**ICBT vs IAR US RCT: Metadata**

**Title**

Efficacy of Internet-based cognitive behavioral therapy and applied relaxation for tinnitus distress in the United States (ICBT vs IAR study): A Randomized Clinical Trial

**Description**

This data set was generated as a part of the clinical trial to examine the efficacy of the Internet-based cognitive behavioural therapy (ICBT) and applied relaxation (IAR) for tinnitus distress in the US population (Clinicaltrials.gov registration no NCT04335812). The study used a parallel randomized controlled trial (RCT) design (n=126).Both the ICBT and IAR treatments were undertaken as Internet-based interventions with minimal guidance from an audiologist. The ICBT group received the full CBT program over an 8 week period. The IAR group received 8 weeks of only applied relaxation before having access to the other CBT modules for a further 4 weeks.

The primary outcome was a change in tinnitus distress (Tinnitus Functional Index; TFI). Secondary outcome measures included measures of anxiety (Generalized Anxiety Disorder; GAD-7), depression (Patient Health Questionnaire; PHQ-9), insomnia (Insomnia Severity Index; ISI), quality of life (EQ-5D-5L), tinnitus and hearing-related difficulties (Tinnitus and Hearing Survey; THS), tinnitus cognitions (Tinnitus Cognitions Questionnaire; TCQ). The weekly measures included measures of tinnitus severity (Tinnitus Handicap Inventory-Screening; THI-S) and newly developed tinnitus qualities (Tinnitus Qualities Questionnaire; TQQ). The pre-intervention demographic questions and response options are provided in a separate attachment.

The primary and secondary outcome data were collected at 3-time points for the ICBT and 4-time points for the IAR groups as listed below. In addition, weekly measures were collected at 8-time points (8 weeks) during the intervention.

* T0: Pre-intervention baseline data for both groups.
* T1: Post-intervention for ICBT group; and Post-relaxation for IAR group.
* T2: Post-CBT for the IAR group; T1 data for ICBT group.
* T3: 2-months follow-up for both groups.

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Additional details about the data:

**WHO created the data:** Prof. Vinaya Manchaiah and Dr. Eldre Beukes at the Lamar University.

**WHAT the data files contain:** This data set contains pre- and post-intervention data of the ICBT US study.

**WHEN the data was generated:** February to August 2021.

**WHERE the data were generated:** This study was conducted over the Internet by recruiting participants from all over the United States. However, the database was installed at Lamar University server when the data was generated.

**WHY the data were generated:** This data was generated as a part of the clinical trial (ClinicalTrials.gov registration NCT04335812).

**HOW the data were generated:** This data was generated by means of administering the questionnaires online before, during and after the ICBT and IAR.