Protocol

Long-Term Mental Health and Functional Outcomes Among Adults Referred for Gender-Affirming Care: Protocol for a Longitudinal Mixed Methods Cohort Study (GLOW)

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Abstract

Background: Gender dysphoria is associated with impaired functioning, reduced quality of life, psychiatric symptoms, and increased health care needs. Although gender-affirming care is increasingly provided, studies of long-term outcomes remain insufficient, particularly studies using prospective designs integrating self-reported, clinical, registry-based, and qualitative data.

Objective: The Gender Longitudinal Outcomes and Well-being (GLOW) study aims to investigate long-term psychosocial, functional, and medical outcomes among adults referred for gender dysphoria assessment within the Swedish National Highly Specialized Care system. The primary aim is to estimate change in functional disability between the time of assessment completion and 24 months afterward. Secondary aims are to assess quality of life, gender congruence, psychiatric symptoms, substance use, self-concept clarity, personality functioning, health care use, work-related outcomes, mortality, and lived experiences of gender-affirming health care.

Methods: GLOW is a prospective longitudinal observational mixed methods cohort study embedded in the Swedish National Highly Specialized Care system for adult gender dysphoria. The target sample is approximately 500 adults. Patient-reported outcomes are collected at baseline, assessment completion, and 24 and 60 months after completion. The primary outcome is World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0). Medical record and national registry data cover clinical exposures, health care use, medication, socioeconomic and work-related outcomes, and mortality. Semistructured interviews will be conducted with a purposive subsample of approximately 25 to 40 participants at either assessment completion or 24 months.

Results: The study was funded in 2025. Recruitment began in December 2025 at the Malmö clinic and in January 2026 at the Linköping clinic. As of September 2026, 174 participants had enrolled. Follow-up data collection is scheduled to continue through December 2030. Data analysis is expected to begin in spring 2027, with the first results expected to be published in autumn 2027.

Conclusions: By describing longitudinal trajectories and associations across self-report, clinical, registry, and qualitative data, the GLOW study is expected to strengthen the evidence base for adult gender dysphoria services. Because care pathways are not randomly assigned, comparisons between pathways will be interpreted as associations rather than causal treatment effects.

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KEYWORDS

gender dysphoria; longitudinal study; self-reported measures; registries

Introduction

Background

Gender dysphoria is the *Diagnostic and Statistical Manual of Mental Disorders* term for clinically significant distress or impairment associated with incongruence between experienced or expressed gender and sex assigned at birth [1]. Gender incongruence is the corresponding diagnostic concept in the *International Classification of Diseases* (11th Revision), where it is classified outside the chapter on mental and behavioral disorders [2]. Transgender and gender-diverse populations experience higher levels of depression, anxiety, suicidality, and other mental health burdens than the general population [3]. These disparities should not be interpreted as inherent to gender diversity. Minority stress theory proposes that stigma, discrimination, anticipated rejection, concealment, and internalized stigma contribute to adverse health outcomes, while social support and affirming environments may be protective [4,5].

Recorded diagnoses of gender dysphoria and referrals to specialized gender identity services have increased in Sweden and internationally, but these trends should be distinguished from population prevalence because estimates depend on definitions, data sources, service availability, and help-seeking patterns [6,7]. Gender-affirming care for adults is an individualized set of services rather than a single intervention. It may include multidisciplinary assessment, psychological or psychosocial support, initiation or continuation of hormone therapy, voice and communication therapy, referral for surgery, surgical procedures, or no medical intervention, depending on assessment outcome, needs, goals, and preferences [8,9].

Recent reviews suggest that gender-affirming medical interventions are associated with improvement in some mental health and psychosocial outcomes, particularly depressive symptoms and psychological distress, while evidence is less consistent for quality of life and broader functioning [10-12]. Interpretation remains limited by small samples, short follow-up, heterogeneous interventions and outcomes, incomplete control of confounding, and selection into care pathways [10-12]. Prospective studies that combine repeated patient-reported outcomes with clinical, registry, and qualitative data are therefore needed to describe longer-term trajectories and factors associated with heterogeneity in those trajectories.

Gender-affirming care is informed by international standards and Swedish national guidance [8,9]. In Sweden, the National Highly Specialized Care system centralizes defined services at designated units with multidisciplinary expertise. Within the participating adult clinics, the assessment documents diagnostic, health, psychosocial, and treatment-preference information and supports individualized care planning. After assessment, participants may receive psychological support, hormone treatment, voice and communication therapy, surgical referral or procedures, other support, or no intervention. The GLOW study therefore treats assessment outcomes and subsequent services as distinct, potentially concurrent, and time-varying exposures rather than as one uniform treatment.

The GLOW study was designed to address these knowledge gaps through a prospective longitudinal mixed methods cohort study embedded within the Swedish National Highly Specialized Care system. By combining repeated patient-reported measures with medical record data, national registry data, and qualitative interviews, GLOW will examine trajectories of functioning, mental health, quality of life, gender congruence, and other psychological and social outcomes over time. The study will also examine individual and clinical factors associated with variation in these trajectories and explore participants' experiences of gender dysphoria, assessment, and gender-affirming care. This multimodal approach provides an opportunity to characterize long-term outcomes across multiple domains and to examine how patterns observed in quantitative data relate to participants' lived experience

In this protocol, functional disability is operationalized as the World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0) total score, transformed to a 0 to 100 scale, with higher scores indicating greater disability across cognition, mobility, self-care, interpersonal functioning, life activities, and participation [13].

