1 **TITLE PAGE**

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3 **Translation, Cross-Cultural Adaptation and Preliminary Validation of the Transsexual Voice**

4 **Questionnaire for Male-to-Female Transsexuals (I-TVQ^MtF) into Italian**

5 Carlo Robotti[1], Francesco Mozzanica[2,3], Chiara Atzori[4], Andrea Cavalot[5], Diego Cossu[5], Adi

6 Primov-Fever[6], Marco Benazzo[1], Luca Negri[7], Antonio Schindler[8]

7

8 1. Department of Otolaryngology - Head and Neck Surgery, University of Pavia, IRCCS Policlinico

9   San Matteo Foundation, Pavia, Italy

10 2. Department of Clinical Sciences and Community Health, University of Milan, Milan, Italy

11 3. Department of Otorhinolaryngology, San Giuseppe Hospital, IRCCS Multimedica, Milan, Italy

12 4. Department of Infectious Diseases, ASST Fatebenefratelli Sacco, Luigi Sacco University

13   Hospital, Milan, Italy

14 5. Otorhinolaryngology Division, Santa Croce Hospital, Moncalieri, Italy

15 6. Department of Otolaryngology and Head and Neck Surgery, Chaim Sheba Medical Center,

16   Ramat-Gan, Israel; Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel.

17 7. Department of Pathophysiology and Transplantation, University of Milan, Milan, Italy.

18 8. Department of Biochemical and Clinical science "L. Sacco", Luigi Sacco University Hospital,

19   University of Milan, Milan, Italy

20

21 **Author for correspondence**

22 Francesco Mozzanica, MD, PhD. Department of Biochemical and Clinical science "Luigi Sacco"

23 Via G.B. Grassi 74, Milan, 20157, Italy;

24 Phone: +39 340 4662852; Email: francesco.mozzanica@gmail.com

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1   **Abstract**

2   **Objective.** To perform a cross-cultural adaptation into Italian and to analyse reliability and validity

3   of the Transsexual Voice Questionnaire for male-to-female transsexuals (I-TVQ^{MtF}).

4   **Study Design.** Cross-sectional non-randomized survey study.

5   **Methods.** For item-generation, a cross-cultural adaptation and translation process was performed

6   following standard guidelines. Transgender women were consecutively recruited and asked to fill

7   out the I-TVQ^{MtF} and a form on social, demographic and transition-related variables. Firstly, data

8   collected from participants were used to perform confirmatory factor analysis (CFA), and to

9   evaluate internal consistency and test-retest reliability Subsequently, convergent validity was

10   evaluated comparing I-TVQ^{MtF} total scores with the two extra items addressing self-perception

11   (SPVF) and aspiration (AVF) of voice femininity. To further evaluate convergent validity, scores of

12   the Italian version of the Voice Handicap Index (I-VHI) were considered for comparisons. A

13   correlation analysis was performed to verify potential association between I-TVQ^{MtF} scores and

14   social, demographic and transition-related variables.

15   **Results.** CFA demonstrated that a two-factor model fits data better than the unidimensional one.

16   Both internal consistency and test retest reliability of the I-TVQ^{MtF} were satisfactory. Negative

17   correlations were highlighted between I-TVQ^{MtF} scores on one side and SPVF and AVF on the

18   other. Positive correlations between I-TVQ^{MtF} and I-VHI scores were also found. Finally, negative

19   correlations were demonstrated between I-TVQ^{MtF} scores and time spent living in the female role.

20   **Conclusion.** The I-TVQ^{MtF} appears to be a reliable and valid instrument for the assessment of

21   voice-related quality of life in transgender women.

22   **Keywords:** transgender; voice; quality of life; cross-cultural adaptation; dysphonia

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1. Introduction

Transgender (or trans) is an umbrella term used to describe people whose gender identities (or gender roles) differ from those typically associated with the sex they were assigned at birth. Gender identity is an individual's inner sense of being a man or a woman. For some individuals, their gender identity does not fit neatly into those two choices. For transgender individuals, the sex they were assigned at birth and their own internal gender identity do not match. [1-4]. This cross-gender identification is usually accompanied by a persistent sense of inappropriateness of the anatomic sex, which may determine subjective discomfort, feelings of inadequacy, and negative societal attitudes in terms of activity limitations and participation restrictions [5]. Therefore, in order to reach an acceptable grade of gender conformity, **transgender** individuals frequently seek medical and surgical treatments. In the search of adequacy between physical appearance and gender identity, voice can represent a critical obstacle, because it acts as a salient cue to the listener's perception of a speaker's gender [6-8]. **Interestingly, the magnitude of that obstacle is peculiarly different between transgender men and transgender women. As far as transgender men are concerned, voice changes are achieved effortlessly in most cases. In fact, hormone replacement therapy (HRT) with androgens (testosterone) induces hypertrophy of the thyroarytenoid muscles, thus increasing the mass of the vocal folds and lowering the fundamental frequency (F0) towards the male range [9-11]. Therefore, transgender men may reach the desired low-pitched voice with HRT alone, with little or no need for further improvements through voice therapy [12]. On the other hand, transgender women usually struggle to achieve a gender-congruent voice, as HRT with antiandrogens (estrogens) feminizes the body but has no effects on their voices [13]**. This is the reason why voice modification is requested **especially** by **trans women,** whose voice characteristics are often male-like and thus **strongly contrasting** with their identity and presentation as women [14, 15]. **Failing to reach a gender congruent voice might determine important negative effects on these subjects. For example, Dacakis and collaborators reported that psychosocial issues were the**

most frequently reported voice-related impacts in transgender women. Specifically, their results highlighted how the anxiety and the frustration caused by the misalignment between physical appearance and voice may raise feelings of inadequacy and self-consciousness towards strangers in transgender women [16]. Conversely, transgender subjects whose voices sound more congruent with the experienced gender, report greater well-being (greater life satisfaction, better QOL and better self-esteem, plus lower levels of anxiety and depression) than the ones with less gender congruent voices [17, 18]. In other words, trans individuals whose vocal gender better corresponds to their experienced gender enjoy a higher level of well-being along a wide-ranging array of measures, not limited to simple satisfaction with their own voices [18]. Because of its potential psychosocial effect, the management of voice change in **transgender** women requires a more comprehensive evaluation, including not only acoustic analysis and auditory-perceptual evaluation, but also the evaluation of the individual's voice-related difficulties and their impacts on everyday life. The importance of evaluating a **transgender** woman's perception of her voice is highlighted by the fact that voice feminization goes way beyond mere pitch elevation, since it has been demonstrated that a higher pitch does not necessarily result in listeners perceiving a voice as female [19]. As a matter of fact, F0 – which is the acoustic correlate of pitch – seems to account for just 10% of the variance in happiness with voice in **trans** women [20]. Likewise, clinicians' perceptions of voices of **trans women** do not consistently correlate with the clients' satisfaction regarding their own voice [21, 22]. Transgender individuals are highly heterogeneous in terms of both current voice perception and future voice expectations. Since each transgender individual experiences different challenges, self-evaluation should represent a crucial element from the very beginning of clinical evaluation. Moreover, objective and subjective voice assessments are not necessarily always correlated [23, 24]. Therefore, given the multitude of factors playing a role in determining voice-related QOL in transgender individuals, clinicians should understand the uniqueness of each trans patient's perspective, in order to tailor client-centered goals.

