

Facial Feminization Surgery and Quality of Life in Transgender Women: Protocol for a Cohort Study on Morphological and Psychosocial Outcomes

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Abstract

Background: Transgender women frequently encounter structural and social barriers to accessing gender-affirming surgical care, adversely affecting their mental health and overall well-being. Facial feminization surgery is a critical intervention that aligns facial features with female anatomical norms and gender identity. Although international studies suggest facial feminization surgery improves psychosocial outcomes, most have emphasized aesthetic results or relied on generic quality-of-life instruments not validated for this population. In Chile, no prior research has assessed the multidimensional impact of facial feminization surgery using patient-centered measures—such as self-perceived and third-party assessments of femininity—integrated with objective cephalometric and photometric analyses. Additionally, there is no validated Spanish-language quality-of-life instrument specifically tailored to transgender women undergoing this kind of surgery.

Objective: This study aims to (1) develop and validate a culturally appropriate quality-of-life questionnaire for transgender women undergoing facial feminization surgery in Chile, and (2) evaluate postoperative changes in quality of life, perception of facial femininity, and cephalometric and photometric parameters.

Methods: The study will include two methodological phases: a cross-sectional validation study and a longitudinal cohort study. In Phase 1, a novel questionnaire will be developed through literature review, expert consultation, and pilot testing. It will then be validated in a sample of 200 Spanish-speaking transgender women. In Phase 2, a cohort of 30 transgender women undergoing facial feminization surgery at a public hospital in Santiago will be followed for 12 months. Outcomes will include pre- and postoperative quality-of-life scores, third-party and self-perceived femininity ratings, and cephalometric changes measured through cone beam computed tomography and clinical photography. Data will be analyzed using exploratory and confirmatory factor analysis, t-tests or Wilcoxon signed-rank tests, and regression models.

Results: Data collection is currently ongoing. Validation of the questionnaire is expected to conclude in late 2025. Postoperative data collection will extend through 2026, with final analysis anticipated by early 2027.

We expect to demonstrate significant improvements in both quality of life and perception of femininity following facial feminization surgery. Cephalometric and photometric analyses are anticipated to reveal key anatomical changes associated with increased femininity perception. The study will also identify specific facial features most strongly correlated with positive psychosocial outcomes in the study population.

Conclusions: This study will provide evidence on the impact of facial feminization surgery on transgender women's quality of

life and perceived femininity in a Latin American context. It also introduces a validated, culturally adapted instrument for future clinical and research use. Findings are expected to inform gender-affirming healthcare policies and support equitable access to surgical care. Clinical Trial: Not applicable.

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Original Manuscript

Facial Feminization Surgery and Quality of Life in Transgender Women: Protocol for a Cohort Study on Morphological and Psychosocial Outcomes

Introduction:

Background

Some countries face persistent challenges related to health inequities, influenced by factors such as socioeconomic status and geographic distribution. These disparities affect access to healthcare services across multiple population groups, including transgender individuals.

Transgender women are defined as individuals who identify with the female gender, independently of any medical or surgical interventions they may have undergone [1]. Facial appearance is a key determinant in gender recognition and social perception [2]. Facial characteristics typically associated with masculinity have been linked to increased exposure to social stigma and discrimination, which may contribute to mental health disparities within this population [2–4]. In Chile, available data indicate that the prevalence of depression among transgender individuals is approximately ten times higher than in the general population, with suicidal ideation rates reaching 68%, compared to 2.2% in the general population [5,6].

Facial feminization surgery is a gender-affirming surgical intervention aimed at modifying facial structures to align with female anatomical norms [7–9]. Although this surgery has been associated with improved psychological and social outcomes, there is limited research evaluating its impact on quality of life using standardized, validated, and population-specific instruments. To date, no studies in Chile have systematically assessed the outcomes of Facial feminization surgery incorporating objective morphological measurements and validated patient-reported outcome measures.

Instruments commonly used to assess quality of life among transgender individuals were originally designed for the general population and later adapted for use in transgender contexts. However, these tools may not comprehensively capture the specific needs and expectations of transgender women undergoing Facial feminization surgery [2,3,7,9–12]. Furthermore, most available instruments have been translated from English without undergoing formal validation for use in

Spanish-speaking populations, potentially limiting their applicability in Latin American healthcare settings. Currently, no validated questionnaire exists in Spanish specifically addressing quality of life in transgender women undergoing facial feminization surgery in Chile.

