# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Oct 2026

## Effectiveness of “Iranian Modified Community Reentry module (CRM)” on relapse prevention, medication compliance and quality of life in patients with schizophrenia

## Protocol summary

**Summary**

Aim: to assess the effectiveness of Iranian modified version of community re- entry program (CRM) on relapse prevention, improvident of quality of life and treatment compliance in patient with schizophrenia. Study plan: The study will be performed on inpatient schizophrenia patients in Iran Psychiatric Hospital, from February, 2012 to January, 2013. This is a randomized controlled clinical trial. Patients will be divided into two equal groups with 50 persons. Interventions: All patients will be treated using standard chemotherapeutic agents. They may use depot anti psychotic medications, however this will be considered as confounding factor. We use the following questionnaires: PANSS and quality of life questionnaire. Patients will be visited regularly during the first month of hospitalization in Iran Psychiatric Hospital. CRM group will be educated according to reference book and training movie. We evaluate patients at months 0, 3, 6 and 12. Primary outcomes: Relapse prevention, improvement of quality of life and treatment compliance in patient with schizophrenia.

## General information

**Acronym**

CRM Project

**IRCT registration information**

IRCT registration number: **IRCT201106226860N1**
Registration date: **2012-02-27, 1390/12/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2012-02-27, 1390/12/08

**Registrant information**

**Name**

Amir Hosein Jalali nadoushan

**Name of organization / entity**

Tehran university of medical sciences

**Country**

Iran (Islamic Republic of)

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+98 21 4452 5615

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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research, Tehran University of Medical Sciences

**Expected recruitment start date**

2012-01-21, 1390/11/01

**Expected recruitment end date**

2013-01-19, 1391/10/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effectiveness of “Iranian Modified Community Reentry module (CRM)” on relapse prevention, medication compliance and quality of life in patients with schizophrenia

**Public title**

Effectiveness of Iranian modified version of CRP in schizophrenia relapse prevention

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: 1. Diagnosis of schizophrenia, based on DSM-IV-TR criteria; 2. Hospitalization; 3. informed consent; 4. age: 18-65 yr; 5. living with at least one closed family member after discharge; 6. no employment after discharge; 7. living in Tehran or Alborz provinces; 8. Availability; 9.Consent of attending physician; Exclusion criteria: 1. Changing Location; 2. No Consent to enter the study; 3. Failure to participate in more than two thirds of the meetings.

**Age**
From **18 years** old to **65 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **100**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Tehran University of Medical Sciences

**Street address**
Keshavarz Blvd

**City**
Tehran

**Postal code**

**Approval date**
2011-12-14, 1390/09/23

**Ethics committee reference number**
90-03-121-15354-39704

## Health conditions studied

### 1

**Description of health condition studied**
schizophrenia

**ICD-10 code**
F20

**ICD-10 code description**
Schizophrenia

## Primary outcomes

### 1

**Description**
Medication compliance

**Timepoint**
months 0, 3, 6, 12

**Method of measurement**
questionnaires

### 2

**Description**
Quality of life

**Timepoint**
months 0, 3, 6, 12

**Method of measurement**
questionnaires

### 3

**Description**
Relapse prevention

**Timepoint**
months 0, 3, 6, 12

**Method of measurement**
questionnaires

## Secondary outcomes

### 1

**Description**
relapse

**Timepoint**
month 12

**Method of measurement**
clinical interview and/or hospitalization

## Intervention groups

### 1

**Description**
CRM (Community Reentry Module), A Program to increase awareness of patients about the disease and drug treatment. Besides increasing awareness of patients. They will also learn social skills.

**Category**
Rehabilitation

### 2

**Description**
Psycho education & group occupational therapy

**Category**
Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Iran Psychiatric Hospital
**Full name of responsible person**
**Street address**
**City**
Tehran

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
F. Golband
**Street address**
Keshavarz Blvd
**City**
Tehran
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Tehran University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
*empty*
**Domestic or foreign origin**
*empty*
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Amir Hossein Jalali Nodushan
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**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*
**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**
*empty*