

# Study of brain health in women of childbearing age

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<b>Registration date</b> 01/04/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/04/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The aim of this project is to investigate the changes in brain cognitive ability and body movement as well as to systematically assess the structural and functional characteristics of the brain in women of childbearing age. By utilizing structural MRI, functional MRI and advanced quantitative imaging techniques (e.g., QSM, DTI, etc.), the brain imaging characteristics of women of childbearing age are depicted. With the help of multimodal data and machine learning methods, an individualized brain health risk assessment model is constructed to provide a basis for early identification of brain function abnormalities. The ultimate goal is to provide scientific and individualized brain health management strategies for women of childbearing age, and to promote the development of the concept of integrating reproductive health and brain health.

### Who can participate?

Women of childbearing age between 18 and 49 years.

### What does the study involve?

The research includes evaluating how people think and move, testing blood for various substances, and taking images of the brain using structural MRI, functional MRI and advanced quantitative imaging techniques (e.g., QSM, DTI, etc.).

### What are the possible benefits and risks of participating?

There will be no immediate direct benefit to those taking part. However, it can provide scientific and individualized brain health management strategies for women of childbearing age and promote the development of the concept of integrating reproductive health and brain health.

### Where is the study run from?

Jinan Maternity And Child Care Hospital Affiliated to Shandong First Medical University (China)

### When is the study starting and how long is it expected to run for?

January 2019 to December 2029

### Who is funding the study?

Jinan Maternity And Child Care Hospital Affiliated to Shandong First Medical University (China)

Who is the main contact?  
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## Contact information

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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**

Neuroimaging study of changes in brain cognitive-motor function in women of childbearing age

### **Study objectives**

This study aims to investigate the trajectory of cognitive function and motor ability in women of reproductive age, and to systematically elucidate how the structural and functional changes in the brain during pregnancy affect the neuropsychiatric state, and to reveal the underlying biological mechanisms. Through this study, we hope to optimize the diagnostic process, improve the accuracy of prognostic assessment, and pinpoint potential therapeutic targets to improve the health of women of childbearing age.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 18/06/2019, The Medical Ethics Committee of Jinan Maternity And Child Care Hospital Affiliated to Shandong First Medical University (2 Jian-guo Xiao Jing-san Road, Jinan, 250001, China; +86 531 8902 9000; 18254887757@126.com), ref: 20190618

### **Study design**

Observational cross sectional

### **Primary study design**

Observational

### **Study type(s)**

Diagnostic, Quality of life

### **Health condition(s) or problem(s) studied**

Changes in cognitive and motor function in women of childbearing age

### **Interventions**

After enrollment, participants will undergo assessments of thinking and movement abilities, blood tests for various substances, and brain imaging using quantitative susceptibility mapping (QSM) technology. The total duration of observation is 10 years, from November 1, 2019, to December 1, 2029. Follow-up will start from enrollment, with QSM brain iron measurements taken at baseline, 2 years, and 5 years, with overall follow-up continuing until December 1, 2029.

### **Intervention Type**

Other

### **Primary outcome(s)**

Brain iron is measured using Quantitative susceptibility mapping (QSM) at pre-pregnancy, pregnancy and post-partum.

### **Key secondary outcome(s)**

There are no secondary outcome measures

### **Completion date**

01/12/2029

## **Eligibility**

### **Key inclusion criteria**

1. Women of childbearing age between 18 and 49 years
2. Right-handedness

### **Participant type(s)**

Healthy volunteer, Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

49 years

### **Sex**

Female

### **Key exclusion criteria**

1. History of brain trauma, surgery, or tumors
2. History of severe cerebrovascular, neurological, or mental diseases
3. Alcohol or drug abuse
4. MRI contraindications

**Date of first enrolment**

01/12/2019

**Date of final enrolment**

01/11/2026

## **Locations**

**Countries of recruitment**

China

**Study participating centre**

**Jinan Maternity And Child Care Hospital Affiliated to Shandong First Medical University**

2 Jian-guo Xiao Jing-san Road

Jinan

China

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## **Sponsor information**

**Organisation**

Jinan Maternity And Child Care Hospital Affiliated to Shandong First Medical University

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Jinan Maternity And Child Care Hospital Affiliated to Shandong First Medical University

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from Linfeng Yang, ylf19860928@126.com

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes