

# Training for schizophrenia patients in the community

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
09/08/2020	No longer recruiting	<input checked="" type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
11/08/2020	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
18/01/2021	Mental and Behavioural Disorders	

## Plain English summary of protocol

### Background and study aims

Schizophrenia is a severe long-term mental health condition. It causes a range of different psychological symptoms. The traditional general practitioner-based model (community-based rehabilitation [CBR]) for schizophrenia patients in China, lacks content-rich, useful, and theoretically-based rehabilitation means. However, according to previous research, Metacognitive Training (MCT) may be effective in the community for schizophrenic patients. The present study aims to compare a combined intervention consisting of MCT and CBR with the control group receiving CBR only.

### Who can participate?

Patients aged 18-65 with schizophrenia

### What does the study involve?

Participants are randomly allocated to the intervention group or the control group. The intervention group receives CBR plus Metacognitive Training (MCT). The MCT consists of 8 modules, each session lasts about 60 minutes, and the whole course lasts for 8 weeks, and a gift worth \$5 is given to the patient after each session. The control group receives a standard CBR in China for mental illness patients for 8 weeks. GPs first work with patients and their respective families to develop an individualized rehabilitation plan in the first week and then follow up once during the project in the form of a phone call or home visits. The total duration of the intervention is 8 weeks, and 1 week for the follow-up.

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

The course may improve the delusions of the patients.

### Where is the study run from?

Ningbo Yinzhou District Center for Disease Control and Prevention (China)

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

August 2016 to December 2018

Who is funding the study?  
Ningbo Medical Science and Technology Plan Project (China)

Who is the main contact?  
Dr Qi Chen  
47229942@qq.com

## Contact information

### Type(s)

Scientific

### Contact name

Mr Qi Chen

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

2016c05

## Study information

### Scientific Title

Metacognitive training for schizophrenia patients in the community

### Study objectives

The present study aims to compare a combined intervention consisting of MCT and CBR with the control group receiving CBR only. The study goes further to confirm the superiority of MCT over CBR for the improvement of delusion. Thus, decreasing the possibilities of violent acts

committed by these patients in the community. The researchers also expect some aspects of the quality of life of these schizophrenic patients to improve. Finally, to find evidence of MCT feasibility on community rehabilitation, and for the government to tailor the community services by taking the MCT as a regular complement strategy to the CBR.

### **Ethics approval required**

Old ethics approval format

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

Approved 20/11/2016, YinZhou Center for Disease Control and Prevention's Research Ethics Board (No.1221, XueShi Rd, YinZhou District, Ningbo, China; +86 (0)57487418723; yzcdcreb@163.com), ref: 2016-11

### **Study design**

interventional randomized controlled assessor-blinded trial

### **Primary study design**

Interventional

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

Quality of life

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

Schizophrenia

### **Interventions**

The researchers use a completely random method for grouping. First, they number the subjects according to the order in which they are recruited. Then, they use the random number table method to give each subject a random number in sequence. Finally, they sort the subjects by the size of random numbers. They assign the first 60 cases to the intervention group, and the latter 60 cases to the control.

The intervention group receives CBR plus Metacognitive Training (MCT), Chinese ver.6.2 (see [https://clinical-neuropsychology.de/metakognitives\\_training\\_psychose/](https://clinical-neuropsychology.de/metakognitives_training_psychose/)). The MCT consists of 8 modules, which covers six cognitive and social biases (attribution biases, jumping to conclusions, belief inflexibility, overconfidence in errors, the theory of mind deficits, and depressive cognitive schemata). Each session lasts about 60 minutes, and the whole course lasts for 8 weeks, and a gift worth \$5 is given to the patient after each session.

The control group receives a standard CBR in China for mental illness patients (see [http://www.gov.cn/gongbao/content/2018/content\\_5338247.htm](http://www.gov.cn/gongbao/content/2018/content_5338247.htm)) for 8 weeks. GPs first work with patients and their respective families to develop an individualized rehabilitation plan at the first week and then follow up once during the project in the form of a phone call or home visits. The rehabilitation plan in CBR consists of six aspects, including medication training, relapse identification, physical management, life skills training, social skills training, and occupational rehabilitation training etc.

The total duration of the intervention is 8 weeks, and 1 week for the follow-up.

### **Intervention Type**

Behavioural

**Primary outcome(s)**

Symptom severity of delusion assessed with the Positive and Negative Syndrome Scale (PANSS) and Psychotic Symptom Rating Scales (PSYRATS) at baseline and the end of the intervention (8 weeks)

**Key secondary outcome(s)**

Quality of life measured using Schizophrenia Quality of Life Scale (SQLS) at baseline and the end of the intervention (8 weeks)

**Completion date**

01/12/2018

## Eligibility

**Key inclusion criteria**

1. Age 18-65
2. Diagnosis of schizophrenia in DSM-IV
3. Total PANNS score 50-120

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

**Total final enrolment**

124

**Key exclusion criteria**

Psychoactive substances and substance abuse over the last 6 months

**Date of first enrolment**

01/01/2017

**Date of final enrolment**

01/12/2017

# Locations

## Countries of recruitment

China

## Study participating centre

Ningbo Yinzhou District Center for Disease Control and Prevention

No.1221

XueShi Rd

YinZhou District

Ningbo

China

315000

# Sponsor information

## Organisation

Ningbo Municipal Health Bureau

# Funder(s)

## Funder type

Government

## Funder Name

Ningbo Medical Science and Technology Plan Project (2016C05)

# Results and Publications

## Individual participant data (IPD) sharing plan

Since the survey subjects are schizophrenic patients, most of the patients signed a privacy protection agreement before the project started in order to protect their privacy. However, the researchers can still provide the original questionnaire records and database of some patients when necessary. Dr Lifang Ren (13777142531@163.com) would be contacted for access to the datasets. The type of data can be Excel or others. The data will become available after 01/12/2020 for 1 year. Data requesters need to apply to Ningbo Municipal Health Bureau and Yinzhou District Center for Disease Control and Prevention, and submit data analysis plans only for scientific usage. Consent from all the participants was obtained and all consent documents have been sealed according to the requirements of project file management, and can be inquired whenever needed.

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	13/01/2021	15/01/2021	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>		12/08/2020	No		No