

Cluster randomised trial comparing outcomes of early psychosis care by a specialist team and augmented community mental health teams (CMHTs)

Submission date 02/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/11/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/09/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Sonia Johnson

Contact details

Department of Mental Health Sciences
Riding House Street
London
United Kingdom
W1W 7EY

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s.johnson@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

03/38

Study information

Scientific Title

Cluster randomised trial comparing outcomes of early psychosis care by a specialist team and augmented community mental health teams (CMHTs)

Acronym

SATS

Study objectives

That the provision of services by specialist teams for people experiencing a first psychotic episode confers no advantage over the provision of services for first episode psychosis provided by augmented non-specialist teams

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)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

First episode psychosis

Interventions

1. Specialist Early Intervention Service - a dedicated team specialising solely in the care of first episode psychosis. The team is multiprofessional and community based, has appropriate inpatient services and would be expected to maintain contact with all first episode patients for a period of 3 years.

2. Augmented community mental health teams. These community based multiprofessional teams provide general mental health services to defined geographical catchment areas. For the purpose of the trial the service will be augmented by two whole time equivalent staff who will focus solely on the care of first episode psychosis and will be expected to maintain contact with patients for a three year period.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Proportion relapsing within 2 years of entry into the trial

Secondary outcome measures

1. Time to relapse
2. Whether engaged in paid employment or education for at least 15 hours per week
3. Quality of Life (MECCA)

Overall study start date

31/01/2005

Completion date

31/01/2008

Eligibility

Key inclusion criteria

All patients with a first psychotic episode aged between 18 and 34 referred to augmented and specialist services who are resident in the catchment area of the services

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

34 Years

Sex

Both

Target number of participants

250

Key exclusion criteria

People will not be accepted for assessment if:

1. Their symptoms appear secondary to a primary diagnosis of emotionally unstable personality disorder or post-traumatic stress disorder
2. Their symptoms appear to be the clear result of drug induced psychosis, narrowly defined. Psychosis will only be viewed as drug induced if symptoms have emerged suddenly in the context of intoxication without any previous decline in functioning and if they subside within a few days
3. They have elevated mood but no psychotic symptoms
4. Their psychotic symptoms are not associated with any decline in functioning, disruption of development, distress or risk
5. They are thought to have taken antipsychotic medication for at least 6 weeks
6. They were first diagnosed as having a psychotic illness by a specialist mental health service more than 1 year ago

Date of first enrolment

31/01/2005

Date of final enrolment

31/01/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Mental Health Sciences

London

United Kingdom

W1W 7EY

Sponsor information

Organisation

Camden and Islington Mental Health and Social Care Trust (UK)

Sponsor details

St Pancras Hospital

4 St Pancras Way

London

England

United Kingdom

NW1 OPE
+44 (0)20 7530 3000
candi@nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.candi.nhs.uk>

ROR

<https://ror.org/03ekq2173>

Funder(s)

Funder type

Other

Funder Name

British Psychological Society

Alternative Name(s)

BPS

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

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