The conceptual model links minority stress theory with the World Health Organization framework of functioning and disability. Minority stress informs the selection and interpretation of psychosocial variables, whereas the functioning framework supports selection of WHODAS 2.0 as the primary outcome. Measures of gender congruence, symptoms, substance use, identity and personality functioning, interoceptive awareness, and autistic traits are included to characterize clinically relevant heterogeneity and to test prespecified correlates, predictors, or moderators. They are not treated as interchangeable primary outcomes.

Objectives

The primary objective is to estimate mean within-participant change in WHODAS 2.0 total score from assessment completion to 24 months after assessment completion. This provides a common 24-month follow-up period for all participants. Changes from baseline to assessment completion and longer-term changes through 60 months will be examined as secondary longitudinal outcomes. Comparisons between care pathways are secondary observational analyses.

The primary estimand is the adjusted mean change in WHODAS 2.0 total score from assessment completion to 24 months after assessment completion in the enrolled cohort, regardless of subsequent care pathway. The primary model includes categorical time and study site. Postdeath WHODAS values will not be imputed because functioning is undefined after death;

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deaths will be reported separately and addressed in sensitivity analyses. Data collected before withdrawal will be retained and analyzed only to the extent permitted by the consent or opt-out process and applicable law.

Research Questions

The research questions are as follows:

1. What are the baseline demographic, clinical, and psychological characteristics of adults referred for gender dysphoria assessment?
2. How do functional disability, quality of life, gender congruence, psychiatric symptoms, substance use, and other psychosocial outcomes change from baseline through assessment completion and 24- and 60-month follow-up, and which baseline characteristics are associated with variation in these trajectories?
3. How are specific clinical and gender-affirming care pathways during and after the clinical assessment associated with functional, psychological, and psychosocial outcomes at 24 and 60 months?
4. How do health care use, work-related and socioeconomic outcomes, and mortality change over time, and how do these outcomes compare with those of matched population comparators?
5. How do individuals with gender dysphoria describe and make meaning of their experiences of assessment, transition, and gender-affirming health care?

Methods

Study Design

GLOW is a prospective longitudinal observational mixed methods cohort study conducted within the Swedish National Highly Specialized Care system for gender dysphoria. Recruitment began in December 2025 at the participating adult clinics in Malmö, Region Skåne, in January 2026 in Linköping, Region Östergötland. The target sample is approximately 500 adults. Participants will be followed from the start of clinical assessment through 60 months after assessment completion. The quantitative component has primary emphasis, with the qualitative component providing complementary insight; findings will be integrated during interpretation

The study protocol and subsequent reporting will be informed by relevant reporting guidelines, including STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) and RECORD (Reporting of Studies Conducted using Observational Routinely Collected Health Data) for the observational and routinely collected data components, COREQ (Consolidated Criteria for Reporting Qualitative Research) for the qualitative interview component, and GRAMMS (Good Reporting of a Mixed Methods Study) for mixed methods reporting [14-17]. Completed checklists will be provided as multimedia appendices.

