Adaptation and Validation of the Italian Singing Voice Handicap Index-10 (SVHI-10-IT) (Validation of I-SVHI)

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Study Finalised

Administrative details

EU PAS number

EUPAS41469

Study ID

41470

DARWIN EU® study

No

Study countries

☐ Italy

Study description

The purposes of this study were to adapt and validate the Italian version of the Singing Voice Handicap Index-10 (SVHI-10-IT) and to determine the cut-off value using videolaryngostroboscopy diagnoses as external criteria. This observational cross-sectional single-center study was conducted in the ENT and Phoniatric private Center of Pisa, Italy. Singers were included from different music genres (Contemporary Commercial Music and Classic) and from a range of experience levels (singing student, amateur or professional). A total of ninety-nine Italian singers who arrived consecutively in the private ENT and Phoniatric Center, were enrolled in the study. The singers showed up at the Center for a voice disorder or for screening. Overall, participants had a mean age of 29.8 yrs (sd 9.7, range 18-54 yrs). All subjects underwent Videolaryngostroboscopic examination and were asked to fill out the self-reported 10-item SVHI-10-IT. Laryngostroboscopic examination was pathological in 56 subjects (study group) (56/99, 56.6%), while it was normal in the remaining 43 singers (control group) (43/99, 43.4%). To confirm test-retest reliability of the SVHI-10-IT, patients were invited to complete the questionnaire for a second time, approximately 2 weeks after the first administration. Medical data was collected by review of medical care records. The researcher checked for absent responses after receiving the questionnaire and asked patients to answer to the missing items.

Study status

Finalised

Contact details

Study institution contact

Andrea Nacci andrea.nacci.an@gmail.com

Study contact

andrea.nacci.an@gmail.com

Primary lead investigator

Andrea Nacci

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2019

Actual: 04/02/2019

Study start date

Planned: 01/10/2019

Actual: 02/12/2019

Data analysis start date

Planned: 01/02/2020

Actual: 25/02/2020

Date of final study report

Planned: 01/05/2020

Actual: 01/06/2020

Sources of funding

- Other

More details on funding

Private centre

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

To adapt and validate the Italian version of the Singing Voice Handicap Index-10 (SVHI-10-IT) and to determine the cut-off value using videolaryngostroboscopy diagnoses as external criteria.

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The aim of the present study was to adapt and validate the Italian version of Singing Voice Handicap Index-10 (SVHI-10-IT).

Study Design

Non-interventional study design

Cross-sectional

Population studied

Short description of the study population

Singers were included from different music genres (Contemporary Commercial Music and Classic) and from a range of experience levels (singing student, amateur or professional).

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Estimated number of subjects

100

Study design details

Data analysis plan

We analyzed the Singing Voice Handicap Index-10 (SVHI-10-IT) statements collected in our study to adapt and validate the Italian version using four standard questionnaire validation steps: 1) Translation procedure of the SVHI-10-IT, 2) Test-Retest Reliability, 3) Internal validity, 4) External validity. Subsequently, 5) we used the Principal Component Analysis (PCA) to explore the SVHI-10-IT factorial structure and identify the latent variables indicated by our observed variables. Finally, we performed a confirmatory factor analysis (CFA) via 6) Structural Equation Modelling (SEM) to confirm the presence of one or more latent variable.

Data management

Data sources

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No