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Ecological Momentary Assessment of Tinnitus Using Smartphone Technology: A Pilot Study

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Abstract

Objective—To explore the feasibility of ecological momentary assessments (EMAs) as a tool to more accurately assess the level of bother from tinnitus.

Study Design—Longitudinal observational study.

Setting—Washington University Department of Otolaryngology - Head and Neck Surgery faculty practice plan.

Subjects and Methods—Twenty participants with moderately to severely bothersome tinnitus were enrolled. All participants owned a smartphone device and all communications were conducted via email, phone, and text messaging. Participants received four EMAs per day for two weeks via text message and a final survey on the fifteenth day. In each survey, participants recorded their level of tinnitus bother, their location at the time of response, their stress level, how they were feeling and what they were doing. Response rates as a proxy for the feasibility of the program.

Results—There were a total of 1120 surveys sent to 20 participants (56 surveys per participant) and 889 (79.4%) of the surveys were completed and returned. The median time to response from the moment of receiving text message was 7 minutes. The distribution of responses to the EMA question, "In the last 5 minutes, how bothered have you been by your tinnitus?" displayed both

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high between and within subject variability. At the end of 2 weeks, the median score on the THI was 37 with range 10–82 points; the median TFI was 43 with range 10– 82 points.

Conclusion—This study suggests bothered tinnitus patients will use smartphones as part of ecological momentary assessment.

Keywords

tinnitus; outcome measure; ecological momentary assessment

INTRODUCTION

Tinnitus is a common clinical problem characterized by the perception of sound in the absence of external stimuli. Tinnitus affects approximately 50 million people in the United States, and 25% of these people report that their symptoms are bothersome.[1, 2] Numerous interventions have been developed with the goal of helping sufferers of tinnitus. The demonstration of treatment efficacy is complicated for the following reasons- tinnitus patients represent a heterogeneous group, symptoms can resolve spontaneously or fluctuate daily, a large placebo effect is often observed, and there is no objective measure of tinnitus. In addition, there is the risk of recall bias with the use of retrospective assessments that attempt to summarize severity of a variety of different symptoms over an extended period of time make it difficult to identify effective treatments.

All self-reported retrospective assessments of tinnitus impact require participants to recall the impact of tinnitus on their daily activities and emotions over a variable time period. Participants rate the impact of tinnitus on various aspects of their lives, and a summation score representing total tinnitus bother is then calculated.[3] Numerous weaknesses of retrospective self-report questionnaires have been documented.[4] Most notably, questionnaires suffer from recall biases and errors in summarizing prior events. Research suggests that patients' interpretations of past experiences are heavily influenced both by their current state and their current environment.[4, 5] Moreover, when patients are asked to summarize prior events, they will give undue weight to events that are more recent and/or more salient.[4] Taken together, these influences can introduce significant systematic biases into tinnitus assessments and evaluation of treatment effectiveness using retrospective self-report questionnaires.[6]

One technique used to limit the biases inherent in self-report questionnaires is the use of ecological momentary assessments (EMA).[7] EMA uses multiple, brief questionnaires to assess the state or quality of a phenomenon in the current moment, limiting the need for recall to summarize past experiences. EMA is used in behavioral research[8, 9], and the validity and reliability well-demonstrated.[10] Killingsworth et al.[11] demonstrated the potential of EMAs collected by participants' smart phones to assess how happiness varies with time and situation. By developing a web app for the iPhone, they obtained and analyzed responses from 2250 adult volunteers. Responses regarding what they were doing, whether their minds were wandering, and their level of happiness were used to determine how happiness correlated with different activities and states of mind.

To date, only one study has looked at the use of EMAs in the assessment of tinnitus bother.[12] Henry et al. used PDA devices to collect EMA survey data from 24 participants with moderate to severe bothersome tinnitus. The investigators programmed the PDA devices to signal participants with audible alerts to complete a short survey about tinnitus severity and the surrounding environment. Expensive PDA devices and the training needed for their use, make this an impractical method.

