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Brixton Early Psychosis Project

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/05/2010	Mental and Behavioural Disorders	

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
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 though existing Sector Teams for the catchment areas

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
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 psychotrophic medication and/or an admission to hospital.

Secondary outcome measures
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

Overall study start date
01/01/2000

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

Age group
Adult

Sex
Both

Target number of participants
144

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
England

United Kingdom

Study participating centre
Kings College London
London
United Kingdom
SE1 7EH

Sponsor information

Organisation

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

Sponsor details
The Department of Health
Richmond House
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (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	06/11/2004		Yes	No
Results article	results	01/05/2010		Yes	No