A Controlled Study of NeurOptimal™ Neurofeedback in Tinnitus Patients

Dr. Raponi

Milano

Preliminary Results

Presented by

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Study and Investigators

“A randomized study of Neuromodulation, using Neurottimo® brain training system, on tinnitus symptoms and associated psychological distress factors in patients diagnosed with tinnitus”.

Investigators are:

- Dott. Aldo Messina, Oto Laryngologist and Audiologist
    - Head Department of Audiology of the University Hospital "Paolo Giaccone" of Palermo
- Dott. Giorgio Raponi, Oto Laryngologist and Oto Neurologist
    - Expert in Tinnitus-Vertigo-Deafness Diagnostic and Management
- Dott. ssa Michela Maria Di Nardo, Masters Statistician
    - Consultant and Analyst, Expert in collection and analysis of clinical data
- Dott.ssa Marianna Franco, Psychotherapist of the University Hospital "Paolo Giaccone" of Palermo
- Dott.ssa Elisa Tocco, Oto Laryngologist of the University Hospital "Paolo Giaccone" of Palermo.

Zengar Institute has supported our research with loaner equipment.

What is Tinnitus?

Perception of a Sound
in the Absence of Acoustic Stimulation

What is Tinnitus?

Tinnitus often causes:

Sleepless Nights,

Constant **Anxiety**,

Crazy **Mood Swings**,

Helpless **Depression**,

Energy Sapping **Exhaustion**,

Overall **Stress in Your Life.**

"The Ringing Just Won't Stop!!!"

Our Thesis:

Research Protocol

- **We are offering NeurOptimal training to up to 60 recruited patients with a run-in using "sham" training to establish the control value or baseline.**

- **The "sham" training should last for 5 weeks (10 sessions) and the standard training should last for 10 weeks (20 sessions).**

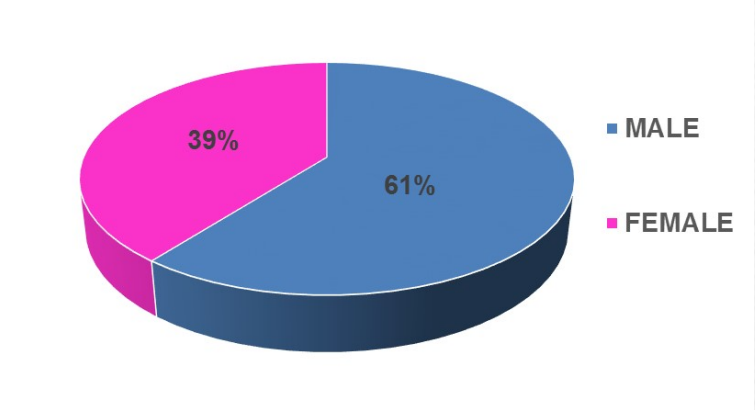
We are collecting baseline data:

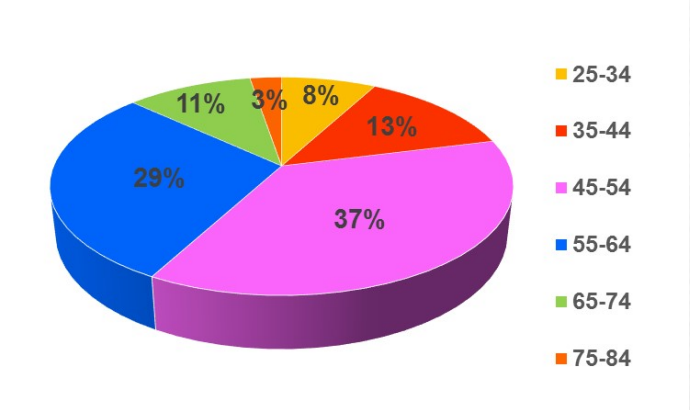
- **Depression, anxiety and stress (DASS21 Questionnaire)**
- **Audiometric measurements of acuphenometry (Residual Inhibition)**
- **Tendency to pathological preoccupation (PSWQ Questionnaire)**
- **Sleep quality (PSQI Questionnaire)**
- **Handicap level provoked by tinnitus (THI Questionnaire).**

Results are to be compared before and after training to see if there is an effect.