1 Only a few instruments specifically designed to investigate the self-perception of voice limitations

2 and the impact of voice on quality of life (QOL) in **transgender women** are available so far **[16,**

3 **25]**. The Transgender Self-Evaluation Questionnaire (TSEQ) was the first patient-reported outcome

4 (PRO) instrument developed for the assessment of voice-related QOL in **transgender** subjects. It

5 was based on the well-known Voice Handicap Index (VHI), which was partially modified to

6 capture relevant voice-related features in **trans** patients [25]. Subsequently, an extensive reviewing

7 and refining process of the TSEQ, conducted by Dacakis and colleagues, led to the Transsexual

8 Voice Questionnaire for Male-to-Female Transsexuals (TVQ^{MtF}) [16]. The TVQ^{MtF} is a self-report

9 measure of vocal functioning and voice-related impact on **transgender** women's QOL. It contains

10 30 items, each rated on a 4-point Likert scale (1 = "never or rarely"; 2 = "sometimes"; 3 = "often";

11 4 = "usually or always"), for a total score ranging from 30 to 120; a lower score represents a more

12 desirable outcome. **As far as the name of the original questionnaire is concerned (TVQ^{MtF}), the**

13 **terminology related to this populations significantly changed during the last few years, and**

14 **terms such as "transsexual" and "male-to-female" may now be considered as offensive by**

15 **members of the population. Therefore, the authors are willing to change the original title, and**

16 **a new name for this outcome instrument will be released in the upcoming months [3].**

17 **Therefore, the title of the original questionnaire will be used in the present paper solely for**

18 **the purpose of referring to the instrument itself.** Through principal component analysis, Dacakis

19 demonstrated the two-component structure of the TVQ^{MtF}, accounting for almost 58% of the

20 variance in the questionnaire: (a) "vocal functioning" (VF), fourteen items, dealing with voice

21 production and its relationship with gender identity; (b) "social participation" (SP), twelve items,

22 relating to the impact of an individual's voice on participation in everyday life. Four items were not

23 allocated to either domain for loading on both factors. The two-domain structure enhances the

24 ability of the questionnaire to provide significant information regarding the nature of the

25 impairment and to tailor strategies and goals of treatment [15]. Moreover, the TVQ^{MtF} comes with

26 two extra items – "Currently my voice is" and "My ideal voice would sound" – dealing with self-

1 perception (SPVF) and **aspiration (AVF)** of voice femininity, both rated on a 5-point Likert scale

2 (1 = "very female"; 2 = "somewhat female"; 3 = "gender neutral": 4 = "somewhat male"; 5 = "very

3 male") [20, 26]. Several studies have already assessed the reliability and the validity of the TVQ^{MtF}

4 [15, 16, 25]. Moreover, the TVQ^{MtF} has been already adapted and validated for different cultural

5 and linguistic contexts [8, 27-30]. To date, however, a validated Italian version of this instrument is

6 not yet available**. In addition, to the best of our knowledge, no studies have been conducted so

7 far to investigate voice-related QOL in Italian transgender women.** Therefore, this study has

8 been structured to evaluate the reliability and the validity of the Italian version of the TVQ^{MtF} (I-

9 TVQ^{MtF}). We surmise that the TVQ^{MtF} can be adapted to the Italian language and that both validity

10 and reliability of the I-TVQ^{MtF} are satisfactory. A validated Italian version of this instrument will

11 allow clinicians to thoroughly assess voice-related impairments and needs in **transgender** women.

12 Additionally, the Italian validated translation of this outcome instrument will be useful in designing

13 cross-cultural and international outcome studies addressing voice-related issues in **transgender**

14 women.

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2. Materials and Methods

This non-randomized cross-sectional survey study was carried out according to the principles stated in the Declaration of Helsinki, after being approved by the Institutional Review Board of our institution (**Luigi Sacco University Hospital, University of Milan, Milan, Italy**). Authors of the original English version of the TVQ^{MtF} were informed about our proposal in conducting the present study, aimed at producing the validated Italian version of this PRO instrument. The study was structured as six different phases: I-TVQ^{MtF} item generation (phase 1); participants recruitment (phase 2); **I-TVQ^{MtF} confirmatory factor analysis (phase 3)**; I-TVQ^{MtF} reliability analysis (phase 4); I-TVQ^{MtF} validity analysis (phase 5); I-TVQ^{MtF} correlation analysis (phase 6). In order to guarantee appropriate conclusions about the psychometric properties of the I-TVQ^{MtF}, the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) checklist [31] was followed.

2.1 Phase 1: I-TVQ^{MtF} item generation

A cross-cultural adaptation process was performed following standard techniques [32, 33] and also in accordance with the World Health Organization (WHO) recommendations for the process of translation and adaptation of instruments [34]. Items of the original TVQ^{MtF} questionnaire were first translated into Italian by two independent bilingual speech and language pathologists (SLPs) familiar with **transgender** patients care and with experience in translation; moreover, both SLPs were instructed to produce a conceptual translation rather than a literal one (*stage 1: forward translation*). Subsequently, a bilingual expert panel (two independent phoniatricians familiar with the process of instrument validation and the SLPs involved in the first stage) examined idiomatic, semantic and conceptual issues of the two translations, in order to further refine them. An Italian final-consensus version was therefore obtained (*stage 2: synthesis*) and given to two independent professional translators, who had no knowledge of the questionnaire, to have it translated back into English (*stage 3: back translation*). Once this task was completed, the two translators and an expert

1   committee reviewed all reports in order to assess conceptual and cultural equivalence and to

2   produce a pre-final version of the instrument (*stage 4: expert committee review*). Finally, twenty-

3   five **transgender women** (mean age 45.4 years, SD ± 9.81 years, age range 19-63 years, **who had**

4   **been at least 1 year in transition**) were enrolled in a pilot study (*stage 5: pretesting*). **Specifically,**

5   **participants of the pretesting stage were consecutively recruited at Otolaryngology and**

6   **Infectious Diseases outpatient clinics of our institution**. Each **trans woman** autonomously filled

7   out the pre-final version of the Italian TVQ^{MtF} and then discussed meaning, relevance and clarity of