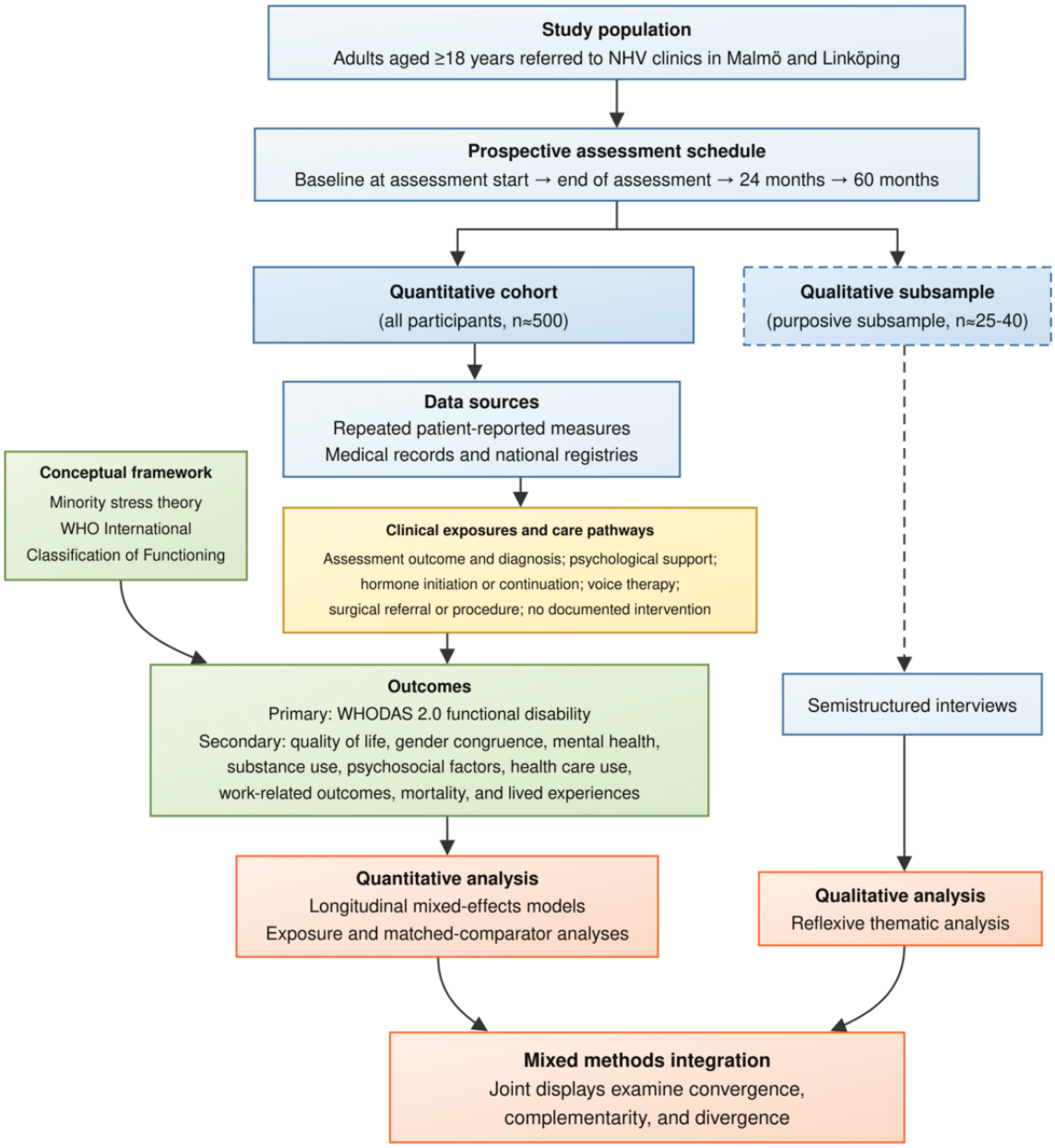
Setting and Recruitment

Participants are recruited at National Highly Specialized Care gender dysphoria clinics in Malmö and Linköping. Before recruitment, the study team will document whether the clinics use equivalent eligibility criteria, assessment pathways, participant information, consent or opt-out procedures, questionnaire platforms, and follow-up processes. Any differences will be described, and study sites will be included in the primary model. Planned recruitment is 400 participants from Malmö and 100 from Linköping. The study workflow is illustrated in Figure 1.

All eligible individuals will receive written study information before enrollment. In Malmö, consent for questionnaires is obtained digitally through Amni Care; in Linköping, consent is obtained via mail. Screening and recruitment logs will record numbers assessed for eligibility, approached, enrolled, declining participation, and excluded, with reasons categorized where legally and ethically permissible. Aggregate available characteristics of participants and eligible nonparticipants will be compared to assess selection bias without compromising confidentiality.

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Figure 1. Proposed overview of the Gender Longitudinal Outcomes and Well-being (GLOW) study design, conceptual framework, data sources, care exposures, outcomes, and mixed methods integration. NHV: National Highly Specialized Care; WHO: World Health Organization; WHODAS 2.0: World Health Organization Disability Assessment Schedule 2.0.



Eligibility Criteria

Individuals are eligible for inclusion if they are aged 18 years or older and have been referred for gender dysphoria assessment at one of the participating National Highly Specialized Care clinics. Exclusion criteria are inability to read and write Swedish and protected identity status.

Data Collection and Follow-Up

Patient-reported measures (Table 1) will be collected at baseline (start of clinical assessment), at completion of the clinical assessment, and at 24 and 60 months after assessment completion.

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Table 1. Overview of the study's self-report measures.

Measures	Swedish version and validation status	No. of items	Scoring method and range	Score interpretation and/or direction	Missing data handling	Licensing and permissions
WHODAS 2.0[a]	Yes [18]	36 (32 if not working and/or studying)	Complex (IRT[b]-based) scoring, 0-100	Higher=more disability	Domain mean imputed if 1-2 items missing (not from same domain); otherwise missing	Free (WHO[c]); registration required
EQ-5D-5L	Yes [19]	5+VAS[d]	Index value (Swedish value set); EQ-VAS 0-100	Higher index and VAS=better health	No index if any item missing; VAS analyzed separately	Free (EuroQol); registration required
GCLS[e]	Yes [20]	38	Mean per subscale (7) and global score, 1-5; 11 items reversed	Higher=more positive outcome	Item 26 set to missing if genital surgery; no other established rule identified	Free
MADRS-S[f]	Yes [21]	9	Sum 0-54	0-12 none, 13-19 mild, 20-34 moderate, ≥35 severe	No established missing data rule identified	Free (Karolinska Institutet)
GAD-7[g]	Yes [22]	7	Sum 0-21	5, 10, or 15=mild, moderate, or severe; ≥10 cut-off	No established missing data rule identified	Free; no permission required
AUDIT[h]	Yes [23]	10	Sum 0-40	Hazardous use: ≥6 women, ≥8 men; ≥20 possible dependence	Items 2-8 scored 0 if item 1=never; otherwise no established rule	Free
DUDIT[i]	Yes [24]	11	Sum 0-44	Higher=more drug-related problems	No established missing data rule identified	Public domain; retain original layout
SCIM[j]	Yes [25]	27	7-point Likert; sum 27-189; Consolidated Identity items reversed	Higher=greater identity disturbance	No established missing data rule identified	Free
LPFS-BF[k]	Yes [26]	12	4-point Likert; sum 12-48; Self-functioning 6-24; Interpersonal functioning 6-24	Higher=greater impairment in personality functioning	≤3 items missing permitted for total score; >3: total score not calculated	Free
PID-5-BF[l]	No Swedish version available	25	4-point Likert (0-3); sum 0-75; 5 domains, 0-15 each	Higher=greater maladaptive personality traits	1-6 items missing: prorate total; ≥7: total not calculated; 1 missing and /or domain: prorate; ≥2 missing and/or domain: domain not calculated	May be reproduced without permission by researchers and clinicians for use with patients (APA[m])
MAIA-2[n]	No Swedish translation available; no published Swedish validation identified	37	6-point Likert (0-5); mean 0-5 for each of 8 subscales	Higher=greater self-reported interoceptive awareness	No established missing data rule identified	Public domain
RAADS-14[o] Screen	Yes [27]	14	Sum 0-42; 3 subscales	Higher=more autistic traits; ≥14 suggested screening cut-off	No established missing data rule identified	Free