Our Sample: Sex and Age

- **We have recruited a sample of 38 patients up to 15th April 2018, in the two sites (Milan + Palermo).**
- **About 60% are males**
- **66% are between 45 and 64 years.**





Our Sample: Origin of Tinnitus and Age of Onset

- **Origin of tinnitus can be auditory Deafferentiation or other sensory (Cross Modal)**
- **In most cases, patients have had tinnitus for less than 2 years.**

ORIGIN	100%= patients at time T0
DEAFFERENTATION TINNITUS	55%
MODAL CROSS	45%

AGE OF ONSET	100%= patients at time T0
0 TO 2 YEARS	73%
FROM 2 YEARS MORE 1 DAY TO 5 YEARS	11%
FROM 5 YEARS MORE 1 DAY TO 10 YEARS	5%
MORE 10 YEARS	11%

Tinnutus at Time T0:
Where, Type and Performance

The highest incidence is for tinnitus Monolateral, Persistent, with sound Whistle.

WHERE	100%= patients at time T0	TYPE	100%= patients at time T0	PERFORMANCE	100%= patients at time T0
MONOLATERAL ON THE LEFT	42%	WHISTLE	50%	PERSISTENT	68%
MONOLATERAL ON THE RIGHT	26%	BUZZ	13%	INTERMITTENT IN THE DAY	19%
BILATERAL	23%	SWISH	7%		
BILATERAL MORE RIGHT	3%	WHISTLE + BUZZ OR BUZZ + SWISH	17%	OCCASIONAL	13%
BILATERAL MORE LEFT	3%	SOUND DEAF	13%		
IN THE CENTER ENCEPHALO OR NUCALE	3%				

Scores at Time T0: Moderate to Severe

Our Tinnitus recruits display, on average baseline scores:

- **Tinnitus Handicap Inventory: Moderate (THI score = 53)**
- **Pathological Preoccupation Tendency: Moderate (PSWQ score = 49)**
- **Sleep Quality: Poor (PSQI score = 7).**

THI	100%= patients at time T0
POOR	0%
MILD	27%
MODERATE	30%
SEVERE	27%
CATASTROPHIC	16%

AVE SCORE 53 VS SEVERITY RATING

0 - 16 POOR
18 - 36 MILD
38 - 56 MODERATE
58 - 76 SEVERE
78 – 100 CATASTROPHIC

PSWQ	100%= patients at time T0
VERY LOW	0%
LOW	18%
MODERATE	68%
HIGH	13%

AVE SCORE 49 VS SEVERITY RATING

0 - 16 VERY LOW
17 - 37 LOW
38 - 59 MODERATE
60 - 80 HIGH

PSQI	100%= patients at time T0
POOR SLEEP QUALITY	78%
GOOD SLEEP QUALITY	22%

AVE SCORE 7 VS SEVERITY RATING

>=5 POOR SLEEP QUALITY

Scores at Time T0: DASS21 Mild to Moderate

Our Tinnitus recruits display, on average DASS baseline scores:

- **DASS Mild Depression (Score = 6),**
- **DASS Moderate Anxiety (Score = 6) and**
- **DASS Mild Stress (Score = 9).**

DASS Depression	100%= patients at time T0
NORMAL	42%
MILD	16%
MODERATE	24%
SEVERE	8%
EXTREMELY SEVERE	11%

AVE SCORE 6 VS SEVERITY RATING

0 - 4 NORMAL
5 - 6 MILD
7 - 10 MODERATE
11 - 13 SEVERE
14 + EXTREMELY SEVERE

DASS Anxiety	100%= patients at time T0
NORMAL	34%
MILD	32%
MODERATE	11%
SEVERE	8%
EXTREMELY SEVERE	16%