8   each item together with the two phoniatricians and the two SLPs. Afterwards, in order to improve

9   the readability of the questionnaire, the wording of each item of the pre-final version of the Italian

10   TVQ^{MtF} was refined according to the suggestions given by the participants of the pretesting stage.

11   This revision process led to the final version of the Italian TVQ^{MtF} (I-TVQ^{MtF}; see Appendix).

12

13   *2.2 Phase 2: Participants recruitment*

14   For the present study, 153 **transgender women** (mean age 39.59 years; standard deviation [SD] ±

15   10.50 years; age range 18-64 years) were consecutively recruited between October 2018 and July

16   2019. **All participants came from regions in the north of Italy. Moreover, none of these**

17   **subjects participated in the pre-testing phase.** Inclusion criteria were as follows: age of 18 years

18   or older; male sex at birth; living in the female role sometimes, often or always; good understanding

19   of Italian; preserved reading skills. Exclusion criteria included: female sex at birth; history of

20   pathologies of the larynx in the previous 6 months; history of head and neck malignancies.

21   Recruitment strategies included: (a) direct recruitment of **transgender women** referred to our

22   institution (71 subjects, 46.41%); (b) advertisement of the study in Facebook groups of Italian

23   lesbian, gay, bisexual and transgender (LGBT) associations, publishing the link to the web version

24   of the study form (82 subjects, 53.59%). **Moreover, transgender women** who heard about the

25   ongoing project from other participants were also allowed to volunteer for this research. All

26   participants were informed about the objectives of the study and gave their consent in written form

1   or online, depending on the recruitment modality. First, all subjects were asked to fill in the I-

2   TVQ^{MtF}. Moreover, social and demographic data were collected for each participant through a

3   dedicated series of questions assessing the following variables: age, education, occupation,

4   relationship status, children. Additionally, the following data regarding the transition process were

5   collected: psychological counselling, frequency and total duration of life in the female role,

6   hormonal therapy, gender-affirming surgery (GAS), voice feminization procedures (speech therapy,

7   surgery). The relevance of the abovementioned questions was discussed together with a team of

8   national and international clinicians with at least a decade of experience in **transgender** patients

9   care.

10

11   *2.3 Phase 3: I-TVQ^{MtF} Confirmatory Factor Analysis (CFA)*

12   **To be consistent with the results from Dacakis and colleagues' principal component analysis**

13   **[35], item 22, 26, 27, and 28 were excluded. Two competitive models were evaluated: (1) a**

14   **unidimensional model with the 26 retained items loading on a single global factor; (2) a two-**

15   **factor (VF and SP) model [35]. The following indices were employed to evaluate each model's**

16   **goodness of fit: Satorra–Bentler scaled chi-squared statistic (SBχ^2), root mean square error of**

17   **approximation (RMSEA), comparative fit index (CFI), and standardized root mean square**

18   **residual (SRMR). Model acceptability was evaluated through the following cutoff criteria:**

19   **RMSEA < 0.08, CFI > 0.95 and SRMR < 0.08 [36]. In order to choose between competing**

20   **models, Akaike's information criterion was employed, with lower values indicating the model**

21   **to be preferred; a scaled difference chi-square test [37] further compared nested models' fit.**

22

23   *2.4 Phase 4: I-TVQ^{MtF} reproducibility analysis*

24   This phase of the study was aimed at evaluating both internal consistency and test-retest reliability

25   of the I-TVQ^{MtF}. **For this purpose, the I-TVQ^{MtF} scores obtained from the enrolled 153**

26   **transgender women were analysed.** Internal consistency assesses the extent to which each item in

1   a factor measures the same underlying construct. It was assessed using Cronbach's alpha (α)

2   coefficient, which measures how much the items of a questionnaire are interrelated as a group.

3   Values of this coefficient may range between 0.0 and 1.0: the higher the value, the stronger the

4   internal consistency of the instrument is. Therefore, Cronbach's alpha estimates between 0.7 and

5   0.9 were taken to indicate acceptable internal consistency [38]. **Out of the 71 transgender women**

6   **directly recruited at our institution, 50 participants (mean age 57.3 years; SD ± 11.47; age**

7   **range 34–77 years) were randomly selected for test–retest reliability analysis. Specifically, this**

8   **analysis was limited to participants physically enrolled at our institution in order to ensure**

9   **that those who were going to complete the questionnaire a second time didn't keep a copy of**

10   **their first completed questionnaire, to which they could later refer to**. All subjects filled out the

11   I-TVQ^{MtF} twice within a three-week interval. Variations of five days before or after the requested

12   interval between trials were considered tolerable, in compliance with the subjects' needs. This

13   three-week interval was selected since no significant changes were expected to take place within

14   this period. **All participants involved in this step of the study did not undergo any intervention**

15   **between the two assessments, nor access to previous responses was allowed when filling out**

16   **the I-TVQ^{MtF} for the second time. Moreover, during the retest evaluation, items of the I-**

17   **TVQ^{MtF} were presented in a different order, with the purpose of preventing participants from**

18   **recalling previous responses.** Test–retest reliability was assessed through two-way random

19   internal consistency coefficient (ICC), which gives a measure of the temporal stability of answers to

20   the items of an outcome instrument. Its value can range between 0.0 and 1.0: the higher the value,

21   the stronger the temporal stability of the answers is. Values between 0.4 and 0.75 indicate a good

22   correlation, while values above 0.75 indicate an excellent one [39].

23

24   *2.5 Phase 5: I-TVQ^{MtF} validity analysis*

25   The aim of this phase of the study was to assess the degree to which the I-TVQ^{MtF} measures the

26   construct it purports to measure [38]. In particular, we analysed convergent validity. Convergent

1 validity, which is a subtype of construct validity, measures the degree to which two measures of

2 constructs that should be theoretically related, are in fact related. Therefore, similarly to the study

3 conducted by Dacakis and colleagues [15], I-TVQ^{MtF} total scores were correlated with the results of

4 the two extra items assessing self-perception and **aspiration** of voice femininity (SPVF, **AVF**).