The increasing prevalence of smartphones provides a similar medium, but utilizes devices already owned by participants. No study has looked at the potential of cell phone technology to evaluate the level of bother that patients with tinnitus experience in their native environments. Smartphone technology provides a novel way to conduct EMAs utilizing technology already available and familiar to many.[13–15] In-the-moment reporting, easily available through smartphone technology, offers researchers a potentially more accurate way to capture the severity of tinnitus.

METHODS

This was a longitudinal study of adult subjects who suffered subjective, unilateral or bilateral, non-pulsatile tinnitus for at least six months' duration or longer. Subjects with tinnitus were eligible to participate if they reported to be *"Extremely bothered," "Bothered a lot," "Bothered more than a little, but not a lot"* by their tinnitus using a standard form of global assessment for chronic diseases, were between the ages of 18–80, owned a Smartphone device with texting and internet (3G or 4G) capabilities, and had access to that phone from 9:00 AM to 8:00 PM Central Time every day of the week.

Subjects were recruited from the Washington University's Otolaryngology Research Participant Registry. A registry of people recruited from the community at large who have self-reported tinnitus and are interested in participating in clinical research at Washington University. Potential participants were contacted via an email that contained a description of the study. Participants completed the baseline assessments, which included the 25-question *Tinnitus Handicap Inventory (THI)*[3], and the 25-question *Tinnitus Functional Index (TFI)*.[16] Consented participants agreed to receive EMA surveys about their tinnitus four times per day for 14 consecutive days. The EMA queries were sent as a text message to their smart phone at random times each day between the hours of 9:00 AM and 8:00 PM, based on a pre-defined electronic schedule of delivery. Each query contained a hyperlink to Washington University's REDCap (Research Electronic Data Capture) survey[17] site that was used to create and host the online survey. The survey consisted of 6 questions (Table 1) and was easily accessed and completed on the participant's smart phone internet browser (Figure 1). The responses to five of the six questions were recorded on a scale 1 to 100. The response to "*What are you doing right now?*" question was reported by endorsing one or more of 22 activities adapted from the day reconstruction method.[18]

At the end of the 14-day period the participants were directed to a follow-up survey where they were asked to retrospectively assess their tinnitus bother over the previous two weeks. The participants were asked to respond to the question, "*Over the last 2 weeks, how bothered have you been by your tinnitus using an analog scale of 0–100, where 0*

represented "Not bothered at all" and 100 represented "extremely bothered". In addition they completed the *THI* and *TFI* instruments.

Statistical Analysis

Standard descriptive statistics were used to describe the study population, tinnitus symptom severity, and results on all of the assessments. Measures of central tendency and dispersion were used to describe the reported score on each assessment as well as across different assessments within the same subject. Frequency distributions were generated to describe all categorical variables. Response rates and the time between message sent and receipt of response were calculated as a proxy for the feasibility of the program. While no value for the response rate as a measure of the validity of the assessment is widely accepted, we felt that a response rate of 75% or more would be reasonable.

Line graphs were used to describe and explore the within subject pattern of change in the level of tinnitus bother. Coefficient of variation was calculated based on mean estimates and standard deviation and was used to compare the variability between participants. Furthermore, the mean, median, and percentiles of bother, loudness, feeling, and stress level scores were calculated as aggregate scores for the possible total of 56 assessments for each individual. The percentile score represents the value below which a given percentage of participant's responses fall. Spearman's test was used to explore which of the above calculated scores had the strongest correlation with the corresponding *THI* and *TFI* assessments at the end of the two weeks. In addition, we explored the correlation of each of the bother aggregate scores (mean, median, and percentiles) with the *Global Rating of Bother* score, THI and TFI score assessed at the end of the 2 weeks.

