ISRCTN76324634 https://doi.org/10.1186/ISRCTN76324634

Adherence therapy for schizophrenia

Submission date
28/09/2011

Recruitment status
No longer recruiting

Registration date
24/02/2012

Overall study status
Completed

Last Edited
24/02/2012

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Schizophrenia is a severe mental illness that requires treatment with medication. About 1 in 2 patients stop taking medication and this makes it more likely they will become mentally unwell again (experience a relapse). The aim of this study is to find out if a talking treatment called adherence therapy will improve schizophrenia patients compliance with treatment.

Who can participate?
Men and women who are over the age of 18 and are currently in psychiatric hospital because of their schizophrenia can take part in this research project.

What does the study involve?
People taking part in the study were randomly allocated to either get eight sessions of adherence therapy or the care they would usually receive.

What are the possible benefits and risks of participating?
Taking part in the study means some patients will get the chance to have a new treatment that may help them be better at complying with their medication.
We do not anticipate that there will be any side effects from adherence therapy.

Where is the study run from?
There are four hospitals taking part in this study, three in Germany; Bielefeld, Warstein and Lippstadt and one in Switzerland; Bern. The co-ordinating centre for the project is Bielefeld.

When is study starting and how long is it expected to run for?
The study started in May 2007 and finished recruiting in July 2010.

Who is funding the study?
The trial is funded by AstraZeneca

Who is the main contact?
Dr Michael Schultz
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
D1449L00035

Study information

Scientific Title
Adherence therapy for schizophrenia: a multi centre randomised controlled trial

Study objectives
Drug intake behaviour would be better after Adherence Therapy compared to treatment as usual (TAU)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University of Münster (Germany) approved on 8th December 2006, AZ 2006-485-f-S

Study design
Multi centre single blind two arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Schizophrenia

Interventions
Intervention group: Adherence therapy (AT)+ Treatment as usual
Control group: Treatment as usual

Patients in the interventions group receive eight sessions of adherence therapy as an add-on to treatment as usual. AT is started whilst the patient is in hospital and completed two weeks after discharge. AT consists of six interventions assessments, structured problems solving, a medication timeline, exploring ambivalence, testing beliefs about medication, and sticking with treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Adherence - determined using drug serum levels (concentration to dose ratio)
2. Symptoms - measured using the postive and negative syndrome scale

Measured at baseline and 26 week follow-up

Secondary outcome measures
1. Attitudes to treatment - assessed using the drug attitude inventory
2. Functioning - determined using the global assessment of functioning

Measured at baseline and 26 week follow-up

Overall study start date
01/05/2007

Completion date
31/03/2010

Eligibility

Key inclusion criteria

1. Patients between 18 and 65 years old
2. Patients with schizophrenia will be enrolled when the initial acute psychotic symptoms are reduced (partial remission) from a clinical point of view so that they were able to provide a written informed consent
3. Clinical diagnosis of schizophrenia will be confirmed by a research diagnosis of schizophrenia, established using the International Diagnostic Checklist for ICD-10
4. Patients will be taking antipsychotic medication at the time of recruitment, and the current treating psychiatrist has recommended the individual patient to stay on antipsychotic medication for a minimum of one year.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Potential study participants will be excluded if they show acute suicidal behaviours including suicidal ideas
2. Insufficient German language capacities
3. Are administered depot medication
4. Are homeless, or suffered from a current substance or alcohol dependence (not caffeine or nicotine dependence) or mental retardation according to International Classification of Diseases (ICD-10) and Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria.
5. Patients are under compulsory treatment, if they are homeless or suffer from severe medical conditions (eg. cancer, severe infection)

Date of first enrolment
01/05/2007

Date of final enrolment
31/03/2010

Locations

Countries of recruitment
England

Switzerland

United Kingdom

Study participating centre
University of East Anglia
Norwich
United Kingdom
NR47TJ

Sponsor information

Organisation
Clinic of Psychiatry and Psychotherapy Bethel (Germany)

Sponsor details
Department of Research
Evaluation and Documentation
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca (ref: D1449L00035)

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

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