5 These correlations were assessed using Spearman's test. In order to further analyse convergent

6 validity, a subgroup of 40 **transgender women** (mean age 51.6 years; SD ± 12.09 years; age range

7 24-73 years) completed the I-TVQ^{MtF} and the Italian version of the Voice Handicap Index (I-VHI)

8 [40, 41] at the same time. **Specifically, 17 participants (42.5%) were selected from the**

9 **transgender women who were directly recruited at our institution, while 23 participants**

10 **(47.5%) were selected from the subjects who were recruited online.** The I-VHI consists of 30

11 items, each one scoring from 0 to 4 (0 = "no disability"; 1 = "mild disability"; 2 = "moderate

12 disability"; 3 = "severe disability"; 4 = "complete disability"), divided into three subscales: (a)

13 *functional*, relating the impact of dysphonia on common daily activities; (b) *emotional*, evaluating

14 the psychological impact of dysphonia; (c) *physical*, dealing with the self-perception of laryngeal

15 and vocal discomfort. **The VHI was the base to develop the TVQ^{MtF}, but it was properly**

16 **modified to capture relevant situations and experiences of trans-persons; previous authors**

17 **also used the VHI to analyse convergent validity [28, 42], showing strong correlation between**

18 **these two measures. Although the VHI and the TVQ^{MtF} do not have an overlaping theoretical**

19 **construct, the VHI was selected as no other voice-related QOL assessment tools specifically**

20 **developed and validated for transgender subjects are available to date**. The correlation between

21 I-TVQ^{MtF} and I-VHI scores was evaluated using Spearman's test.

22

23 *2.6 Phase 6: I-TVQ^{MtF} Correlation analysis*

24 In order to assess potential relationships between I-TVQ^{MtF} scores on one side and social,

25 demographic and transition-related variables on the other, a correlation analysis was conducted.

26 Point-biserial correlation was used for binary coded (yes/no) variables (partner, psychological

1 counselling). Spearman's test was used instead for all other variables (age, educational level, job,

2 children, time living as a woman, frequency of living as a woman, hormonal therapy, GAS, name

3 change, civil status change, speech therapy for voice feminization, voice feminization surgery).

4 Correlational strength was considered strong for values above 0.5, moderate for values ranging

5 between 0.3 and 0.5, and weak for values below 0.3 [43].

6

7 *2.7 Statistical analysis*

8 **CFA was conducted using Lisrel ver. 8 [44], while** other statistical tests were performed using the

9 SPSS ver. 24.0 statistical software (SPSS, Inc., Chicago, IL). Kolmogorov–Smirnov test was used

10 to test the normality of the distribution of I-TVQ^{MtF} scores among **transgender women**. Since this

11 test demonstrated that the distribution of the scores among the participants was not normal, non-

12 parametric tests were used when requested. For all statistical comparisons an $\alpha = 0.05$ and a power

13 of 0.80 were used [45].

14

15

3. Results

3.1 Phase 1: I-TVQ^{MtF} item generation

The cross-cultural adaptation process for the adaptation of the TVQ^{MtF} questionnaire into Italian was conducted, leading to the final version of the I-TVQ^{MtF} (see Appendix).

3.2 Phase 2: Participants recruitment

The time required to fill in the questionnaire and the additional form never exceeded 10 minutes in the group of participants directly recruited in our institution. For the group of participants recruited online, this parameter could not be verified. Moreover, given the peculiar recruitment strategies of this survey study (direct recruitment and online advertisement), the exact number of potential participants who received notification of the study was not available; therefore, the response rate could not be calculated. Social, demographic and transition-related data of the participants are reported in Table 1, Table 2 and Table 3. Eighty-six participants (87.58%, $n = 134$) indicated that they had been living full-time in the female role. Specifically, one hundred and fifteen subjects (75.16%) had been living as women for more than 5 years. Of all participants, one hundred and seventeen (76.47%) were taking hormones, thirty (19.61%) had undergone GAS, twelve (7.84%) had chosen speech-therapy for voice feminization and six (3.92%) had undergone voice feminization surgery. Mean scores for all the items of the questionnaire are reported in Table 4. The mean total score for the I-TVQ was 58.43 (SD ± 23.89; range 30-114). Regarding the two extra items dealing with voice femininity, SPVF had a mean score of 2.96 (SD ± 1.15), while a mean score of 1.63 (SD ± 0.82) was calculated for **AVF**.

3.3 Phase 3: I-TVQ^{MtF} Confirmatory Factor Analysis

Satorra-Bentler scaled chi square was employed to account for non-normal data distribution resulting from Mardia's multivariate omnibus test ($\chi^2 = 1300.13$; $p < 0.001$). The goodness of fit values of the unidimensional and the two-factor models are reported in Table 5. Both

models showed acceptable to good goodness-of-fit indices, RMSEA score associated with the unidimensional model was the sole index slightly below acceptance threshold. When models were compared, the two-factor model showed a lower AIC value (ΔAIC = 24.24); further, the scaled difference chi-square test was found to be significant (ΔSB$\chi^2_{(1)}$ = 89.89; p < 0.001). Both these results suggest that the two-factor model fits data better than the unidimensional one. The standardized loading estimates for the two-factor model are reported in Table 4. Loadings ranged from 0.39 (item 1) to 0.85 (item 6); VF and SP factors were very highly correlated (ρ = 0.96).

3.4 Phase 4: I-TVQ^{MtF} reproducibility analysis

The internal consistency of the I-TVQ^{MtF}, assessed using Cronbach's alpha, was satisfactory (α = 0.912). Also test-retest reliability analysis for the I-TVQ^{MtF} yielded satisfactory results (ICC = 0.849, 95% confidence interval, range 0.791-0.898).

3.5 Phase 5: I-TVQ^{MtF} validity analysis

As far as convergent validity of the I-TVQ^{MtF} is concerned, total scores recorded for all participants were compared with the scores of the two extra items assessing voice femininity (SPVF, **AVF**), This analysis, conducted using Spearman's test, revealed a strong negative correlation between the I-TVQ^{MtF} total score and SPVF (r = -0.612; p = 0.001), while a weak negative correlation was found between the I-TVQ^{MtF} total score and **AVF** (r = -0.311; p = 0.001). For convergent validity analysis, the correlations between I-TVQ^{MtF} and I-VHI total scores in a subgroup of 40 participants were analyzed using Spearman's test. The mean I-VHI total score was 34.19 (SD $\pm$ 30.30, range 0-107), while the mean I-TVQ^{MtF} score was 62.62 (SD $\pm$ 21.77, range 30-113). A strong positive correlation between I-TVQ^{MtF} and I-VHI total scores was observed (r = 0.862; p = 0.001).

3.6 Phase 6: I-TVQ^{MtF} correlation analysis

1   A correlation analysis was conducted to assess potential association between social, demographic

2   and transition-related variables on one side and I-TVQ^{MtF} total scores on the other. No relevant

3   correlations were found for the following variables: age, educational level, job, partner, children,

4   psychological counselling, hormonal therapy, GAS, name change, civil status change. Interestingly,

5   a weak but significant negative correlation between I-TVQ^{MtF} total score on one side and time spent

6   living in the female role on the other was found ($r = -0.266$, $p < 0.01$). A week negative correlation

7   was also highlighted between I-TVQ^{MtF} total score and frequency of living in the female role ($r = -$

8   0.189, $p < 0.05$). Finally, moderate positive correlations were revealed between I-TVQ^{MtF} total

9   score on one side and voice therapy ($r = 0.388$, $p < 0.01$) and vocal folds surgery ($r = 0.348$, $p <$

10   0.01) for voice feminization on the other.