AVE SCORE 6 VS SEVERITY RATING

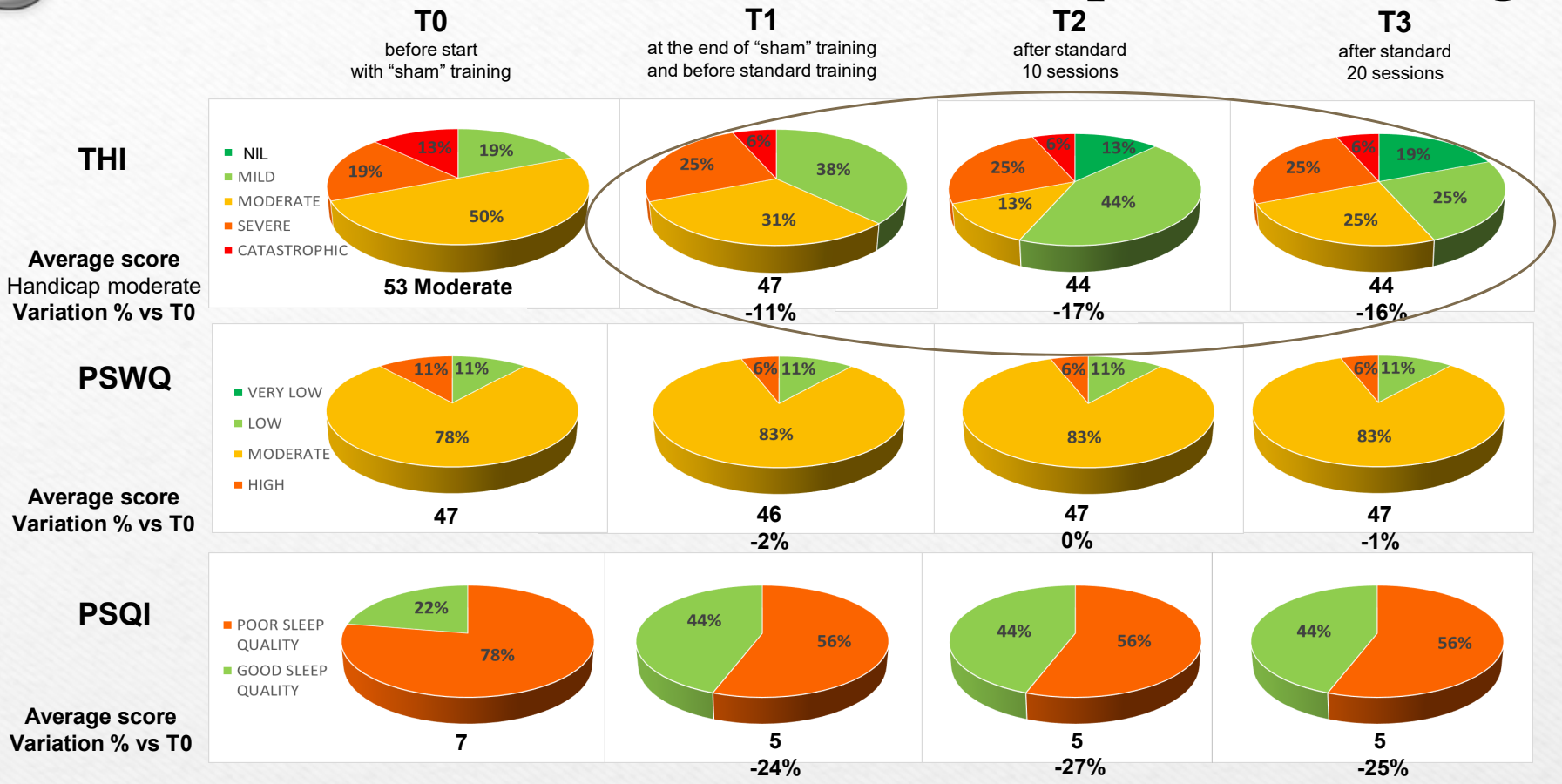
0 - 3 NORMAL
4 - 5 MILD
6 - 7 MODERATE
8 - 9 SEVERE
10 + EXTREMELY SEVERE

