ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: September 6, 2021

ClinicalTrials.gov ID: NCT05042739

Study Identification

Unique Protocol ID:	ky2018.45
Brief Title:	Early Identification and Predictive Parsing for High Risk Group of Schizophrenia
Official Title:	Early Identification and Predictive Parsing for High Risk Group of Schizophr
Secondary IDs:	

Study Status

Record Verification:	August 2021
Overall Status:	Completed
Study Start:	May 1, 2017 [Actual]
Primary Completion:	January 1, 2019 [Actual]
Study Completion:	April 1, 2021 [Actual]

Sponsor/Collaborators

Sponsor:	Wuhan Mental Health Centre
Responsible Party:	Sponsor
Collaborators:	Health Commission of Hubei Province

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Not required
Data Monitoring:	Yes
FDA Regulated Intervention:	Yes

Study Description

Brief Summary:	An accurate identification of individuals at ultra-high risk (UHR) based on psychometric tools to prospectively identify psychosis as early as possible is required for indicated preventive intervention. The diagnostic comparability of several psychometric tools is unknown. To address the psychometric comparability of the CAARMS, SIPS and BSABS for subjects who are

the immediate family and three-generation blood kinship of patients with schizophrenia. To verify the viability and reliability of the three instruments for these subjects. subjects who all are immediate family and three-generation blood kinship of patients with schizophreniawere interviewed. All the subjects were assessed for a UHR state by three psychometric tools including CAARMS, SIPS and BSABS. The psychometric diagnosis results including at risk of psychosis (UHR+), not at risk of psychosis (UHR-), and Psychosis. Demographic and clinical characteristics interviewed by these three instruments were also measured. The inter-rater agreement was assessed for evaluation of the coherence of the three scales. Transition rates of CAARMS, SIPS and BSABS for UCH+ subjects within 2 years were also recorded.There is good diagnostic agreement between the CAARMS, SIPS and BSABS towards identification of UHR subjects who are immediate family and three-generation blood kinship of patients with schizophrenia. Also, these three instruments are reliable and valid for assessing and detecting at risk mental states in these subjects.

Detailed Description:

Conditions

Conditions: High Risk Group of Schizophrenia

Keywords: Psychosis; UHR; CAARMS;SIPS; BSABS

Study Design

Study Type: Observational

Observational Study Model: Family-Based

Time Perspective: Prospective

Biospecimen Retention: Samples Without DNA

Biospecimen Description:

Enrollment: 189 [Actual]

Number of Groups/Cohorts: 1

Groups and Interventions

Intervention Details:

Diagnostic Test: CAARMS;SIPS; BSABS;

Comprehensive Assessment of At Risk Mental State (CAARMS); Structured Interview for Psychosis-Risk Syndrome (SIPS); Bonn Scale for the Assessment of Basic Symptoms (BSABS);

Outcome Measures

Primary Outcome Measure:

1. The overall agreement percent
   diagnostic comparison of CAARMS and SIPS, SIPS and BSABS, CAARMS and BSABS.

   [Time Frame: 2 years]

2. the inter-rater reliability
   Inter-rater correlation (ICC) coefficients of CAARMS, SIPS and BSABS subscales.

   [Time Frame: 2 years]

3. the transition rates of UHR+ to psychosis within 2 years
   Transition rates of CAARMS, SIPS and BSABS for UCH+ subjects within 2 years follow-up.

   [Time Frame: 2 years]

Eligibility

Study Population:	All are immediate family and three-generation blood kinship of patients with schizophrenia diagnosed in Affiliated Wuhan Mental Health Center, Tongji Medical College of Huazhong University of Science & Technology. Subjects are recruited from Wuhan Mental Health Center who can be contacted by telephone or an internet homepage.
Sampling Method:	Non-Probability Sample
Minimum Age:	
Maximum Age:	
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	Yes
Criteria:	Inclusion Criteria: • all are immediate family and three-generation blood kinship of patients with schizophrenia Exclusion Criteria: -

Contacts/Locations

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IPDSharing

Plan to Share IPD:	Undecided

References

Citations:	

Links:	
Available IPD/Information:	