counseling PPPs in the conceptualization of the SOC to counter such thinking and to emphasize the counseling role required to execute the protocol effectively.

Empathy and validation of patients' perceptions are fundamental in establishing a therapeutic relationship. Hence, the onus is on clinicians to ensure that such relationships evolve. Given universal evidence that the patient-practitioner relationship is crucial to outcomes, counseling professions have been encouraged to emphasize the qualities and behaviors of clinicians that promote therapeutic relationships in practice guidelines (Norcross & Wampold, 2011). Although audiologists work with patients with hearing impairment and tinnitus (chronic conditions that warrant long-term collaborative relationships), the importance of developing a therapeutic relationship is not routinely emphasized in audiologists' education. Many of the audiologists found that embracing listening and reflection strengthened the relationships they developed with participants in the TRTT's SOC arm.

There was also a tendency for the clinicians providing the SOC to recommend treatment options rather than collaboratively arriving at treatment decisions. In short, here again, there was a tendency to adhere to a medical model or top-down approach in which providers do something to or for patients rather than with patients. This "fix-it" mentality, unfortunately, tends to result in a "one suit fits all" approach to care rather than a "tailored" approach that is based on the patient's specific needs, values, and preferences. The clinicians were reminded of the PCC adages, "Nothing about me without me," and "Patients aren't unengaged as much as providers are not very engaging." Most discovered that engaging participants in the decision-making process was a constructive approach that resulted in satisfaction for both parties.

There is, of course, considerable variability in the extent to which patients wish to be included in the decision-making process and definitions of SDM reflect this variability (Elwyn, Frosch, & Kobrin, 2016; Epstein, 2013; Epstein & Street, 2011; Makoul & Clayman, 2006). To manage participants who expected the clinician to make decisions or recommendations, the SOC protocol suggested the use of framing questions that would ultimately lead to identification of the individual's preferences. Although patients may initially indicate they want to rely on the "expert's opinion," it is always preferable to engage them and, if necessary, guide them through the pros and cons of options and ensure that these are feasible and amenable to them. The successful adoption of coping strategies is always contingent upon patients' self-efficacy beliefs (i.e., their belief that they will be able to do so). Asking even the most reticent patients which of two options they prefer or how easy it would be for them to implement a particular technique or strategy is a simple way to ascertain whether or not they think it is something they can and will do. Many of the decisions that participants in the SOC had difficulty making related to logistical problems. For example, could a particular

environmental sound device be utilized at work? Would environmental sound interfere with a spouse's sleep? Collaborative planning, reviewing alternatives, and strategizing enabled participants to reach an "I can do this" mindset.

In summary, aspects of the SOC approach that were appealing to the clinicians included the flexible/individualized treatment options that addressed participants' specific needs and the extent to which the approach engaged and empowered participants. From the audiologists' perspective, involving participants resulted in better understanding and retention of tinnitus concepts over time. One of the participating centers has already implemented the TRTT's SOC approach as their first option for treating all patients with tinnitus.

Conclusions

Development of any SOC intervention takes thought and requires melding of concepts and practice patterns already in place. Although the PCC philosophy incorporated in the SOC was a somewhat novel approach for some of the military audiologists, they found that the framework was an effective and efficient way to integrate and deliver tinnitus care in a systematic, comprehensive manner. They have found the approach easy to implement, cost-effective, and easily adapted to individual patients' needs, which is consistent with reported benefits of PCC throughout health care, including the fact that PCC leads to decreased use of health care resources and therefore to a reduction in costs (Bertakis & Azari, 2011; Epstein, Fiscella, Lesser, & Stange, 2010; Stewart, Ryan, & Bodea, 2011). Although some clinicians initially had difficulty in transitioning from the top-down to the shared decision-making mode, the PCC framework for the TRTT SOC worked well during the trial and provided effective treatment for a majority of the study participants assigned to this intervention arm. The PCC framework provided an efficient, systematic, and yet flexible way for audiologists to structure the array of information and strategies that were at their disposal to provide individualized care to the TRTT participants. Moreover, because the PCC framework is replicable and its key elements are observable and measureable, it was ideally suited for the TRTT and is an excellent option for structuring research on behavioral interventions.

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