[a]WHODAS 2.0: World Health Organization Disability Assessment Schedule 2.0.

[b]IRT: item response theory

[c]WHO: World Health Organization.

[d]VAS: visual analog scale.

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[e]GCLS: Gender Congruence and Life Satisfaction Scale.

[f]MADRS-S: Montgomery-Åsberg Depression Rating Scale—Self-Report.

[g]GAD-7: Generalized Anxiety Disorder 7-item scale.

[h]AUDIT: Alcohol Use Disorders Identification Test.

[i]DUDIT: Drug Use Disorders Identification Test.

[j]SCIM: Self-Concept and Identity Measure.

[k]LPFS-BF: Level of Personality Functioning Scale—Brief Form.

[l]PID-5-BF: Personality Inventory for *DSM-5*—Brief Form.

[m]APA: American Psychiatric Association.

[n]MAIA-2: Multidimensional Assessment of Interoceptive Awareness, Version 2.

[o]RAADS-14 Screen: Ritvo Autism and Asperger Diagnostic Scale, 14-item version.

The primary contrast is change from assessment completion to 24 months after assessment completion. Assessment start and completion dates will be recorded for each participant. Change from baseline to assessment completion and longer-term change through 60 months will be examined as secondary longitudinal outcomes. Baseline data include demographic characteristics and study-specific self-harm items. Table 2 presents the timing of study assessments and data collection.

Medical record and national registry data will complement the patient-reported measures and provide information on clinical characteristics, care pathways, health care use, medication use, socioeconomic and work-related outcomes, and mortality.

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Table 2. Schedule of enrollment, assessments, and data collection in the GLOWa studyb.

Procedure or measure	Baseline	Assessment completion	24 mo after assessment completion	60 mo after assessment completion
Informed consent	✓			
Demographics	✓			
WHODAS 2.0[c]	✓	✓	✓	✓
EQ-5D-5L	✓	✓	✓	✓
GCLS[d]	✓	✓	✓	✓
MADRS-S[e]	✓	✓	✓	✓
GAD-7[f]	✓	✓	✓	✓
AUDIT[g]	✓	✓	✓	✓
DUDIT[h]	✓	✓	✓	✓
SCIM[i]	✓	✓	✓	✓
LPFS-BF[j]	✓			
PID-5-BF[k]	✓			
MAIA-2[l]	✓			
RAADS-14[m] Screen	✓			
Medical record data			✓	✓
Registry data	5-y look-back			Final extract
Qualitative interview		(✓)	(✓)	

[a]GLOW: Gender Longitudinal Outcomes and Well-being.

[b]✓ indicates a scheduled assessment or data collection point; (✓) indicates that each participant in the qualitative subsample will complete one interview, either at assessment completion or at 24 months. The prespecified primary contrast is change in WHODAS 2.0 from assessment completion to 24 months; change from baseline to assessment completion and longer-term change through 60 months will be examined as secondary longitudinal outcomes. LPFS-BF, PID-5-BF, MAIA-2, and RAADS-14 Screen are administered at baseline only, whereas Self-Concept and Identity Measure is repeated at all 4 assessment points.

[c]WHODAS 2.0: World Health Organization Disability Assessment Schedule 2.0.

[d]GCLS: Gender Congruence and Life Satisfaction Scale.

[e]MADRS-S: Montgomery-Åsberg Depression Rating Scale—Self-Report.

[f]GAD-7: Generalized Anxiety Disorder 7-item scale.

[g]AUDIT: Alcohol Use Disorders Identification Test.

[h]DUDIT; Drug Use Disorders Identification Test.

[i]SCIM: Self-Concept and Identity Measure.

[j]LPFS-BF: Level of Personality Functioning Scale—Brief Form.

[k]PID-5-BF: Personality Inventory for *DSM-5*—Brief Form.

[l]MAIA-2: Multidimensional Assessment of Interoceptive Awareness, Version 2.

[m]RAADS-14: Ritvo Autism and Asperger Diagnostic Scale, 14-item version.

Patient-Reported Measures

Primary Outcome

The primary outcome is functional disability measured with the self-administered 36-item WHODAS 2.0 [13]. It assesses functioning during the preceding 30 days across cognition, mobility, self-care, getting along, life activities, and participation. Complex scoring will be applied according to the World Health Organization (WHO) manual, and the total will be transformed to a 0 to 100 scale, where higher scores indicate greater disability. Functioning was prioritized because it captures day-to-day functioning across health conditions and extends beyond disorder-specific symptoms, quality of life, or gender congruence. The Swedish self-administered 36-item version has demonstrated reliability and convergent validity in psychiatric outpatient and general population samples [18,28].

