ISRCTN17333276 https://doi.org/10.1186/ISRCTN17333276

Training for schizophrenia patients in the community

Submission date
09/08/2020

Recruitment status
No longer recruiting

Registration date
11/08/2020

Overall study status
Completed

Last Edited
18/01/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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

ORCID ID
http://orcid.org/0000-0001-7186-8593

Contact details
Room 2505
No.1221
XueShi Rd
YinZhou District
Ningbo
China
315000
+86 (0)57487418723
47229942@qq.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

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/). 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) 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 measure
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)

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

Overall study start date
01/08/2016

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
120

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

Sponsor details
22 Northwest Street
Haishu District
Ningbo
China
315010
+86 (0)57487362555
13777142531@163.com

Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Ningbo Medical Science and Technology Plan Project (2016C05)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/12/2021

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?
Protocol file			12/08/2020	No	No
Results article	results	13/01/2021	15/01/2021	Yes	No