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12

1   **4. Discussion**

2   The present study was designed to produce and validate the Italian version of the TVQ^{MtF}. In order

3   to guarantee the cross-cultural equivalence of the questionnaire and to allow comparisons of results

4   between populations divided by language, the five-step items generation method suggested by

5   Beaton and colleagues [34] and the WHO recommendations for the process of translation and

6   adaptation of instruments [34] were applied thoroughly. Both the experts and the bilingual

7   translators involved in the item generation phase judged the cross-cultural equivalence between the

8   English version of the TVQ^{MtF} and the Italian one as satisfactory, suggesting that the items of the

9   latter had retained the meaning of the original instrument. All study participants directly recruited at

10   our institution (n = 71, 46.40%) managed to fill out autonomously the questionnaire and the form

11   assessing social, demographic and transition-related variables in less than 10 minutes. Therefore,

12   even though data regarding the time required to complete the task was not available for participants

13   who were enrolled online, it might be speculated that the I-TVQ^{MtF} can be easily administered with

14   no major comprehension difficulties.

15   The mean I-TVQ^{MtF} total score recorded for the enrolled 153 **transgender women** was 58.43 (SD ±

16   23.89, range 30-114). In previous reports, the mean baseline total score ranged between 51.55 (SD

17   ± 18.90, range 30-97) [15] and 71.23 (SD ± 22.27, range 34-107) [16]. Interestingly, as shown in

18   Table 5, items of the "vocal function" (VF) domain recorded on average higher scores than the

19   items of the "social participation" (SP) domain. A similar trend was also highlighted for previous

20   validation studies, for which mean items scores were published and thus available for comparison

21   (Table 6). This trend suggests that voice impairments in **transgender women** may affect QOL

22   mostly by reason of the intimate connections between vocal functioning and gender identity, rather

23   than the potential impact of those impairments on participation in everyday life. **As far as voice**

24   **feminization treatments are concerned, very few participants underwent voice therapy (n =**

25   **12; 7.84%) and voice surgery (n = 6; 3.92%). Therefore, as this subpopulation is too small, no**

26   **assumptions can be made regarding treatment satisfaction. Future studies should investigate**

1 **patient satisfaction with voice feminization therapies, in order to identify the most effective**

2 **strategies and to better select the right option for each transgender patient, in a perspective of**

3 **"patient-tailored" gender-affirming voice therapy (either towards feminization or**

4 **masculinization).**

5 The psychometric properties of the I-TVQ^{MtF} were analyzed following the COSMIN checklist. The

6 results revealed good internal consistency, test-retest reliability and validity, supporting the

7 adoption of the I-TVQ^{MtF} for the self-assessment of voice-related QOL in **transgender women**,

8 both in clinical practice and in outcome research. **In terms of CFA, both the unidimensional and**

9 **two-factor models were found to adequately fit the data. Results from model comparison,**

10 **however, showed that the two-factor model – the one including more freely estimated**

11 **parameters – fits data better than the unidimensional model. All items were found to load on**

12 **the expected factor [35] with standardized loadings well above the 0.40 threshold, apart for**

13 **item number 1 ("People have difficulty hearing me in a noisy room"). The correlation**

14 **between factors was found to be positive and very high; hence, future studies should further**

15 **focus on the level of association between VF and SP to determine the clinical benefit in**

16 **considering these two constructs as unique or as separated components.**

17 The internal consistency of the I-TVQ^{MtF} appeared to be excellent, with an overall Cronbach's α

18 coefficient value of 0.912 in 153 **transgender women**. This result is similar to the ones obtained by

19 the English ($\alpha = 0.964$) [16], Portuguese ($\alpha = 0.911$) [8], Spanish ($\alpha = 0.976$) [29], French ($\alpha =$

20 0.97) [30] and German ($\alpha = 0.97$) [28] versions of the instrument. As far as the reliability of the I-

21 TVQ^{MtF} is concerned, the results of test-retest analysis, with an ICC of 0.849, support the high

22 stability and reproducibility over time of the Italian version of this PRO instrument. Similar results

23 were highlighted for the English (ICC = 0.979) [16], Spanish (ICC = 0.885) [29] and Portuguese

24 (ICC = 0.957) [8] validated versions. Convergent validity analysis, as done in a previous study by

25 Dacakis and colleagues [15], was conducted comparing I-TVQ^{MtF} total scores with the scores of the

26 two extra items assessing self-perception and **aspiration** of voice femininity (SPVF, **AVF**).

1   Significant negative correlations were highlighted, in accordance with the findings by the

2   abovementioned research, demonstrating that a lower self-rating of voice femininity was associated

3   with a more negative impact of voice impairments on **transgender women's** QOL. Pasricha [5]

4   explained how **transgender women** may be assisted in being perceived as women in diverse

5   contexts by feeling proud of and comfortable with who they are. Consequently, a more solid self-

6   perception of voice femininity should induce a more confident approach to communication tasks,

7   with a higher chance to be perceived as women and, therefore, reducing the impact of voice

8   impairments on QOL [16]. **Basing on these evidences, it can be surmised that psychological**

9   **counseling might be helpful for transgender women in reducing the negative impact of vocal**

10   **impairments on QOL. Centering counseling on what the patient perceives as voice femininity**

11   **and improving patient's self-awareness – both internally (how the patient sees her own values,**

12   **passions, aspirations, fit with her environment) and externally (how the patient understands**

13   **how other people view her in terms of the same factors) – might strengthen the results of voice**

14   **feminization therapies.** However, further studies are necessary to assess the potential beneficial

15   effect of psychotherapy on voice-related QOL during and after the transition process. **Convergent**

16   **validity was assessed comparing I-TVQ^{MtF} and I-VHI total scores in a subgroup of 40**

17   **participants. A significant strong correlation was highlighted ($r = 0.862$), in accordance with**

18   **the findings by the research group led by Salm ($r = 0.88$) [28], which tested this correlation in**

19   **a group of 108 German transgender women. However, it must be stressed that the VHI has**

20   **been previously described as inappropriate for the evaluation of vocal impairments in**

21   **transgender women [46], not having being specifically designed to address the very specific**

22   **vocal needs of transgender subjects. Moreover, Hancock [42], Salm [28] and the present study**

23   **revealed that the generic VHI might over-rate or under-rate voice-related QOL of**

24   **transgender women. Therefore, except for the purposes of cross-cultural validation studies,**

25   **the recommendation of not including the VHI in voice-related QOL assessment protocols for**

26   **transgender women can be further emphasized.**

1 Findings of the correlation analysis, conducted to verify potential associations between the I-

2 TVQ^{MtF} total score and all the screened variables (social, demographic and transition-related), are

3 noteworthy. In particular, weak but significant negative correlations were demonstrated for the

4 variables "time living in the female role" (r = -0.266) and "frequency of living in the female role" (r

5 = -0.189). A significant correlation between the total TVQ^{MtF} score and time spent in the female

6 role was also demonstrated by a previous report [28], suggesting that the lower (and the less

7 frequent) the time spent living in the female role, the higher is the subjective voice-related

8 impairment on overall QOL. Remarkably, moderate positive correlations were found for the

9 variables "speech therapy for voice feminization" (r = 0.388) and "voice feminization surgery" (r =

10 0.348). It might be hypothesized that, since these treatment options are not mandatory, only

11 **transgender** women experiencing significant vocal impairments are prone to resort to speech

12 therapy and surgery for voice feminization.

