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The impact of routine utilization of two assessment scales on management of antipsychotic-induced side effects

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 25/04/2014	**Condition category** 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
N0146155662

Study information

Scientific Title

Study objectives
To identify the effects of introduction of two assessment scales to regularly appraise antipsychotic-induced side effects in forensic psychiatric patients on management of these side effects and patients' clinical outcome.

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
Mental and Behavioural Disorders: Psychosis

Interventions
Two assessment scales

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Changes/differences in the scales ratings at the baseline and the end-assessment within the control and study group and between groups. Differences in the general mental health rating at the beginning and the end-assessment between the control and the study groups. Associations between side effects assessment and the general mental health status.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2003

Completion date
30/04/2004

Eligibility

Key inclusion criteria
30 (study) and 30 (control) patients in the Forensic Mental Health Unit, Homerton

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
30 (study) and 30 (control) patients

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/10/2003

Date of final enrolment
30/04/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Homerton Hospital NHS Trust
London
United Kingdom
E9 6SR

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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SW1A 2NL
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
East London and The City Mental Health NHS Trust (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