WHODAS 2.0 will be administered at baseline, at completion of the clinical assessment, and at 24 and 60 months after assessment completion. The primary analysis will examine change in WHODAS 2.0 from assessment completion to 24 months after completion, providing a common 24-month follow-up period for all participants. Changes from baseline to

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assessment completion will describe functioning during the assessment phase, while the 60-month assessment will provide secondary long-term follow-up.

Secondary Outcomes

Secondary outcomes were selected to capture complementary domains of health and psychosocial functioning that may change during the study period.

Health-related quality of life will be assessed using the official Swedish EQ-5D version and, if applicable, the EQ visual analog scale; the selected Swedish value set and EuroQol registration or license will be documented [19,29]. Gender congruence and life satisfaction will be assessed using the 38-item Gender Congruence and Life Satisfaction Scale (GCLS) with a 6-month reference period and scoring according to the published instructions [20,30]. Depressive symptoms will be assessed using the 9-item Montgomery-Åsberg Depression Rating Scale—Self-Report (MADRS-S), scored 0 to 54 [21]. Anxiety symptoms will be assessed using the GAD-7, scored 0 to 21 [31]. Alcohol and drug use will be assessed using the Alcohol Use Disorders Identification Test (AUDIT) [23,32], scored 0 to 40, and the Drug Use Disorders Identification Test (DUDIT) [24], scored 0 to 44; their largely 12-month recall periods will be considered when interpreting change. These measures indicate symptom or screening severity and will not by themselves determine diagnoses or treatment pathways. Self-harm will be assessed with prespecified study-specific items.

Other Measures and Potential Predictors

Additional measures were selected to characterize heterogeneity that may be associated with functional and psychosocial trajectories. Self-concept and identity functioning will be assessed using the Self-Concept and Identity Measure (SCIM) [25,33], personality functioning using the Level of Personality Functioning Scale—Brief Form (LPFS-BF) [26,34], maladaptive personality traits using the Personality Inventory for *DSM-5*—Brief Form (PID-5-BF) [35], interoceptive awareness using the Multidimensional Assessment of Interoceptive Awareness, Version 2 (MAIA-2) [36], and autistic traits using the Ritvo Autism and Asperger Diagnostic Scale, 14-item version (RAADS-14) Screen [27]. These constructs may identify subgroups with different baseline support needs or longitudinal trajectories; they are not diagnostic tests within this study.

Baseline values of LPFS-BF, PID-5-BF, MAIA-2, and RAADS-14 will be examined as potential predictors of subsequent functional and psychosocial trajectories. SCIM will be assessed at all 4 time points and may be examined both as a baseline predictor and as a longitudinal measure of change in self-concept and identity functioning. Analyses involving these measures will be considered secondary or exploratory.

Gender-Affirming Care and Clinical Exposures

Gender-affirming care in the GLOW study will be conceptualized as a sequence of clinical exposures and care pathways rather than as a single intervention. All participants enter the study at the start of a multidisciplinary gender dysphoria assessment, and exposure to the assessment process will be characterized by its start and completion dates, duration, and assessment outcome.

Following assessment, participants may follow different care pathways according to clinical assessment, individual needs, and treatment preferences. Clinical exposures will be identified from medical records and, where applicable, national registry data. These will include assessment outcome and diagnosis; referral to and initiation of hormone therapy; referral to voice and communication therapy; referral for gender-affirming surgical procedures and, where data are available, completion of surgical procedures; psychological or psychosocial support; and other documented gender-affirming interventions. Participants who do not receive or proceed to a specific intervention will remain part of the cohort and contribute follow-up data.

Clinical exposures will be represented by separate, nonmutually exclusive indicators for assessment outcome, diagnosis, psychological or psychosocial support, hormone initiation, continuation of hormone treatment present at baseline, voice and communication therapy, surgical referral, surgical procedure, and no documented intervention. Exact dates will be used to update exposure status over follow-up. We will examine associations between these clinical exposures and outcomes at 24 and 60 months, depending on when the exposures occur. Exposure-outcome analyses will be secondary and interpreted as associations.

Medical Record Data

Medical records will be reviewed using a prespecified standardized extraction form covering assessment dates and outcomes, diagnoses and relevant comorbidities, psychological or psychosocial support, hormone treatment status and dates, voice and communication therapy, surgical referrals and procedures, other documented gender-affirming interventions, and relevant adverse or safety events. Relevant clinical history documented as part of the assessment will be extracted to characterize participants at baseline, including gender-affirming treatment already initiated before study entry. Prospective extraction will cover the period from the start of clinical assessment through follow-up.

Medical record data will be extracted after the 24-month follow-up and updated after the 60-month follow-up. Before full-scale extraction, the standardized extraction form and review procedure will be piloted by 2 reviewers who will independently review the same 20 medical records. Agreement will be evaluated and the extraction procedure refined where necessary. Discrepancies will be resolved through discussion and, when needed, consultation with a senior member of the research team.

National Registry Data

National registry data will be obtained from 5 Swedish population-based registries maintained by the Swedish National Board of Health and Welfare and Statistics Sweden. Individual-level linkage between study data and national registries will be performed using the unique personal identity number assigned to Swedish residents.