Univariable and multivariable Ordinary Least Squares robust regression analysis with measurement clustered by participants was pursued to investigate the role of multiple variables as predictors of level of bother from tinnitus. All statistical tests were two-sided and tested at the 0.05 alpha level. SAS version 9.3 (SAS institute Inc., Cary, NC) and IBM SPSS Statistics for Windows, Version 20.0 (IBM Corporation, Armonk, NY) were used for data presentation and statistical calculations. This study was approved by the Washington University Human Research Protection Office.

RESULTS

Twenty participants enrolled in this study. The description of the characteristics of the study population is provided on Table 2. When asked to indicate the overall amount of disturbances of "bother" that the participant experienced in life as result of tinnitus 3 (15%) participants reported that they were "*Bothered a little, but not much*"; 11 (55%) were "*Bothered more than a little, but not a lot*"; and 6 (30%) were "*Bothered a lot*". The *THI* ranged between 16 and 84 points on a scale 0 to 100 with a median of 33 points; the TFI score at initial assessment ranged between 7 and 90 points on a scale 0 to 100, with a median of 43 points.

There were a total of 1120 surveys sent to 20 participants (56 surveys per participant) and 889 (79.4%) of the surveys were completed and returned. The majority of the participants

(13/20 or 65%) completed at least 42 (75%) of the assessments and 8 of the 20 (40%) participants completed at least 50 (90%) of the assessments. The median time to response from the moment of receiving text message was 7 minutes. At the final survey on the 15th day, 18 (90%) participants responded that they would recommend this study to a friend.

The distribution of responses to the EMA question, "In the last 5 minutes, how bothered have you been by your tinnitus?" displayed both high between and within subject variability. As can be seen in Figure 2, the scoring of tinnitus bother varied significantly across the four representative participants. For example, responses from Participants A and C suggest considerably more bother, on average, than responses from Participants B and D. In addition, responses from Participants A and C show considerably more within subject variability than responses from Participants B and D and the coefficients of variation support this observation (Participant A-44.9%, Participant B-28.2%, Participant C-47.8%, and Participant D-11.5%). The coefficients of variation for the bother score calculated for each patient (n=20) had a median of 48.4% and ranged from 11.5% to 109.9%.

At the end of 2 weeks, the median *THI* score was 37 points with a range from 10 to 82 points; the *TFI* was 43 points with a range from 10 to 82 points. The median overall retrospectively-assessed *Global Rating of Bother* was 56 points with a range from 9 to 88 points.

The distribution of individual EMA-assessed aggregate scores was determined as mean, mode, median, and various percentiles. The correlation value for *THI* and EMA score was highest for the 80th percentile score for EMA. The correlation value for TFI and EMA was highest for the mean EMA score and the correlation between *Global Rating of Bother* and EMA was highest for the 70th percentile of EMA score. These results suggest that patients' retrospective rating of tinnitus bother as assessed with the *THI*, *TFI*, and *Global Rating of Bother* rating instruments tend to reflect a higher level of bother then as assessed by EMA.

The degree of correlation between the Week 1 and Week 2 scores on the *THI*, *TFI*, and for the EMA-derived scores on *Bother*, *Loudness*, and *Stress* for each subject was calculated using Spearman's rho coefficient. The correlation for *THI* was 0.853, *TFI* 0.837, and for EMA-derived *Bother* 0.762, *Loudness* 0.845, and *Stress* 0.773.

The summary of responses to the categories of question "*What are you doing right now?*" is displayed in Table 3. The most common activities performed at the time of EMA assessment were *Working (27%)*, *Watching Television* (18%), *Talking/Conversing* (13%), and *Relaxing/ Nothing Special* (10%).

The intra-class correlation coefficient for the EMA-defined *Bother* score (dependent variable) was 0.45, indicating a strong within-subject clustering effect. Ordinary Least Squares robust regression analysis with measurement clustered by participants was pursued to investigate the role of multiple variables as predictors of tinnitus bother. Univariate regression showed that participants who were engaged in talking or reported feeling better (higher score on the "*How you are feeling?*" question) were more likely to have lower bother scores, while participants who were engaged in playing at the time of assessment and rated high tinnitus loudness or stress were associated with higher bother scores. The final

multivariable model included only tinnitus loudness and feeling bad at time of assessment as significant predictors of the bother score.