The surgery involves modifications to both hard and soft tissues, which can be assessed using cone beam computed tomography and standardized clinical photography. The international literature identifies the frontal-naso-orbital complex (including the forehead, supraorbital crest, frontomalar prominence, temporal ridges, and frontonasal transition) and the mandibular region (chin, mandibular body, angle of the mandible, ascending ramus, and basilar ridge) as the primary anatomical determinants of facial gender [1,8,13]. Secondary regions of importance include the nose, zygomatic region, and thyroid cartilage. However, there is a lack of local data in Chile describing the frequency and extent of surgical modifications to these anatomical regions.

Cephalometric differences between male and female facial structures are influenced by biological sex, ethnic background, and genetic inheritance. Typically, male individuals present larger craniofacial dimensions, more acute nasolabial angles, and more obtuse mandibular angles, while female individuals exhibit more convex profiles, smaller nasal dimensions, and less prominent chins [8,13-15].

Objectives of the study

This study aims to develop and validate a culturally and linguistically appropriate quality-of-life questionnaire specifically tailored to the transgender population in Chile. It also seeks to evaluate the impact of facial feminization surgery through the analysis of changes in cephalometric and photometric parameters and their association with perceived femininity, as assessed both by third-party evaluators and by the participants themselves.

The study hypothesizes that transgender women undergoing facial feminization surgery will experience measurable improvements in quality of life, particularly when facial parameters more closely align with female anatomical standards. Additionally, variables such as social participation, employment status, self-perception, and psychosocial stress will be examined to provide a comprehensive understanding of the effects of facial feminization surgery. By integrating multidimensional assessments of psychological well-being, facial morphology, and gender perception, the study aims to generate evidence to inform clinical decision-making and support the development of inclusive, evidence-based healthcare policies for transgender individuals.

Methods

Study Design

This study consists of two complementary methodological components: Questionnaire Development and Validation and a Longitudinal Cohort Study.

Questionnaire Development and Validation: A cross-sectional validation study will be conducted to develop and psychometrically validate a novel quality-of-life instrument tailored for transgender women undergoing facial feminization surgery in a public Hospital in Santiago – Chile.

Longitudinal Cohort Study: A prospective longitudinal cohort analytical study will be conducted to evaluate the effects of facial feminization surgery across three primary domains: (1) quality of life, (2) perception and self-perception of facial femininity, and (3) cephalometric and photometric changes in hard and soft facial tissues.

Quality of life will be assessed using the validated questionnaire, administered preoperatively and at least 12 months postoperatively. Femininity perception will be evaluated through standardized facial photographs assessed by independent raters. Cephalometric and photometric changes will be measured using cone beam computed tomography (CBCT) and analyzed with Dolphin™ Imaging Version 12 software (Chatsworth, California, USA).

STUDY PHASES:

Phase 1: Questionnaire Development and Validation: The instrument, titled *Quality of Life and Perception of Femininity in Facial Feminization Surgery*, will be developed and validated for use in both pre- and postoperative contexts. The development and validation process will follow five sequential stages [16]

1. A systematic literature review using Boolean operators in PubMed and Embase to identify relevant quality-of-life domains.
2. Initial construction of the questionnaire, incorporating dimensions reflective of the lived experiences and health priorities of transgender women.
3. Content validation by an expert panel composed of sociologists, maxillofacial surgeons, public health professionals, and transgender individuals.
4. Pilot testing among transgender women enrolled in the gender program at San Juan de Dios Hospital.
5. Statistical validation and data collection through recruitment from the hospital's gender program, private healthcare services, civil society organizations, and social media platforms.

Participants:

Participants eligible for the questionnaire validation study must meet the following inclusion criteria: Self-identified transgender women aged 18 years or older, live in Chile by the time of questionnaire completion and Proficiency in Spanish (speaking, reading, and comprehension).

Recruitment and Questionnaire Distribution:

Participants for the validation phase will be recruited through multiple channels to ensure a diverse and representative sample of transgender women in Chile. Recruitment strategies will include:

Telephone outreach to individuals currently enrolled in the gender program at San Juan de Dios Hospital, invitations extended to patients receiving private care from professionals affiliated with the gender program, snowball referrals, whereby participants may suggest other eligible transgender women within their social networks and open call dissemination through social media platforms and digital networks of civil society organizations.

The questionnaire will be distributed digitally through an hyperlink and hosted on the Google Forms platform. This format will allow participants to complete the instrument remotely, at their convenience, while ensuring data security and accessibility.

Sample size for questionnaire validation

Sample size determination for questionnaire validation was based on established methodological recommendations for psychometric studies. While some authors suggest including 5 to 10 participants per item of the instrument], others propose a minimum of 200 participants to ensure sufficient statistical power and stability of factor structures, regardless of the number of items. Following these recommendations, the validation phase of this study will include a minimum of 200 Spanish-speaking transgender women [17].

This sample size is considered adequate for conducting exploratory and confirmatory factor analyses, evaluating internal consistency, and supporting the generalizability and reliability of the final instrument.

Data Analysis

Exploratory and confirmatory factor analyses will be conducted using polychoric correlation matrices and maximum likelihood estimation. Internal consistency will be assessed using Cronbach's alpha, with a threshold of ≥ 0.70 considered acceptable.

Phase 2: Longitudinal Cohort Study

Participants

This cohort will consist of transgender women undergoing facial feminization surgery at San Juan de Dios Hospital in Santiago, Chile. Participants eligible for the longitudinal cohort study phase must meet the following inclusion criteria:

- Self-identified transgender women aged 18 years or older.
- Currently enrolled in the gender program at San Juan de Dios Hospital.
- Clinical indication for facial feminization surgery, including but not limited to genioplasty, mandibular reshaping (angle and basilar crest modification), frontal-nasal-orbital complex remodeling, rhinoplasty, and zygomatic-malar complex remodeling.
- Absence of cranio-maxillofacial syndromes or contraindications to surgery.
- Completion of a multidisciplinary evaluation by a psychologist and a social worker, confirming psychological and emotional readiness for surgery.
- Willingness to undergo pre- and postoperative CBCT scans and standardized facial photography.
- Proficiency in Spanish (speaking, reading, and comprehension).
- Capacity and willingness to provide written informed consent.

Sample Size Calculation for Cohort Study

The gender program at San Juan de Dios Hospital currently includes 70 transgender women who are undergoing hormone therapy and attend regular medical follow-up appointments. Based on this population size, a sample of 30 participants was calculated using a 95% confidence level and an estimated margin of error of $\pm 12\%$. This adjustment reflects logistical and ethical considerations related to long-term follow-up, while maintaining sufficient statistical validity for exploratory analyses of surgical outcomes.

Data Collection

Quality of Life Assessment

Participants in the cohort study will complete the validated quality-of-life questionnaire prior to surgery and again at 12 months postoperatively.

Femininity Perception Assessment

Femininity will be assessed both through self-perception and third-party evaluation. Self-perceived femininity will be measured using the questionnaire answers regarding this matter.

To assess changes in third-party perception of femininity, a blinded evaluation will be conducted using standardized frontal and lateral clinical photographs taken preoperatively and at least 12 months postoperatively. All images will be coded using an alphanumeric identifier (e.g., FFS01, for Facial Feminization Surgery participant 01), which will not be visible to evaluators. A control group of cisgender women will be included, using anonymized clinical photographs from the Maxillofacial Surgery Service at Hospital San Juan de Dios, authorized for academic and research purposes.

Forty undergraduate students from non-health-related fields (e.g., arts, philosophy, architecture, and social sciences) at the University of Chile will serve as evaluators. Participants will be recruited through institutional emails and social media.

Inclusion criteria require students to be over 18 years old, without training or experience in health, facial anatomy, or aesthetics. Exclusion applies to students with prior engagement with transgender individuals from the hospital's gender program. Each student will provide informed consent. Evaluators will rate randomized images (including preoperative, postoperative, and control cases) using a 5-point Likert scale ranging from "feminine appearance" (1) to "non-feminine appearance" (5).