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From the Swedish National Board of Health and Welfare, data will be obtained from the National Patient Register, which contains information on inpatient and specialized outpatient health care; the Prescribed Drug Register, which contains information on dispensed prescription medications; and the Cause of Death Register, which contains information on dates and causes of death. From Statistics Sweden, data will be obtained from the Total Population Register, including information on residency and migration, and the Longitudinal Integrated Database for Health Insurance and Labour Market Studies (LISA), which contains longitudinal information on education, income, employment, sick leave, and disability benefits.

Registry data will cover the period from 5 years before baseline through 60 months after completion of the clinical assessment. Diagnoses and causes of death will be identified using the diagnostic classification systems applicable to the respective registry and calendar period, and dispensed medications will be classified using Anatomical Therapeutic Chemical codes. Health care use will include inpatient admissions and specialized outpatient visits. Work-related and socioeconomic outcomes will include employment, sick leave, disability benefits, education, and income. Income will be adjusted for inflation to a prespecified reference year. Emigration will be treated as censoring for outcomes that cannot be observed after emigration. The completeness of registry linkage and relevant missing registry data will be described.

Matched Population Comparator

For selected registry-based outcomes, comparators will be sampled from the Swedish Total Population Register. Each GLOW participant will be matched to up to 5 population comparators (1:5) on birth year, the registry sex variable available for matching, and county or region of residence. The GLOW participant's assessment start date will serve as the index date for both the participant and the matched comparators. Comparators must be alive and resident in Sweden on the index date, must not be members of the GLOW cohort, and will be sampled without replacement. Comparators with a recorded diagnosis of gender dysphoria or gender incongruence before the index date will be excluded.

Balance between the GLOW cohort and matched comparators will be assessed using standardized mean differences for prespecified baseline characteristics. Registry-based outcomes will be analyzed using models appropriate to each outcome while accounting for the matched design. Time-to-event analyses will use the same time origin and follow-up window for GLOW participants and comparators, with censoring at emigration, death when not the outcome, or end of available follow-up. Detailed outcome definitions and analysis choices will be prespecified in the statistical analysis plan before outcome analyses are conducted.

Qualitative Data Collection

The qualitative component explores lived experiences of gender dysphoria, clinical assessment, transition, and gender-affirming health care. A purposive subsample of questionnaire participants will be selected to achieve variation in age, gender identity, clinic, assessment outcome, and care pathway. Each participant will complete 1 interview at either the end of assessment or 24 months; the timing will be selected to capture experiences at different stages and will be included in the sampling matrix. Interviews will last approximately 60 minutes, take place in person or secure video or telephone, and be conducted by trained research assistants or doctoral students. The semistructured guide was developed from the study aims, conceptual framework, and stakeholder input and will be piloted and refined. Interviews will be audio-recorded, transcribed verbatim, deidentified, and checked against the recording. Sampling will continue until the dataset has sufficient information power to address the qualitative aim; 25 to 40 interviews are expected to provide variation across key characteristics.

Qualitative Analysis

The qualitative team will use reflexive thematic analysis following Braun and Clarke [37]. Analysis will proceed recursively through familiarization, coding, initial theme development, theme review and refinement, naming, and analytic writing. Coding will be inductive while remaining sensitized to the study questions and conceptual framework. The analytic team will maintain reflexive memos and an audit trail of coding and theme decisions, discuss alternative interpretations, and document each researcher's disciplinary position and relationship to the clinical setting. Credibility will be supported through sustained engagement with the dataset and attention to divergent cases; dependability and confirmability through transparent documentation and reflexivity; and transferability through detailed reporting of the sample, setting, and care context. In reflexive thematic analysis, discussions will deepen interpretation rather than pursue interrater reliability or coding consensus.

The interview guide is provided as Multimedia Appendix 1.

Sample Size and Power Calculation

The target sample size is 500 participants. Assuming 20% attrition by the primary 24-month follow-up, approximately 400 participants are expected to contribute 24-month data. Power calculations were based on the prespecified contrast in the WHODAS 2.0 total score between assessment completion and the 24-month follow-up. Because no well-established minimal clinically important difference is available for the 36-item WHODAS 2.0 in this population, a 5-point difference on the 0 to 100 scale was selected as the smallest difference of interest for the primary power analysis.

An SD of 22 points was assumed based on longitudinal data from a psychiatric population using the 36-item WHODAS 2.0 [38]. Using a 2-sided α level of .05 and a conservative 2-time point paired approximation with 400 participants at 24 months, a 5-point difference corresponds to approximately 97% power, assuming a within-participant correlation of 0.30. Power exceeds 99% for correlations of 0.50 or higher. Sensitivity analyses considering differences of 5, 7.5, and 9 points, SDs of 18 to 25 points, and within-participant correlations of 0.30 to 0.70 indicated adequate power across plausible assumptions. The planned sample size therefore provides sufficient power for the

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primary analysis while allowing for attrition and secondary analyses.

Quantitative Statistical Analysis

Baseline characteristics will be summarized using descriptive statistics appropriate to each variable. Continuous variables will be summarized using means and SDs or medians and IQRs, and categorical variables will be summarized using frequencies and percentages.

The primary analysis will examine change in WHODAS 2.0 scores from assessment completion to 24 months after assessment completion using a linear mixed-effects model with a participant-specific random intercept. Time will be treated as a categorical fixed effect, and study site will be included as a fixed effect. The primary contrast will be the adjusted mean difference in WHODAS 2.0 score between assessment completion and 24 months, reported with a 2-sided 95% CI. Model assumptions will be assessed using residual diagnostics, and alternative model specifications will be considered if assumptions are substantially violated. Change from baseline to assessment completion and longer-term change through 60 months will be examined in secondary longitudinal analyses.