13 **In conclusion, the I-TVQ^{MtF} appears to be a reliable and valid instrument for the assessment**

14 **of voice-related QOL in transgender women. Research aimed at assessing and improving**

15 **QOL in transgender subject is a compelling need and it should be implemented. In fact, a**

16 **recent systematic review and meta-analysis demonstrated that transgender people generally**

17 **display poor QOL, regardless of the domain investigated [47]. Moreover, transgender people**

18 **appear to report poorer mental health compared to the general population [47]. Specifically, a**

19 **study conducted on a sample of the US transgender population revealed how respondents had**

20 **a high prevalence of clinical depression (44.1%), anxiety (33.2%), and somatization (27.5%);**

21 **moreover, social stigma was positively associated with psychological distress [48]. Therefore,**

22 **the introduction of the I-TVQ^{MtF} as an additional instrument to assess and possibly improve**

23 **QOL in transgender women is highly recommended in everyday clinical practice as well as in**

24 **research settings.**

25 The present study has several limitations. First of all, the number of enrolled subjects is quite small

26 even if in line with previous reports. Thus, the results reported in this paper should be considered as

preliminary. Second, a selection bias might be postulated since only 46.4% of individuals were directly recruited at our institution, while the remaining participants were recruited through advertisements in Facebook groups of LGBT associations. For the latter individuals, study participation was possible only if they had access to the Internet and were connected with peers via social media and networks. These aspects may have had an impact on the representativeness of the sample. In addition, it is also possible that the majority of the **transgender women** recruited online who decided to participate in the study were those more concerned about their voice [28]. Third, a responsiveness analysis was not performed and, consequently, no information regarding the sensitivity to changes (for example after voice therapy or surgery) of the I-TVQ^{MtF} is available. Further studies analyzing this aspect are therefore needed. **Fourth, reliability analysis was performed using the results obtained from individuals directly recruited at our institution and no information regarding the reliability of the online-administered questionnaire is available.**

5. Conclusions

The findings of this preliminary validation study support the reliability and the validity of the I-TVQ^{MtF} for the assessment of voice-related QOL in Italian **transgender women**. The application of this patient-reported outcome instrument in everyday clinical practice and in outcome research is therefore recommended, as it could represent a more rigorous assessment strategy of voice-related needs and impairments in MtF patients. Finally, given the cross-cultural equivalence of the I-TVQ^{MtF}, cross-country and multi-center studies are advisable in order to test the responsiveness of this voice-related PRO instrument.

1 **6. Acknowledgments**

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3

1   **Table 1.** General demographic characteristics of the enrolled transgender women.

Parameter	Value (*N* = 153)	
Age ± SD (years)	39.59 ± 10.14	
Age range (years)	18 – 64	
Education (*n*, %)	No school	5 (3.27%)
	Elementary school	13 (8.50%)
	Middle school	23 (15.03%)
	High school	72 (47.06%)
	University	33 (21.57%)
	Master/PhD	7 (4.58%)
Job (*n*, %)	No job	50 (32.68%)
	Part-time job	49 (32.03%)
	Full-time job	54 (35.29%)
Partner (*n*, %)	Yes	63 (41.18%)
	No	90 (58.82%)
Children (*n*, %)	No	136 (88.89%)
	Yes, but we're not in touch	0 (0.0%)
	Yes, and we're in touch	17 (11.11%)
Psychological counselling (*n*, %)	Yes	23 (15.03%)
	No	130 (84.97%)

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2 **Table 2.** Transition-related characteristics of the enrolled transgender women.

Parameter	Value (N = 153)	
Time living in the female role (*n*, %)	Less than 1 year	12 (7.84%)
	Between 1 and 5 years	26 (16.99%)
	More than 5 years	115 (75.16%)
Frequency of living in the female role (*n*, %)	Rarely	0 (0.0%)
	Sometimes	0 (0.00%)
	Often	19 (12.42%)
	Always	134 (87.58%)
Hormonal therapy (*n*, %)	No	36 (23.53%)
	Yes, less than 1 year	10 (6.54%)
	Yes, between 1 and 5 years	22 (14.38%)
	Yes, more than 5 years	85 (55.56%)
GAS[1] (*n*, %)	No, not planned	65 (42.48%)
	No, but considering it	44 (28.76%)
	No, but planned	14 (9.15%)
	Yes	30 (19.61%)
Name change (*n*, %)	No	68 (44.44%)
	Yes, but not legally	40 (26.14%)
	Yes, legally	45 (29.41%)
Civil status change (*n*, %)	No	105 (68.63%)
	Yes, but not legally	9 (5.88%)
	Yes, legally	39 (25.49%)

3 [1]GAS = Gender-affirming surgery
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2 **Table 3.** History of voice feminization treatments (speech and language therapy, surgery).

Parameter	Value (N = 153)	
Speech and language therapy for voice feminization (*n*, %) (*N* = 153)	No, not planned	70 (45.75%)
	No, but considering it	54 (35.29%)
	No, but planned	17 (11.11%)
	Yes	12 (7.84%)
Speech and language therapy for voice feminization: satisfaction (*n*, %) (*N* = 12)	Not satisfied	2 (16.67%)
	Little satisfied	7 (58.33%)
	Very satisfied	1 (8.33%)
	Extremely satisfied	2 (16.67%)
Voice feminization surgery (*n*, %) (*N* = 153)	No, not planned	87 (58.86%)
	No, but considering it	53 (34.64%)
	No, but planned	7 (4.58%)
	Yes	6 (3.92%)
Voice feminization surgery: satisfaction (*n*, %) (*N* = 6)	Not satisfied	0 (0.0%)
	Little satisfied	3 (50.0%)
	Very satisfied	0 (0.0%)
	Extremely satisfied	3 (50.0%)

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2 **Table 4.** I-TVQ^{MtF} and voice femininity mean values and standard deviations and Confirmatory

3 Factor Analysis standardized factor loadings (two-factor model). I-TVQ^{MtF} items are listed in

4 descending order of mean score.

