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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

Submission date
29/06/2006

Recruitment status
No longer recruiting

Registration date
27/07/2006

Overall study status
Completed

Last Edited
04/02/2010

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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?
Results article	results	01/09/2008		Yes	No