Secondary patient-reported outcomes will be analyzed using models appropriate to the type and distribution of each outcome. Analyses of clinical care pathways will be exploratory and will describe outcomes according to documented assessment outcomes and subsequent care pathways, including specific gender-affirming interventions where sample sizes permit. Descriptive or stratified analyses may be used to examine variation according to prespecified participant characteristics, such as age and gender identity. These analyses will be interpreted as observational associations rather than causal treatment effects. Potential confounding will be considered separately for each secondary pathway analysis based on clinically relevant baseline characteristics and the specific exposure-outcome relationship.

Registry-based comparisons with matched population comparators will use models appropriate to each outcome while accounting for the matched design. Health care use will be analyzed as counts or rates where appropriate, and work-related and socioeconomic outcomes will be analyzed according to their distributions. Time-to-event outcomes may be examined where the number of observed events permits meaningful analysis. Effect estimates will be reported with 95% CIs.

The extent and patterns of missing data and attrition will be described. Missing questionnaire items will be handled according to the scoring rules for each instrument. The primary mixed-effects analysis will use all available WHODAS 2.0 observations. Missing baseline covariates may be handled using multiple imputation where appropriate. Sensitivity analyses will examine the robustness of findings to missing data and attrition. No WHODAS 2.0 values will be imputed after death.

The contrast in WHODAS 2.0 scores between assessment completion and 24-month follow-up will constitute the prespecified primary analysis. Analyses of secondary outcomes, longer-term 60-month outcomes, care pathways, predictors, and moderators will be considered secondary or exploratory. Effect estimates and 95% CIs will be emphasized, and exploratory findings will be interpreted accordingly.

Interactions involving participant characteristics or care pathways will be considered exploratory unless prespecified for a specific analysis. No multiplicity adjustment will be applied to exploratory analyses; these findings will be interpreted cautiously, with emphasis on effect estimates and 95% CIs rather than significance alone.

Analyses will be performed using R (version 4.6.2; R Foundation for Statistical Computing).

Mixed Methods Integration

GLOW uses a convergent mixed methods design in which quantitative and qualitative data are analyzed separately and integrated during interpretation. The quantitative component has primary emphasis, while the qualitative component provides complementary insight into participants' experiences and perspectives. Interview data will be linked to questionnaire and clinical data through study codes where permitted. Integration will occur through comparison of quantitative and qualitative findings, including joint displays where appropriate, to identify convergence, complementarity, expansion, and divergence. Divergent findings will be explored rather than treated as inconsistencies requiring resolution [39].

Ethical Considerations

The Swedish Ethical Review Authority approved the study (Dnr 2024-07577-02) and an amendment (Dnr 2025-06297-02). The study will be conducted in accordance with the Declaration of Helsinki, the approved protocol, and applicable Swedish data protection law.

Participants provide informed consent for questionnaires and qualitative interviews. Medical record and national registry components use an opt-out procedure approved by the Swedish Ethical Review Authority.

Study data will be pseudonymized with a unique study code. The reidentification key will be stored separately with access limited to authorized staff. Research data will be stored on access-controlled Region Skåne servers, and registry transfers will follow the security requirements of each register holder and the ethics approval. Reports will use aggregated or otherwise disclosure-controlled data.

Questionnaires include items concerning self-harm and current suicidal ideation. In Malmö, responses submitted through Amni Care that meet prespecified risk thresholds are automatically flagged. Alerts are reviewed by designated members of the research team within 1 working day, documented, and managed according to a written safety procedure. In Linköping, where questionnaires are completed on paper, designated members of the research team will review completed questionnaires on an ongoing basis to identify responses indicating potential self-harm or suicide risk. When a potential risk is identified, the procedure may include contacting the participant for further assessment, contacting the responsible clinical service, or referral to emergency services when imminent risk is suspected. Interviewers will receive training and a written action plan for disclosures of imminent risk. All participants will receive crisis

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and emergency contact information and will be informed that research participation does not replace clinical assessment or emergency care.

Participants will not receive financial or other material compensation for participation.

This study has been registered on ClinicalTrials.gov (NCT07480590).

Results

The study was funded in 2025, and recruitment began in December 2025 at the Malmö clinic and in January 2026 at the Linköping clinic. As of September 2026, a total of 174 participants had been enrolled across 2 active sites. The registered study completion date is December 2030. No outcome analyses had been completed as of the data-cut date. The first results are expected in autumn 2027.

Discussion

Anticipated Principal Findings

The GLOW study is expected to provide a detailed longitudinal description of functioning, mental health, quality of life, gender congruence, health care use, work-related outcomes, and lived experiences during and after gender dysphoria assessment. A particular contribution will be the combination of repeated patient-reported outcomes with clinical, registry-based, and qualitative data over a 5-year follow-up, allowing trajectories and individual variation in outcomes to be examined from complementary perspectives.

Comparison With Prior Work

Previous longitudinal studies and recent reviews have focused primarily on mental health and quality-of-life outcomes following specific gender-affirming medical interventions, often with relatively short follow-up and limited assessment of broader functioning, health care use, and work-related outcomes [10-12]. GLOW extends this literature by combining repeated assessment of functional disability with detailed characterization of individual care pathways, national registry linkage, and qualitative data over a longer follow-up period. This broader approach may provide a more comprehensive understanding of changes during and after gender dysphoria assessment and subsequent care. Associations between care pathways and outcomes will nevertheless require cautious interpretation, as differences may reflect baseline characteristics, treatment preferences, comorbidities, access to care, and waiting times, in addition to the care received.

