A multidisciplinary study of the management of neuroleptic medication in schizophrenia: Educational and collaborative approaches

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/10/2000		☐ Protocol		
Registration date 23/10/2000	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 19/02/2020	Condition category Mental and Behavioural Disorders	Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G9322371

Study information

Scientific Title

A multidisciplinary study of the management of neuroleptic medication in schizophrenia: Educational and collaborative approaches

Study objectives

- 1. To investigate the determinants of psychotic patients' adherence to prescribed neuroleptic medication
- 2. To compare two different approaches to enhancing patients' adherence to prescribed neuroleptic medication

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

Interventions

- 1. Compliance intervention (patients educated about benefits of neuroleptic medication)
- 2. Alliance intervention (structured intervention in which patients are encouraged to rationally appraise the costs and benefits of their neuroleptic medication)
- 3. Treatment as usual

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Neuroleptics

Primary outcome measure

- 1. Attitudes towards neuroleptic medication as measured by the Drug Attitudes Inventory
- 2. Psychotic symptoms as measured by the Positive and Negative Syndromes Scale

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/06/1995

Completion date

01/06/2000

Eligibility

Key inclusion criteria

Patients suffering from Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) schizophrenia or schizoaffective disorder admitted to acute psychiatric wards in the North West of England and North Wales.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

228

Total final enrolment

228

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/06/1995

Date of final enrolment

01/06/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Psychology Department

Manchester United Kingdom M13 9PL

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent London United Kingdom W1B 1AL +44 (0)20 7636 5422 clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

http://www.mrc.ac.uk

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/1998		Yes	No
Results article	results	01/02/2003		Yes	No
Results article	results	01/11/2003		Yes	No
Results article	results	01/12/2003		Yes	No
Results article	results	01/07/2005		Yes	No
Results article	results	01/07/2005	19/02/2020	Yes	No