Four groups of ten evaluators each will be formed, ensuring diversity in terms of gender and age. Each group will be randomly assigned a set of photographs, including preoperative, postoperative, and control images, all displayed in a randomized sequence. As a critical methodological safeguard, pre- and postoperative images of the same patient will not be included within the same group to minimize direct comparative bias.

Cephalometric and Photometric Analysis

Facial morphological changes will be measured pre- and postoperatively using CBCT and an imaging software and extraoral pictures taken in a frontal and lateral view. The following parameters will be assessed: Forehead inclination, true vertical distance, nasofrontal angle, mandibular angle, mandibular plane angle, facial profile, nasolabial angle, mentolabial angle and mentocervical angle.

Data Analysis for the cohort study

Descriptive statistics will summarize sociodemographic variables (absolute and relative frequencies). The Shapiro–Wilk test will assess the distribution of continuous variables. Normally distributed variables will be reported as mean $\pm$ standard deviation; non-normal distributions will be reported as median and interquartile range. Pre- and postoperative comparisons of continuous variables will be made using paired t-tests or Wilcoxon signed-rank tests, as appropriate. Categorical variables will be compared using Pearson's chi-square test or Fisher's exact test. Linear regression models will evaluate associations between cephalometric/photometric changes and perceived femininity scores. Statistical significance will be set at $p \leq 0.05$. All analyses will be conducted using STATA 11 (StataCorp, College Station, TX, USA).

Ethics Approval

This study will adhere to established ethical guidelines for human subject's research and will be conducted in compliance with the principles outlined in the Declaration of Helsinki. The full research protocol, including participant recruitment strategies and informed consent procedures has been reviewed and approved by the Scientific Ethics Committee of San Juan de Dios Hospital in Santiago, Chile.

To ensure participant confidentiality, each subject will be assigned a unique identification code consisting of the acronym FFS (Facial Feminization Surgery) followed by a sequential number based on the order of enrollment (e.g., FFS01). This code will be used consistently throughout the study, including for labeling pre- and postoperative photographs, analyzing semi-structured interviews, and organizing the research database, thereby safeguarding the anonymization of sensitive information.

Informed Consent

Informed consent will not be required for the questionnaire validation. The decision to exclude informed consent for the questionnaire validation will be made in accordance with ethical guidelines, as the validation process will not involve direct intervention or pose any risk to the participants.

Written informed consent will be obtained from all participants prior to enrollment. For the longitudinal surgical cohort—participants will be informed about the study's objectives, procedures,

risks, benefits, data confidentiality measures, and their right to withdraw at any time without affecting their care. The consent process will be conducted by trained members of the research team, led by the principal investigator.

Confidentiality and Data Management

Data from both study components will be stored securely. Digital data (e.g., questionnaires, coded identifiers, imaging files) will be saved in password-protected files and backed up on institutional servers and a secure Google Drive account associated with the University of Chile, with restricted access. Physical records, including signed informed consent forms, will be stored in locked cabinets within the Maxillofacial Service at the San Juan de Dios Hospital.

The principal investigator and authorized research team members will be responsible for ensuring data confidentiality and secure storage. All data will be retained for a period of five years after study completion, in accordance with institutional and national guidelines.

After this retention period, the research team will evaluate whether extended data storage is necessary. If not, all physical and digital data will be permanently destroyed to safeguard participant anonymity.

Protocol Amendments and Study Termination

Any significant amendments to the research protocol—including changes in study procedures, eligibility criteria, or data management—will be submitted to the Scientific Ethics Committee of San Juan de Dios Hospital for review and approval prior to implementation.

In the event that study termination becomes necessary due to unforeseen circumstances, a structured and ethically responsible discontinuation plan will be followed. This includes timely notification to the ethics committee and study participants, documentation of the reasons for termination, and analysis and dissemination of any data collected up to the point of termination as preliminary findings, when appropriate. A final report will be submitted to ensure transparency and maximize the scientific contribution of the study, even if it is not completed as initially planned.

Discussion

One of the main challenges of this study lies in the complexity of its design. The development and

validation of a quality-of-life questionnaire specifically tailored to transgender women in Chile presents a substantial methodological undertaking. The absence of pre-existing instruments written and validated in Spanish for this population necessitates the creation of a new tool that is both culturally sensitive and contextually relevant.