Strengths and Limitations

Strengths of GLOW include its prospective design, repeated patient-reported measures, long-term follow-up, integration of medical record and population register data, and qualitative exploration within a specialized national care setting. The use of national registries enables assessment of health care, socioeconomic, work-related, and mortality outcomes that are difficult to capture through self-report alone.

Several limitations should also be considered. As an observational study, GLOW cannot establish causal effects of specific interventions or care pathways. Differences between care pathways may reflect baseline needs, treatment preferences, comorbidities, access, waiting times, and other measured or unmeasured factors. Attrition and missing data may introduce additional bias during long-term follow-up. The requirement that participants are able to read and write Swedish may reduce representativeness, and findings from Swedish highly specialized care may not be directly generalizable to health care systems with different assessment and treatment pathways. Matched population comparators will provide context for selected registry-based outcomes but cannot eliminate residual confounding.

Future Directions

Findings from GLOW will be used to identify outcomes, trajectories, and subgroups that warrant further investigation and to generate hypotheses for future studies. The combination of patient-reported, clinical, registry-based, and qualitative findings may also inform the development of outcome measurement and follow-up within gender dysphoria care. Findings will be discussed with clinical and community stakeholders to identify areas relevant to future research and service development.

Conclusions

GLOW will provide longitudinal evidence on functioning and related health and psychosocial outcomes among adults referred for gender dysphoria assessment in Swedish specialized care. By integrating patient-reported, clinical, registry-based, and qualitative data, the study will provide a multidimensional perspective on changes over time and variation between individuals and care pathways. These findings may inform future research, clinical follow-up, and the development of gender dysphoria services.

Dissemination and Stakeholder Involvement

The study has been developed in collaboration with clinical stakeholders and patient advocacy organizations, including RFSL (Swedish Federation for Lesbian, Gay, Bisexual, Transgender, Queer and Intersex Rights) and Transammans. Stakeholders have contributed to the study design and will remain involved through consultations during the study period and dissemination phase.

Findings will be disseminated through peer-reviewed publications, national and international conferences, policy briefs, clinical education, and accessible summaries for patient organizations and community networks. This dissemination strategy aims to support evidence-based clinical practice, inform health care planning, and ensure that results are communicated to both professional and community audiences.

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Data Availability

The data are not publicly available because they contain sensitive personal health information and are restricted under Swedish law and the General Data Protection Regulation. Aggregated or nonidentifiable information may be available from the corresponding author upon reasonable request.

Generative AI Use

The authors used ChatGPT 5.5, an AI language model developed by OpenAI, for English-language editing, wording suggestions, and improvement of clarity and readability during manuscript preparation. No AI tool was used to generate ideas or make scientific conclusions. The authors reviewed and edited all AI-assisted suggestions and take full responsibility for the final content of the manuscript.

Authors' Contributions

Conceptualization: EC-K, JB, MN, SA, MK
Methodology: EC-K, MN, JB, SA, MK
Formal analysis: EC-K, MN, JB
Investigation: EC-K, MN, JB
Data curation: EC-K, MN, JB
Writing—original draft: EC-K, JB, MN, SA, MK
Writing—review and editing: EC-K, JB, MN, SA, MK
Visualization: EC-K, JB, MN
Supervision: EC-K
Project administration: EC-K, MN
Funding acquisition: EC-K, MN
All authors approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Interview protocol.
[DOCX File , 15 KB-Multimedia Appendix 1]

Multimedia Appendix 2

STROBE checklist.
[PDF File (Adobe PDF File), 204 KB-Multimedia Appendix 2]

Multimedia Appendix 3

COREQ checklist.
[PDF File (Adobe PDF File), 82 KB-Multimedia Appendix 3]

Multimedia Appendix 4

GRAMMS checklist.

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[PDF File (Adobe PDF File), 50 KB-Multimedia Appendix 4]

Multimedia Appendix 5

RECORD checklist.
[PDF File (Adobe PDF File), 198 KB-Multimedia Appendix 5]

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Abbreviations

AUDIT: Alcohol Use Disorders Identification Test
COREQ: Consolidated Criteria for Reporting Qualitative Research
DUDIT: Drug Use Disorders Identification Test
GAD-7: Generalized Anxiety Disorder 7-item scale
GCLS: Gender Congruence and Life Satisfaction Scale
GLOW: Gender Longitudinal Outcomes and Well-being
GRAMMS: Good Reporting of a Mixed Methods Study
IRT: item response theory
LISA: Longitudinal Integrated Database for Health Insurance and Labour Market Studies
LPFS-BF: Level of Personality Functioning Scale–Brief Form
MADRS-S: Montgomery-Åsberg Depression Rating Scale—Self-Report
MAIA-2: Multidimensional Assessment of Interoceptive Awareness, Version 2
PID-5-BF: Personality Inventory for DSM-5–Brief Form
RAADS-14: Ritvo Autism and Asperger Diagnostic Scale, 14-item version
RECORD: Reporting of Studies Conducted using Observational Routinely Collected Health Data
SCIM: Self-Concept and Identity Measure
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
WHO: World Health Organization
WHODAS 2.0: World Health Organization Disability Assessment Schedule 2.0

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