DASS Stress	100%= patients at time T0
NORMAL	55%
MILD	8%
MODERATE	8%
SEVERE	18%
EXTREMELY SEVERE	11%

AVE SCORE 6 VS SEVERITY RATING

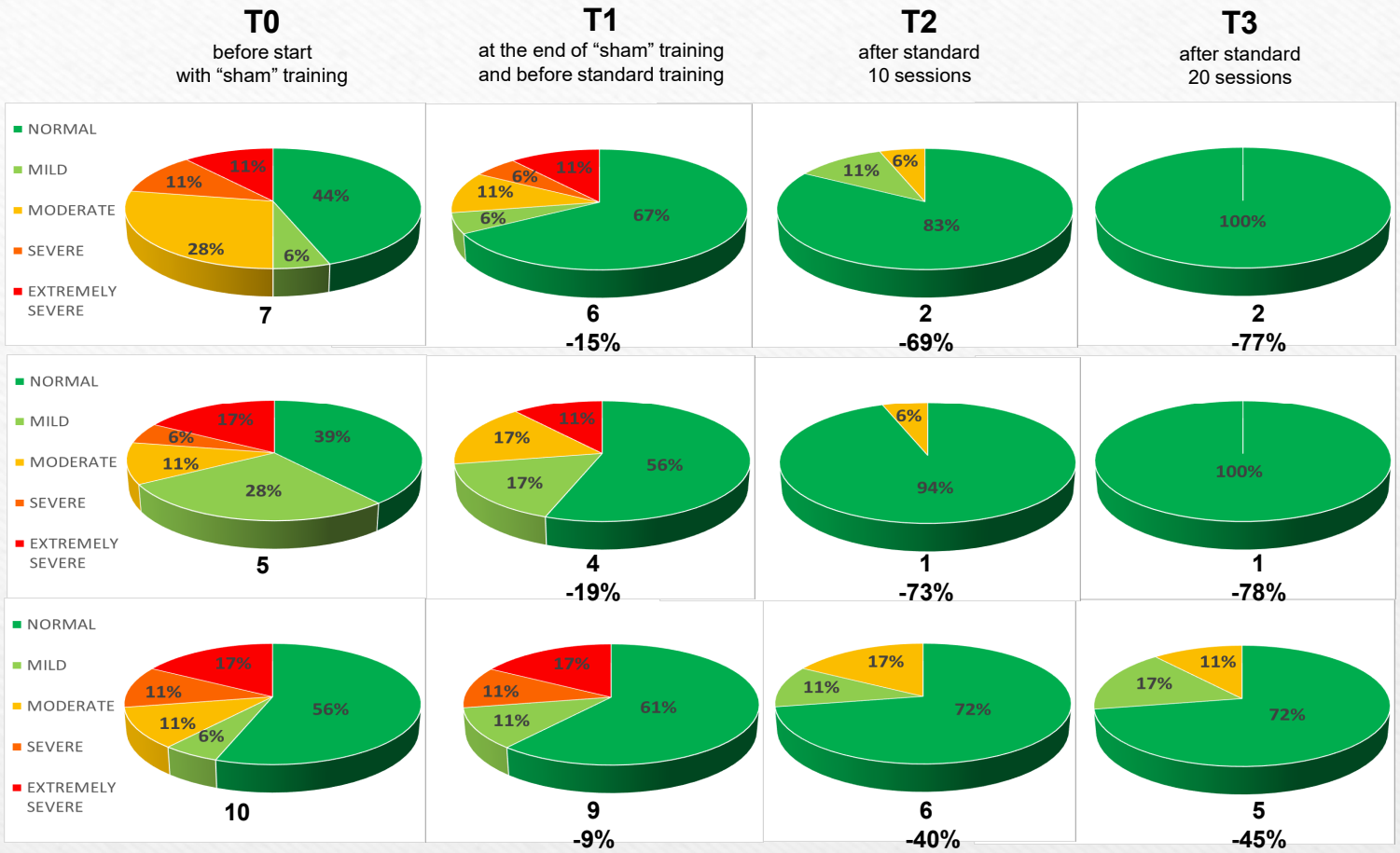
0 - 7 NORMAL
8 - 9 MILD
10 - 12 MODERATE
13 - 16 SEVERE
17 + EXTREMELY SEVERE

Tinnitus Patient Profile after NeurOptimal Training



Note: Patients that concluded sham + standard training and completed all questionnaires up to 15th April (18 cases).

