

# Brixton Early Psychosis Project

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/05/2010	<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

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## Additional identifiers

**Protocol serial number**  
RDC01657

## Study information

**Scientific Title**

**Study objectives**

The objective is to investigate whether patients randomly allocated to the Early Psychosis Service have better social and clinical outcomes than those managed by standard community teams. The primary outcomes are relapse, readmission and detention. Secondary outcomes of interest will include clinical and social functioning, user and carer satisfaction and burden. The research will also assess fidelity to the ACT model and describe team and services processes, training and any adaptations of the model needed to target early psychosis.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**Study type(s)**

Not Specified

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

Schizophrenia and other psychoses

**Interventions**

1. Experimental group: will receive care from the Early Psychosis Service (a multi professional Assertive Community Treatment team targeted at people suffering their first or second episode of psychotic illness)
2. Control group: will receive standard care as currently delivered through existing Sector Teams for the catchment areas

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Relapse, readmission and detention at 18 months. We define relapse as any case noted record of a change in clinical state that has resulted in an increase in psychotropic medication and/or an admission to hospital.

**Key secondary outcome(s)**

Secondary outcome measures will include a range of clinical social and service use outcomes:

1. Clinical measures at all three time points:
  - 1.1. Brief psychiatric rating scale (BPRS)
  - 1.2. Positive and negative syndrome scale (PANSS)
  - 1.3. Global Assessment of Functioning (GAF) scale
  - 1.4. Calgary Depression Scale

- 1.5. Insight Scale
- 1.6. Treatment compliance at 6 and 18 months
2. Social functioning at all three time points:
  - 2.1. Employment status
  - 2.2. Housing status
  - 2.3. Benefit uptake
  - 2.4. Social network scale
  - 2.5. Life Skills Profile (LSP)
3. Patient and carer satisfaction/burden:
  - 3.1. Verona satisfaction scale
  - 3.2. Family burden at 18 months
4. Service use and costs: assessed retrospectively at 18 months based on a combination of service records and a standard instrument - the Client Service Receipt Inventory. Resource use will be identified for both treatment and control group and will include:
  - 4.1. Medication costs
  - 4.2. NHS services
  - 4.3. Local authority services accommodation
  - 4.4. Contact with criminal justice and all other services
  - 4.5. Indirect economic impacts (particularly lost employment and caregiver burden) will also be included.
5. Team process measures and fidelity - team activity logs e.g.:
  - 5.1. Contacts per client
  - 5.2. Out of hours contacts
  - 5.3. Interventions offered
  - 5.4. Adherence to ACT model

**Completion date**

01/07/2003

## **Eligibility**

**Key inclusion criteria**

1. Aged 16 - 35 years
2. Living in the catchment areas served by the team (pop. approx 150,000)
3. Presenting with a first or second episode of a psychotic disorder (International Statistical Classification of Diseases and Related Health Problems, tenth edition [ICD-10] schizophrenia spectrum disorder including unspecified non-organic psychosis)

Every effort will be made to include as many eligible patients as possible. For example, assistance of interpreters associated with the clinical service will be enlisted in order to include patients whose first language is not English..

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

Patients with primary substance use disorder will not be eligible for the study.

**Date of first enrolment**

01/01/2000

**Date of final enrolment**

01/07/2003

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Kings College London**

London

United Kingdom

SE1 7EH

**Sponsor information****Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

**Funder(s)****Funder type**

Government

**Funder Name**

NHS Executive London (UK)

**Results and Publications**

## 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	06/11/2004		Yes	No
<a href="#">Results article</a>	results	01/05/2010		Yes	No