The validation process will involve multiple stages, including expert review, pilot testing, and large-scale field validation. While the planned sample of 200 participants is essential to ensure robust psychometric properties, it also presents logistical challenges. The use of a non-probabilistic sampling strategy—based on community outreach, institutional networks, and social media—facilitates access to a geographically and socially diverse group but may introduce selection bias, potentially limiting the generalizability of findings to the broader transgender population in Chile.

The longitudinal cohort evaluating surgical outcomes will include 30 participants, a number determined by the eligible population currently enrolled in the gender program at San Juan de Dios Hospital. Although appropriate for exploratory analysis and reflective of real-world clinical constraints, this sample size may reduce the statistical power to detect subtle associations between cephalometric changes and psychosocial variables.

Limitations

Several limitations should be considered when interpreting the results of this study. First, participant retention over the 12-month follow-up period may be affected by factors such as emotional fatigue, life changes, or decreased interest, potentially leading to attrition and incomplete datasets. Second, the use of self-reported measures for quality of life and femininity perception may introduce response biases, particularly in areas influenced by stigma or social expectations. Third, although third-party evaluations are included to complement self-assessments, perceptions of gender expression and facial aesthetics are inherently subjective and may vary widely across sociocultural contexts. Finally, the inclusion of a control group composed of cisgender women does not fully eliminate normative comparisons, which may influence interpretation of femininity scores.

Strengths

The study is strengthened by several factors that enhance both its feasibility and scientific value.

Institutional support from the gender program at San Juan de Dios Hospital provides a solid foundation, including access to clinical infrastructure, a defined study population, and ethical oversight. Additionally, collaboration with civil society organizations in Santiago contributes to expanded recruitment efforts and sustained engagement with the transgender community. To further support retention, the study will leverage digital tools such as mobile messaging and social media to maintain regular contact with participants and overcome potential geographic or logistical barriers.

This study is expected to make a meaningful contribution to transgender health research by addressing a critical evidence gap in Latin America. It also introduces a validated, culturally sensitive instrument for clinical and academic use. Institutional support from the gender program at San Juan de Dios Hospital ensures access to infrastructure, a defined patient population, and ethical oversight. Moreover, collaboration with civil society organizations facilitates recruitment and promotes community engagement. To minimize attrition, the study will implement participant-centered retention strategies, including personalized follow-up and the use of mobile communication tools to address geographic and logistical barriers.

Conclusions

This study protocol outlines a two-phase research project designed to address critical gaps in the evaluation of facial feminization surgery among transgender women in Chile. By developing and validating a culturally appropriate quality-of-life questionnaire, and by assessing postoperative changes in femininity perception and facial morphology, the study aims to provide multidimensional evidence to inform both clinical practice and public health strategies. Despite logistical and methodological challenges, the integration of quantitative, anatomical, and psychosocial data is expected to generate meaningful insights that contribute to more inclusive, patient-centered gender-affirming care in Latin America.

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Conflict of Interest

The authors declare no conflicts of interest related to the content of this manuscript. No financial relationships with commercial entities or organizations that could be perceived to influence the work reported have been disclosed. The funding source had no role in the design, execution, analysis, or reporting of this study.

Data Availability

The study protocol is currently in the questionnaire content validation stage. Upon completion, the validated pre-surgical quality-of-life questionnaire will be administered starting second semester 2025 to over 30 transgender women currently on the waiting list for facial feminization surgery. The surgeries are planned to take place throughout 2025, with the administration of the post – surgical quality-of-life questionnaire starting 12 months post-surgery. Data collection is expected to conclude at the beginning of 2027.

All relevant data underlying the findings of this study will be made available through OPENICPSR repository. Data will be de-identified to protect participant confidentiality in accordance with ethical guidelines. The repository link and DOI will be provided upon publication. Access to sensitive data that cannot be fully anonymized will be restricted due to ethical considerations. Requests for access to this restricted data can be directed to the scientific ethics committee of San Juan de Dios Hospital, Santiago -Chile and will be considered on a case-by-case basis

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Supplementary Files

Multimedia Appendixes

Peer Review Document and Ethics Committee Approval from Hospital San Juan de Dios.

URL: <http://asset.jmir.pub/assets/441dd5966a37987d86accd4c1bb06b15.pdf>

Internal evaluation document peer-review.

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