

# Relapse Prevention Group Programme for service users with an international statistical classification of diseases and related health problems (ICD10, chapter F20) diagnosis of schizophrenia in a community setting - a randomised controlled trial

<b>Submission date</b> 29/06/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/07/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/02/2010	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

JUMRC6002

## **Study information**

**Scientific Title**

**Acronym**

RPGP

**Study objectives**

Following an eight week Relapse Prevention (RP) programme, service users have:

1. Decrease in admission rates
2. Decrease in length of stay following admission
3. Increase in the attendance rates of hospital appointments
4. Increased their self-efficacy
5. Greater knowledge in medication, support services and illnesses
6. Improved quality of life
7. Reduced severity of symptomatology

It is expected that there will be a significant difference in these variables between individuals receiving the RP programme (treatment group) and individuals receiving treatment as usual (comparison group) that this is maintained at three and six months follow-up.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

COREC - Brent Medical Ethics Committee

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

## **Participant information sheet**

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

Schizophrenia

### **Interventions**

Relapse prevention programme as opposed to treatment as usual

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

1. Increased self-efficacy
2. Greater knowledge in medication, support services and illnesses
3. Improved quality of life
4. Reduced severity of symptomatology

### **Secondary outcome measures**

1. Decrease in admission rates
2. Decrease in length of stay following admission
3. Increase in the attendance rates of hospital appointments

### **Overall study start date**

11/09/2006

### **Completion date**

11/05/2007

## **Eligibility**

### **Key inclusion criteria**

1. Newly diagnosed by a Community Psychiatric Nurse (CPN)
2. Age group 18-45, men and women
3. Have a diagnosis of schizophrenia (ICD 10-F20)
4. Sufficiently stable to take part in the programme
5. Assessment conducted by CPN
6. Living in the community
7. Be able to consent to participate
8. Be on a therapeutic dose of anti-psychotic medication

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

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

**Upper age limit**

45 Years

**Sex**

Both

**Target number of participants**

96

**Key exclusion criteria**

1. Patients who do not speak English or cannot use an interpreter because this will be another confounder to the study
2. Patients with drug dependency as indicated by the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) although alcohol/drug abusers will still be eligible for the study. The DSM- IV criterion for abuse is very restrictive and would capture most alcohol/drug use by mental health service users. The CPNs will be provided with this to make this assessment
3. Organic brain diseases (e.g. dementia) as assessed by the psychiatrist. The psychiatrist will be asked to assess whether the patient is capable of giving informed consent and understanding what they have been asked to do
4. Patients who have previously been treated with RP
5. Patients who refuse to provide consent

**Date of first enrolment**

11/09/2006

**Date of final enrolment**

11/05/2007

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Park Royal Centre for Mental Health**

London

United Kingdom

NW10 7NS

## **Sponsor information**

## Organisation

Brent Mental Health Service (UK)

## Sponsor details

32 London Road  
Wembley  
Middlesex  
England  
United Kingdom  
HA9 7SS

## Sponsor type

Hospital/treatment centre

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Funded by Brent Mental Health Service and The Brent Relapse Prevention Programme (UK)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2008		Yes	No