DISCUSSION

In this methods development study, tinnitus patients demonstrated that they will use smartphone technology to submit information about various aspects of tinnitus bother. This observation suggests that smartphone technology is feasible for the momentary assessment of tinnitus and the enhancement of capturing patient-reported outcomes. These findings show that the degree of tinnitus bother varies considerably between patients and even within individual patients including considerable fluctuation over the course of a single day.

One of the challenges facing the development and evaluation of new treatments for tinnitus is the availability of valid patient-reported outcome measures that accurately quantify the experience of tinnitus. In order to test and demonstrate the efficacy of new treatments, the symptoms experienced before and after treatment must be measured in an accurate and precise manner. Because of the fluctuating nature of tinnitus, EMAs may be more effective than retrospective questionnaires in characterizing the experience of tinnitus. Based on previous research demonstrating the influence of salient experiences on recall bias[19], we expected sufferers of tinnitus to assign a higher amount of bother when assessed by retrospective questionnaire when compared to EMAs of the same two week period. In short, the recall of tinnitus bother seems to over rate the degree of bother as compared to momentary assessment.

Moment-to-moment responses seem to define unique and different patterns of tinnitus bother. Some patients display wide moment-to-moment variation in tinnitus bother while other patients display more stable and less variable responses. Patients with large degree of moment-to-moment variability might be bothered because of the unpredictability and severity of the change in symptom and not necessarily because of the perceived loudness of the tinnitus. *THI* and *TFI* cannot capture this moment-to-moment variability. This clinical situation of moment-to-moment variability in tinnitus is similar to variability in blood pressure measurement. For a variety of reasons, including the inclusion of blood pressure as an outcome measure in clinical trials, the ability to obtain an accurate measure of blood pressure is important. The use of automatic ambulatory blood-pressure monitoring in place of the auscultatory technique in a medical setting[20] increased the accuracy of blood pressure measurement. Several interesting observations were made after the introduction of automatic ambulatory blood-pressure monitoring in clinical trials of anti-hypertensives. First, fewer patients needed to be enrolled in the clinical trials due to a reduction in the random error associated with blood pressure measurement and, second a greater correlation between change in blood pressure and clinical outcomes was observed.[21] Third, the placebo effect was observed to be negligible on ambulatory defined blood-pressure monitoring.[22] All three of these aspects - reduction in sample size, correlation of change in physical problem with patient-centered clinical outcomes, and impact of the placebo effect are important features of tinnitus clinical trials.

When planning a clinical trial to determine the efficacy of an intervention, it is most advantageous to enroll subjects who are likely to demonstrate response to treatment and in whom the true response to treatment can be detected above the background "noise" of day-to-day variation. This pilot study only focused on moderate to severe bothersome tinnitus because these are the patients who seek treatment and who are generally enrolled in clinical trials and other types of clinical research. Among the EMA responses for the four participants displayed in Figure 2, tinnitus patients with EMA responses like Participant D may be best suited for clinical trials as the degree of bother is high and the degree of moment-to-moment variability is low. While tinnitus patients with small moment-to-moment variability with responses like Participant B would be desirable to demonstrate an effect, the degree of bother is much smaller and therefore the ability to impact improvement is small ("floor" effect). Tinnitus patients with large variability in moment-to-moment tinnitus bother as demonstrated by Participants A and C may not be desirable for enrollment in a clinical trial assessing the efficacy of tinnitus treatment. Once efficacy has been established, then the effectiveness of the treatment can be assessed in a wider selection of tinnitus patients with greater variability in tinnitus.

Tinnitus participants in this and previous EMA studies[11, 12] demonstrate high response rates. This suggests that EMA is a feasible tool for the collection of real-time symptoms. To date, the wide use of smart phones removes limitation of the previous EMA tinnitus study[12] related to the purchase of expensive equipment. Our study used participants' own smart phone devices and was entirely conducted via phone interviews and email. Coupling EMAs as an outcome measure of a treatment trial with multiple office visits and satisfactory follow-up would likely increase the response rate and provide better understanding of impact of potential treatments.

Limitations of this study include a small sample size with significant selection bias and restriction of sampling time between 9:00 AM and 8:00 PM. Participants were predominantly white and highly educated, and all participants were required to own their own smartphones. The generalizability of the results to the tinnitus population may therefore be limited. The time-of-day constraints imposed in this study made it unlikely for EMAs to capture the distress caused by the interference of sleep by tinnitus. Indeed, sleep disturbance is one of the most common problems reported by patients with tinnitus.[23] However, it is possible to add a question regarding sleep quality that the participants receive early each morning. As a result, it may be that our aggregate assessment of bother by EMAs underestimates the true amount of overall bother. In future use, assessments during the 8:00 pm to 9:00 am period could be considered. Other methods, such as direct questioning of the impact of tinnitus on sleep with the first EMA of the day or actigraphy[24], may be required for assessment of the impact of tinnitus on sleep.

The positive results of this method development study warrant further validation of EMAs as a measure of tinnitus bother. Further work should be conducted to refine this method of collection, culminating in a web or native smartphone application designed specifically for the collection of tinnitus data. Such an application could be made widely available, both to researchers for use in clinical trials of tinnitus therapies and to the tinnitus population,

providing more data for analysis to researchers, as well as readily accessible information for the individual patient on his/her own experience with tinnitus.

CONCLUSIONS

Tinnitus patients will use smartphones as part of ecological momentary assessment and, when compared to retrospective assessment, EMAs may provide a more accurate and informative measure of tinnitus bother. Valid EMA technology has the potential to improve the efficiency of tinnitus clinical trials by enrolling patients whose tinnitus complaints are more stable and thus treatment effects can be better identified. In addition, the use of moment-to-moment measurement of tinnitus, as was found in ambulatory blood pressure monitoring, may lead to a reduction in the placebo response when compared with one-time static measurements. Therefore, we believe the use of EMA technology will result in the enrollment of patients with less extreme fluctuations of tinnitus bother and a reduction of the placebo effect. Both of these effects will result in greater power to detect a true difference with a smaller sample size than currently possible with retrospective assessment of tinnitus bother.

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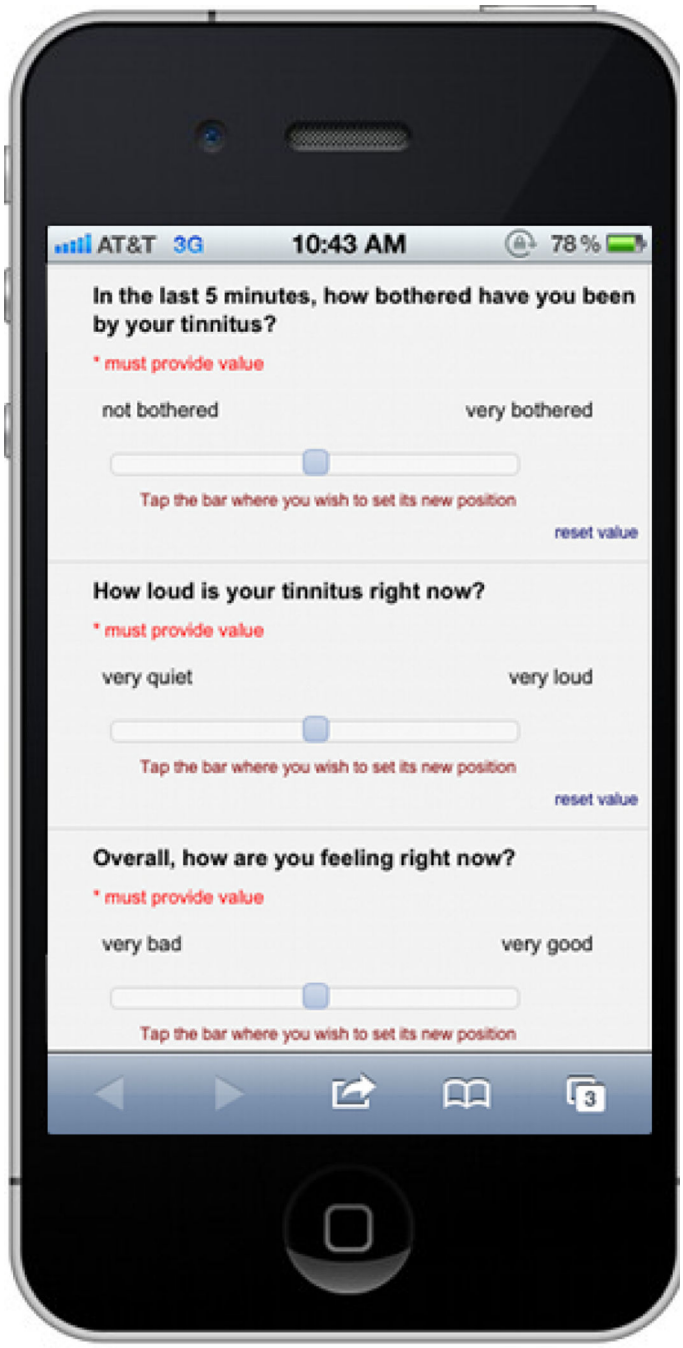

