



The Arab Republic of Egypt
Ministry of Higher Education
Health Research Ethics Committee
Assiut University
Faculty of Medicine

NATIONAL	APPLICATION	<b>FORM</b>	FOR	<b>ETHICAL</b>	APPROVAL	OF	A
RESEARCH I							

# Applicant

□ Name: Sherifa Ahmed Hamed				
☐ Institute: Assiut University, Faculty of Medicine				
☐ Current position: Professor of Neurology				
□ Address / e-mail:				
Department of Neurology and Psychiatry, Floor #7, Room #4, Hospital of Neurology and Psychiatry,				
Assiut University Hospital				
Assiut, Egypt				
P.O.Box 71516				
Telephone: +2 088 2085106				
Cell phone: +2 01115324560				
Fax : +2 088 2333327				
+2 088 2332278				
email: <a href="mailto:hamed_sherifa@yahoo.com">hamedsherifa@aun.edu.eg</a>				
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□ Signature				

#### Title of the study

## Evaluation of chronic idiopathic tinnitus and its psychosocial triggers

#### Introduction/methodology/data collection/data analysis

Tinnitus is a very frequent subjective symptom in adults. It has been found that 15-30% of patients with tinnitus had no clinically manifest hearing loss or even had no subclinical sensorineural hearing loss when evaluated using advanced auditory testing. Previous studies found that there are several comorbid psychiatric conditions and disorders in sufferers of tinnitus, which also may contribute to its persistence and increased severity. They include stress, anxiety, depression, sleep disturbance, increased forgetfulness, major depression and anxiety and somatoform disorders. However, the relationship of these comorbidities to the onset of tinnitus is still unclear. Also the psychosocial triggers for initiation, increased severity and chronicity of tinnitus are understudied in many areas of the world. Whether psychological/psychiatric factors are risks for bringing tinnitus is understudied in different countries, therefore, in this work, we aimed to determine (a) the comorbid psychosocial factors and behaviors associated with tinnitus's onset, severity and chronicity, and (b) the predictors for the increase in its severity. This will be a cross-sectional study. It will include at least 100 adults with chronic tinnitus. Patients will be recruited from the out-patient Otolaryngology and Neuropsychiatry clinics of Assiut University hospital, Assiut Egypt. The following will be the measures which will be used to assess the patients including Tinnitus Handicap Inventory (THI), Depression Anxiety Stress Scale (DASS 21), Perceived Stress Scale (PSS) and Insomnia Severity Index (ISI). Data will be analyzed with SPSS (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp). The distributional properties of variables and the appropriateness of the analyses of covariance will be confirmed. Comparative statistics will be done using two-sided Student's t test, Chi square test and one way analysis of variance (ANOVA) with Bonferroni post hoc correction. Inferential statistics will be performed using Spearman's Correlation Coefficient between (a) scores of tinnitus variables, patients' demographics and results of different questionnaires. Multivariate analysis will be done to determine the independent variables associated with tinnitus severity. Results will be expressed as odd ratios (OR) and 95% Confidence Intervals (CI). Significances will be calculated with probability value less than 0.05.

## **Budget**

Personal

### **Confidentiality**

As a corresponding author, I declare that written informed consent was obtained from the patients for publication of their clinical, laboratory and socioeconomic and psychometric data.

## For office use only

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# Approved

