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Chinese gender incongruence population mental health research

Submission date 11/04/2024	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/05/2024	**Overall study status** Ongoing	
Last Edited 28/08/2025	**Condition category** Other	

Plain English summary of protocol
Background and study aims
Gender incongruence refers to an individual's experienced gender not conforming with their assigned sex at birth, which could both affect appearance and personal feelings and may cause social problems and mental health crises. China may have the largest population of gender incongruence, which requires medical care and societal understanding. However, the cause of gender incongruence is still unknown. This study aims to search for possible social and psychological characteristics and biological markers to support the healthcare of people with gender incongruence.

Who can participate?
Individuals aged 18 to 45 years who come to Shanghai Mental Health Center and meet the ICD-11 diagnostic criteria for gender incongruence

What does the study involve?
Participants complete mental health and gender incongruence screening scales and questionnaires. They also undergo an MRI scan and provide a blood sample for genetic sequencing and hormone tests.

What are the possible benefits and risks of participating?
Participants are recommended to clinical qualified consultants and HRT doctors for further healthcare. The possible risks include the required blood sample.

Where is the study run from?
Shanghai Mental Health Center (China)

When is the study starting and how long is it expected to run for?
January 2021 to December 2030

Who is funding the study?
Shanghai Mental Health Center (China)

Who is the main contact?
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Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Social psychological characteristics and related biological studies of gender incongruence populations

Study objectives
1. Based on the Gender Incongruence population in the outpatient clinic of Shanghai Mental Health Center, investigate the basic situation and psychosomatic health level of the gender incongruence population, and explore the psychological characteristics and related influencing factors of the gender incongruence population.
2. Develop a screening questionnaire for gender incongruence populations and form a localized screening tool.
3. Preliminarily explore the biological characteristics of genetics and imaging in gender incongruence populations, so as to provide a theoretical basis for the diagnosis of gender incongruence.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/02/2022, Shanghai Mental Health Center Ethics Committee (SMHC-IRB (Shanghai Mental Health Center, Shanghai, 200030, China; +86 (0)34773308; wuyanru_qiushui@aliyun.com), ref: 2021-76

Study design
Observational cross-sectional study

Primary study design
Observational

Study type(s)
Diagnostic, Other, Screening

Health condition(s) or problem(s) studied

Social psychological characteristics and related biological markers of gender incongruence populations

Interventions
Based on the gender incongruence population in the outpatient clinic of Shanghai Mental Health Center, this study will investigate the basic situation and psychosomatic health level of the gender incongruence population, and explore the psychological characteristics and related influencing factors of the gender incongruence population.

Participants complete mental health and gender incongruence screening scales and questionnaires. They also undergo an MRI scan and provide a blood sample for genetic sequencing and hormone tests.

Intervention Type
Other

Primary outcome(s)
1. Psychological characteristics measured using the Minnesota Multiphasic Personality Inventory (MMPI), the self-report symptom inventory, Symptom Checklist (SCL-90), the Self-rating Depression Scale (SDS), Self-Rating Anxiety Scale (SAS), Life Events Scale (LES) and Yale-Brown Obsessive-Compulsive Scale at baseline
2. Biological characteristics measured using MRI, whole exome sequencing and hormone test at baseline

Key secondary outcome(s))
1. Degree of gender incongruence measured using the Gender Incongruence Screening scale at baseline
2. The basic information of the gender incongruence population measured using a self-made questionnaire at baseline

Completion date
31/12/2030

Eligibility

Key inclusion criteria
Meets ICD-11 diagnostic criteria for gender incongruence

Participant type(s)
Patient, Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
All

Key exclusion criteria
Mental retardation and/or inable to complete the questionnaires and scale assessments

Date of first enrolment
03/06/2022

Date of final enrolment
31/12/2030

Locations

Countries of recruitment
China

Study participating centre
Shanghai Mental Health Center
Affiliated Shanghai Jiaotong University School Of Medicine
600 Wanping South Road
Shanghai
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Study participating centre
Tongji Hospital of Tongji University
389 Xincun Road
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200065

Sponsor information

Organisation
Shanghai Mental Health Center

ROR
https://ror.org/05bd2wa15

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Shanghai Mental Health Center

Results and Publications

Individual participant data (IPD) sharing plan
This study chooses not to provide raw data because it involves GI populations' personal privacy. It may be provided in a statistical format and images. Please contact Liu Na (liunamsx@126.com).

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/08/2025	28/08/2025	Yes	No
Other files			11/04/2024	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes