

Chinese gender incongruence population mental health research

| | | |
|--|---|--|
| Submission date 11/04/2024 | Recruitment status Recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 06/05/2024 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 11/04/2024 | Condition category Other | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

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?
Liu Na, liunamsx@126.com

Contact information

Type(s)

Principal Investigator

Contact name

Dr Liu Na

Contact details

Shanghai Mental Health Center
Affiliated Shanghai Jiaotong University School Of Medicine
600 Wanping South Road
Shanghai
China
200030
+86 (0)137 7426 2925
liunamsx@126.com

Type(s)

Scientific

Contact name

Prof Lu Zheng

Contact details

Tongji Hospital of Tongji University
389 Xincun Road
Shanghai
China
200065
+86 (0)136 7190 2719
Luzheng@tongji.edu.cn

Type(s)

Public

Contact name

Dr Bai JingYi

Contact details

Tongji Hospital of Tongji University
389 Xincun Road
Shanghai
China

200065
+86 (0)13500017019
2211512@tongji.edu.cn

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cause/relative factors study

Study setting(s)

Hospital, Internet/virtual, Other

Study type(s)

Diagnostic, Other, Screening

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2021

Completion date

31/12/2030

Eligibility**Key inclusion criteria**

Meets ICD-11 diagnostic criteria for gender incongruence

Participant type(s)

Patient, Population

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Both

Target number of participants

10000

Key exclusion criteria

Mental retardation and/or unable 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

China

200030

Study participating centre

Tongji Hospital of Tongji University

389 Xincun Road

Shanghai
China
200065

Sponsor information

Organisation

Shanghai Mental Health Center

Sponsor details

Affiliated to Shanghai Jiaotong University School Of Medicine
600 Wanping South Road
ShangHai
China
200030
+86 (0)21 34773756
yjszssmhc@163.com

Sponsor type

Hospital/treatment centre

Website

http://www.smhc.org.cn/index_en.aspx

ROR

<https://ror.org/05bd2wa15>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Shanghai Mental Health Center

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/12/2027

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? |
|-----------------------------|---------|--------------|------------|----------------|-----------------|
| Other files | | | 11/04/2024 | No | No |