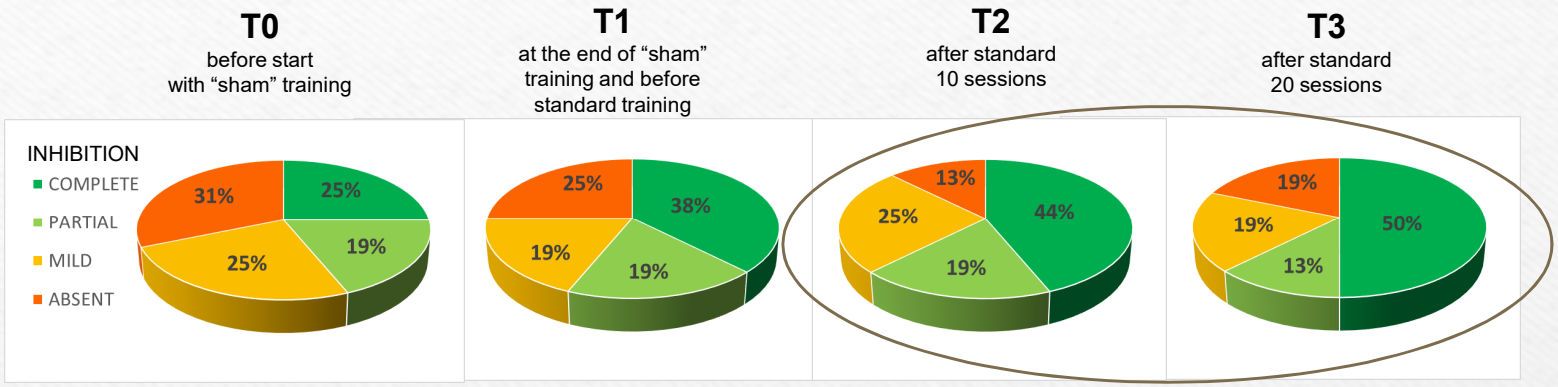
Tinnitus Patient Profile after NeurOptimal Training



Note: Patients that concluded sham + standard training and completed all questionnaires up to 15th April (18 cases).

Residual Inhibition Profile after NeurOptimal Training

Residual Inhibition: The Residual Inhibition test evaluates the "residue" of the tinnitus after administering a masking tone for one minute.



Acuphenometry (Average acufenometry: average of frequencies from 250hz to 8.000hz and average of right ear and left ear in case of bilateral tinnitus).

Variation % vs T0	**-12%**	**-15%**	**-21%**

Note: Patients that concluded sham + standard training and completed all questionnaires up to 15th April (18 cases).

Preliminary Results and Next Steps

- **Basing on these measurements of the partial sample, the impact of NeurOptimal training seems to be *very positive on emotional states, stress and sleep quality.***
- **For tinnitus handicap and pathological preoccupation, slight improvement has been seen in the mild-moderate groups.**
- **In addition, both Acufenometry and Residual Inhibition measurements have improved, permitting this relief modality to be used.**
- **Other positive effects that we have detected are: improvement in concentration and management of emotions, important reduction or disappearance of headache, sense of serenity and self-control.**

Preliminary Results and Next Steps

- **We agree to recruit a minimum of 60 patients, to be able to confirm and validate these results.**

- **With a larger sample, we'll analyze acuphenometry/ audiometric measurements and questionnaires score to evaluate if there are statistically significant differences between T0 and T1 and T2 and T3.**

- **It may also be checked (according to sample size) if there are significant differences in the effect of training between cluster/target identified by sex, by age, by tinnitus type, by audiometric type, by THI type, by PSWQ type, by PSQI type and by DASS type.**

Thank You
For Your Attention