Figure 1.
Survey questions were accessible through smartphone's internet browser.

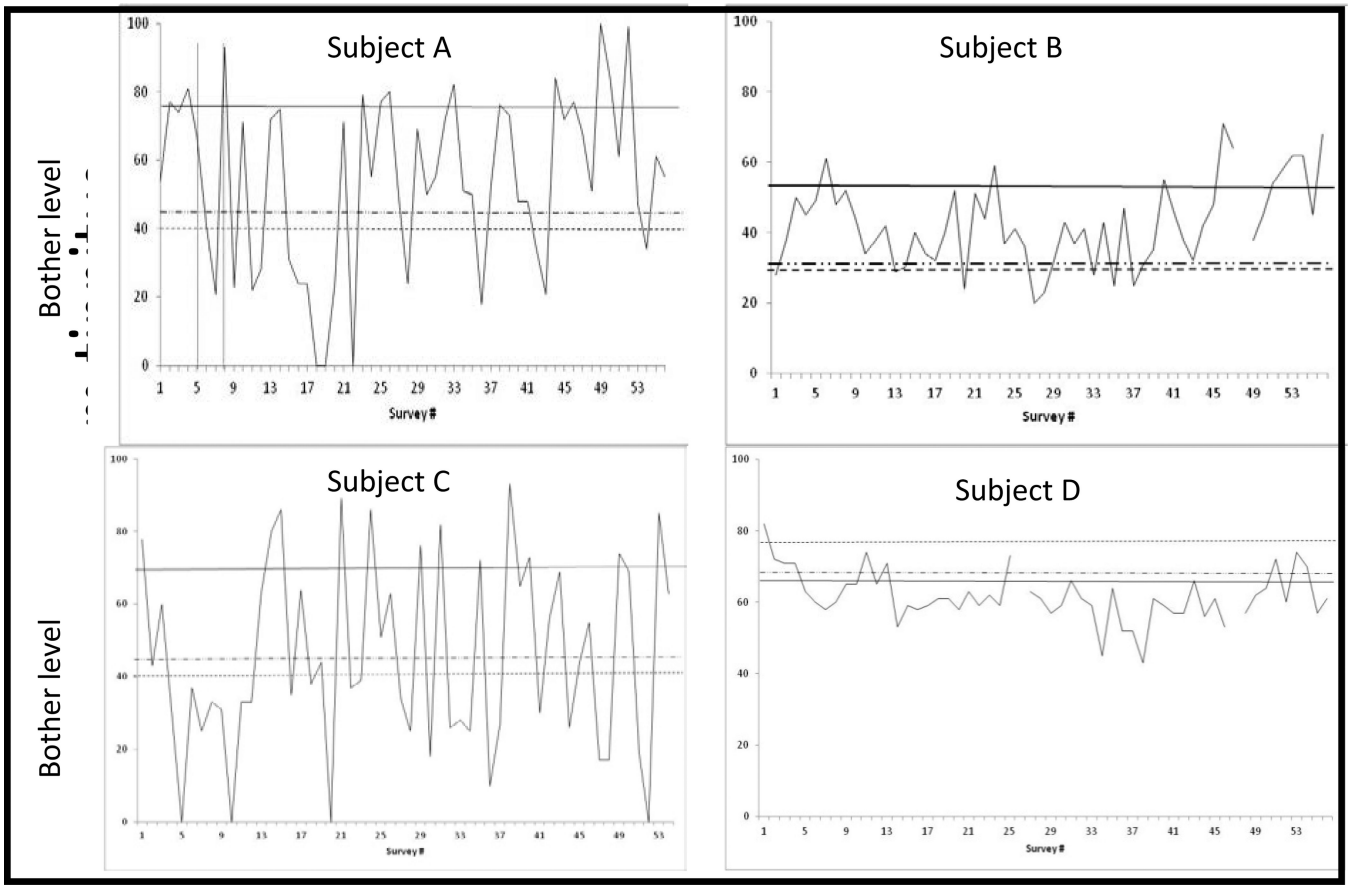

Figure 2.
Examples of variation of bother from tinnitus within the subject and between subjects through all 56 assessments

Global Rating of Bother _____

TFI – .. – .. – .. – .. –

THI ----------

Table 1

Survey Questions and Formatting of Answers

	Question	Answer format
1	In the last 5 minutes, how **bothered** have you been by your tinnitus?	Scale 1 to 100: 1 represents no bother, and 100 represents maximum bother
2	How **loud is your tinnitus**?	Scale 1 to 100: 1 represents “very quiet”, and 100 represents “very loud”
3	How are you **feeling** right now?	Scale 1 to 100: 1 represents “very bad”, and 100 represents “very good”
4	What are you **doing** right now?	List of 22 activities
5	How **loud is the environment** you are currently in?	Scale 1 to 100: 1 represents “very quiet”, and 100 represents “very loud”
6	How **stressed** do you feel right now?	Scale 1 to 100: 1 represents “not stressed”, and 100 represents “very stressed”

Table 2