N°	VF[1]	SP[2]	Item	Mean	SD
			I-TVQ^{MtF}		
3	*0.78*		My voice makes me feel less feminine than I would like	2.32	1.06
20	*0.78*		My voice doesn't match my physical appearance	2.32	1.18
24	*0.82*		I feel my voice does not reflect the "true me"	2.24	1.25
18	*0.74*		When I am not paying attention, my pitch goes down	2.22	1.11
28			It distresses me when I'm perceived as a man because of my voice	2.20	1.23
15	*0.65*		I have to concentrate to make my voice sound the way I want it to sound	2.14	1.13
26			I feel self-conscious about how strangers perceive my voice	2.12	1.09
4	*0.78*		The pitch of my speaking voice is too low	2.10	1.09
5	*0.57*		The pitch of my voice is unreliable	2.10	0.94
6		*085*	My voice gets in the way of me living as a woman	2.06	1.13
2		*0.73*	I feel anxious when I know I have to use my voice	2.01	1.02
19	*0.76*		When I laugh I sound like a man	2.01	1.10
16	*0.81*		I feel frustrated with trying to change my voice	1.99	1.10
11	*0.72*		When I speak the pitch of my voice does not vary enough	1.94	0.89
22			My voice gets tired quickly	1.94	1.09
29	*0.66*		The pitch range of my speaking voice is restricted	1.92	1.01
8		*0.79*	I'm tense when talking to others because of my voice	1.91	0.99
10	*0.82*		My voice makes it hard for me to be identified as a woman	1.90	1.02
25		*0.82*	I am less outgoing because of my voice	1.87	1.06
9	*0.72*		My voice gets croaky, hoarse or husky when I try to speak in a female voice	1.83	1.05
13		*0.80*	I avoid speaking in public because of my voice	1.83	1.08
21	*0.74*		I use a great deal of effort to produce my voice	1.83	0.98
12		*0.81*	I feel uncomfortable talking to friends neighbors and relatives because of my voice	1.80	1.04
17		*0.79*	My voice difficulties restrict my social life	1.77	1.04
30		*0.82*	I feel discriminated against because of my voice	1.74	1.05
7		*0.70*	I avoid using the phone because of my voice	1.71	0.97
23		*0.77*	My voice restricts the sort of work I do	1.69	1.08
1		*0.39*	People have difficulty hearing me in a noisy room	1.67	0.83
14		*0.77*	My voice sounds artificial	1.65	0.91
27			My voice "gives out" in the middle of speaking	1.58	0.89
I-TVQ^{MtF} VF score				**28.87**	**11.55**
I-TVQ^{MtF} SP score				**21.71**	**9.69**
I-TVQ^{MtF} Total Score				**58.43**	**23.89**
Voice Femininity					
			Item	**Mean**	**SD**
SPVF[3] Currently, my voice is				2.96	1.15
AVF[4] My ideal voice would sound				1.63	0.82

5 [1]VF = Vocal Functioning domain; [2]SP = Social participation domain; [3]SPVF = Self-perception of voice femininity; [4]AVF = Aspiration of voice
6 femininity
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Table 5. Confirmatory Factor Analysis goodness of fit indices ($N = 153$).

Model	SBχ2	*df*	RMSEA	CFI	SRMR	AIC
Unidimensional	599.98*	299	.081	.98	.058	703.98
Two Factors	573.74*	298	.078	.98	.057	679.74

Note. SBχ2 = Satorra-Bentler Scaled Chi-Square; df = Degree of Freedom; RMSEA = Root Mean Square Error of

Approximation; CFI = Comparative Fit Index; SRMR = Standard Root Mean Square Residual; AIC = Akaike's

Information Criterion. * p<.001.

1
2 **Table 6.** Comparison of mean items scores and standard deviations between different validated
3 versions of the TVQ^MtF (Italian, French, English). TVQ^MtF items are listed in descending order of
4 mean score.

Italian TVQ^MtF (Robotti et al, 2020)					French TVQ^MtF (Morsomme et al, 2019)					English (original) TVQ^MtF (Dacakis et al, 2013)				
N°	VF[1]	SP[2]	Mean	SD	N°	VF[1]	SP[2]	Mean	SD	N°	VF[1]	SP[2]	Mean	SD
3	■		2.32	1.06	15	■		2.89	1.14	28			3.09	1.20
20	■		2.32	1.18	4	■		2.72	0.88	15	■		3.09	1.17
24	■		2.24	1.25	18	■		2.67	1.01	4	■		2.98	1.03
18	■		2.22	1.11	28			2.67	1.22	26			2.89	1.11
28			2.20	1.23	20	■		2.53	1.13	24	■		2.87	1.25
15	■		2.14	1.13	3	■		2.50	1.13	3	■		2.83	1.07
26			2.12	1.09	11	■		2.44	0.97	16	■		2.64	1.10
4	■		2.10	1.09	24	■		2.42	1.11	20	■		2.71	1.18
5	■		2.10	0.94	19	■		2.31	1.12	18	■		2.86	1.00
6		■	2.06	1.13	1		■	2.28	0.88	29	■		2.80	1.02
2		■	2.01	1.02	29	■		2.28	0.88	21	■		2.54	1.12
19	■		2.01	1.10	5	■		2.25	0.77	10	■		2.51	1.10
16	■		1.99	1.10	21	■		2.22	1.10	11	■		2.49	0.95
11	■		1.94	0.89	2		■	2.19	1.14	19	■		2.49	1.17
22			1.94	1.09	10	■		2.19	0.98	5	■		2.46	0.92
29	■		1.92	1.01	26			2.19	1.12	1		■	2.29	0.96
8		■	1.91	0.99	7		■	2.17	1.13	22			2.29	1.07
10	■		1.90	1.02	22			2.17	1.03	2		■	2.17	0.99
25		■	1.87	1.06	16	■		2.14	1.15	13		■	2.09	1.07
9	■		1.83	1.05	27			2.06	0.86	14		■	2.09	0.98
13		■	1.83	1.08	8		■	2.03	0.94	8		■	1.91	0.92
21	■		1.83	0.98	13		■	2.03	1.16	27			1.85	0.81
12		■	1.80	1.04	9	■		2.00	0.86	25		■	2.26	1.22
17		■	1.77	1.04	6		■	1.89	1.09	6		■	2.09	1.31
30		■	1.74	1.05	23		■	1.89	1.19	17		■	2.00	1.11
7		■	1.71	0.97	17		■	1.86	1.10	30		■	1.97	1.18
23		■	1.69	1.08	25		■	1.81	1.09	9	■		1.94	1.00
1		■	1.67	0.83	30		■	1.72	1.03	23		■	1.79	0.96
14		■	1.65	0.91	12		■	1.47	0.81	12		■	1.63	0.88
27			1.58	0.89	14		■	1.47	0.77	7		■	1.63	0.77

