

The London East Anglia randomised controlled trial for cognitive-behaviour therapy for psychosis: effects of the treatment phase

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/11/2022	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NMH13C

Study information

Scientific Title

The London East Anglia randomised controlled trial for cognitive-behaviour therapy for psychosis: effects of the treatment phase

Study objectives

A series of small, mainly uncontrolled, studies have suggested that techniques adapted from cognitive-behavioural therapy (CBT) for depression can improve outcome in psychosis, but no large randomised controlled trial of intensive treatment for medication-resistant symptoms of psychosis has previously been published.

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Schizophrenia and other psychoses

Interventions

Participants randomised into the treatment group received up to nine months of individual cognitive behaviour therapy for psychosis. Sessions were conducted weekly initially, and then fortnightly. Participants randomised into standard care received routine care from their clinical team, which as part of the study entry criteria consisted of case management and medication.

Intervention Type

Behavioural

Primary outcome measure

Measures were taken at baseline of demographic, clinical and cognitive variables. Changes over time were assessed on the Brief Psychiatric Rating Scale and the relationship between potential predictor variables and outcome was investigated using analysis of variance and covariance.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1993

Completion date

31/12/1997

Eligibility

Key inclusion criteria

60 participants who each had one positive and distressing symptom of psychosis that was medication resistant (28 in a treatment group received a cognitive behaviour therapy and 32 a standard care only control condition).

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

60

Total final enrolment

60

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1993

Date of final enrolment

31/12/1997

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Institute of Psychiatry

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Mental Health National Research and Development 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

Not provided at time of registration

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		01/10/1997		Yes	No
Results article		01/11/1997		Yes	No
Results article		01/07/1998		Yes	No