Characteristics of The Study Population

	N	%
Age (years)		
Median (Min-Max)	55	38–65
Gender		
Female	10	50
Male	10	50
Race		
White	19	95
Asian	1	5
Education		
High school Diploma or GED Equivalent	1	5
Associate Degree or Some College	3	15
Bachelor Degree	6	30
Masters Degree or other Masters Equivalent	7	35
PhD, MD, JD, or other Higher Degree	3	15
Current Employment Status		
Full-Time	14	70
Part-Time	2	10
Full-Time Homemaker	1	5
Unemployed	1	5
Retired	2	10

Table 3

Distribution of Responses To The Question *"What Are You Doing Right Now?"*

Response category	N*	%
Working	239	27
Watching television	162	18
Talking/conversing	112	13
Relaxing/nothing special	91	10
Home in computer	82	9
Commuting/traveling	73	8
Eating	71	8
Shopping/errand	56	6
Preparing food	49	6
Listen to music	39	4
Reading	30	3
Rest/sleep	26	3
Listen to radio news	17	2
Exercising	16	2
Grooming/self care	13	1
Walking	11	1
Playing	11	1
Taking care of children	5	0.6
Praying/worshipping/meditating	3	0.3
Homework	2	0.2
Other activity	89	10

* A total of 889 responses were provided from all study participants across all time points.