5 [1] VF = Vocal Functioning domain; [2] SP = Social participation domain
6

1 Appendix

2

3 **Italian Transsexual Voice Questionnaire for male-to-female Transsexuals (I-TVQ^{MtF})**

4

5 In base alla tua esperienza di vita nel ruolo femminile, rispondi alle seguenti domande segnando la

6 risposta che descrive al meglio la tua condizione attuale. Per favore, fornisci una risposta per ciascuna

7 delle domande riportate. Considera inoltre la seguente legenda:

8

9 1 – "mai" o "molto raramente"

10 2 – "a volte"

11 3 – "spesso"

12 4 – "frequentemente" o "sempre"

		1	2	3
		4		
1.	Le persone hanno difficoltà a sentire la mia voce in un ambiente rumoroso.	☐ ☐	☐	☐
2.	Provo ansia quando so di dover utilizzare la mia voce.	☐ ☐	☐	☐
3.	La mia voce mi fa sentire meno femminile di quanto vorrei.	☐ ☐	☐	☐
4.	Il tono della mia voce parlata è troppo grave.	☐ ☐	☐	☐
5.	Il tono della mia voce è imprevedibile.	☐ ☐	☐	☐
6.	La mia voce rappresenta un ostacolo per vivere come donna.	☐ ☐	☐	☐
7.	Evito di utilizzare il telefono a causa della mia voce.	☐ ☐	☐	☐
8.	Mi sento tesa nel parlare con altre persone a causa della mia voce.	☐ ☐	☐	☐
9.	La mia voce è gracchiante o rauca quando provo a parlare con una voce femminile.	☐ ☐	☐	☐
10.	La mia voce mi crea difficoltà nel farmi identificare come donna.	☐ ☐	☐	☐
11.	Quando parlo il tono della mia voce non varia abbastanza.	☐ ☐	☐	☐
12.	Mi sento a disagio quando parlo con amici, vicini e familiari a causa della mia voce.	☐ ☐	☐	☐
13.	Evito di parlare in pubblico a causa della mia voce.	☐ ☐	☐	☐
14.	La mia voce suona come se fosse artificiale.	☐ ☐	☐	☐
15.	Devo concentrarmi per far si che la mia voce suoni come vorrei.	☐ ☐	☐	☐
16.	Mi sento frustrata quando cerco di cambiare la mia voce.	☐ ☐	☐	☐
17.	Le difficoltà connesse alla mia voce limitano la mia vita sociale.	☐ ☐	☐	☐
18.	Quando non presto attenzione, il tono della mia voce diventa più grave.	☐ ☐	☐	☐
19.	Quando rido, la mia voce suona come quella di un uomo.	☐ ☐	☐	☐
20.	La mia voce non rispecchia il mio aspetto fisico.	☐ ☐	☐	☐

21.	Devo utilizzare un grande sforzo per produrre la mia voce.	☐ ☐ ☐ ☐
22.	La mia voce si affatica rapidamente.	☐ ☐ ☐ ☐
23.	La mia voce limita la tipologia di lavoro che posso svolgere.	☐ ☐ ☐ ☐
24.	Credo che la mia voce non rifletta il mio "vero io".	☐ ☐ ☐ ☐
25.	Sono meno estroversa a causa della mia voce.	☐ ☐ ☐ ☐
26.	Mi sento a disagio per come gli estranei percepiscono la mia voce.	☐ ☐ ☐ ☐
27.	La mia voce si esaurisce a metà della conversazione.	☐ ☐ ☐ ☐
28.	Provo angoscia quando vengo percepita come uomo a causa della mia voce.	☐ ☐ ☐ ☐
29.	L'estensione vocale della mia voce parlata è limitata.	☐ ☐ ☐ ☐
30.	Mi sento discriminata a causa della mia voce.	☐ ☐ ☐ ☐

Per favore, formula ora un giudizio globale sulla tua voce:

(SPVF) Attualmente la mia voce è: ☐ ☐ ☐ ☐ ☐

molto   in parte   neutra   in parte molto
femminile   femminile   maschile
maschile

(AVF) La mia voce ideale sarebbe: ☐ ☐ ☐ ☐ ☐

molto   in parte   neutra   in parte molto
femminile   femminile   maschile
maschile

Vitae

- **Carlo Robotti**. Born in Voghera (Italy) in 1987. Medical Degree in 2014. Specialization in Otorhinolaryngology in 2019. Research Fellow in Otorhinolaryngology at University of Pavia (Pavia, Italy) since 2020.

- **Francesco Mozzanica**. Born in Milan (Italy) in 1981. Medical Degree in 2007. Specialization in Otorhinolaryngology in 2014. PhD in Nutritional Sciences in 2018. Assistant Professor of Otorhinolaryngology at University of Milan (Milan, Italy) since 2019.

- **Chiara Atzori**. Born in Milan (Italy) in 1964. Medical Degree in 1989. Specialization in Infectious Diseases in 1993.

1 • **Andrea Cavalot**. Born in Turin (Italy) in 1960. Medical Degree in 1986. Specialization in
2 Otorhinolaryngology in 1990.

3 • **Diego Cossu**. Born in Genova (Italy) in 1961. Medical Degree and Specialization in
4 Audiology and Phoniatrics.

5 • **Adi Primov-Fever**. Born in Tel Aviv (Israel) in 1968. Medical Degree in 1995.
6 Specialization in Otorhinolaryngology in 2005. Laryngology Fellowship in 2006. Lecturer
7 of Otorhinolaryngology at Sackler Faculty of Medicine, Tel Aviv University (Tel Aviv,
8 Israel) since 2014.

9 • **Marco Benazzo**. Born in Pavia (Italy) in 1959. Medical Degree in 1984. Specialization in
10 Otorhinolaryngology in 1987. Specialization in Audiology in 1991. Associate Professor of
11 Otorhinolaryngology at University of Pavia (Pavia, Italy) from 2000 to 2010. Full Professor
12 of Otorhinolaryngology at University of Pavia (Pavia, Italy) since 2011.

13 • **Luca Negri**. Born in Chiaravalle (Italy) in 1979. Psychology degree in 2007. Ph.D in
14 Neuropsychobiology in 2013. Specialization in Cognitive Psychotherapy in 2013. Post-doc
15 Research Fellow at University of Milan. (Milan, Italy)

16 • **Antonio Schindler**. Born in Turin (Italy) in 1972. Medical degree in 1997. Specialization in
17 Audiology and Phoniatrics in 2001. Specialization Otorhinolaryngology in 2005. Associate
18 Professor of Audiology at University of Milan (Milan, Italy) since 2015.