ISRCTN75841675 https://doi.org/10.1186/ISRCTN75841675

Clinical decision making and outcome in routine care for people with severe mental illness

Submission date	Recruitment status
11/08/2010	No longer recruiting
Registration date	**Overall study status**
15/09/2010	Completed
Last Edited	**Condition category**
25/01/2017	Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.cedar-net.eu

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
223290

Study information

Scientific Title
Clinical decision making and outcome in routine care for people with severe mental illness: a multicentre observational longitudinal study

Acronym
CEDAR

Study objectives
The main objective of this project is to develop a methodology to assess the scope and quality of clinical decisions in the care of people with severe mental illness (SMI) from both the patient and clinician perspective, and to specify how and to what degree clinical decision making (CDM) in routine care affects patient behaviour and short- and long-term treatment outcome.

The main study hypotheses are:
1. The quality of CDM is positively related to treatment outcome in the routine care of people with SMI
2. The quality of CDM can be adequately described by taking into account decision making styles, satisfaction with decision making, and type of decision making ("paternalistic" versus "shared" versus "informed")
3. Actual CDM in routine care depends on the context, i.e. varies for different kinds of decisions and is susceptible to change over time
4. The relation between quality of CDM and outcome is affected by a number of covariates

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ulm University Ethics Commission, 15/12/2008, ref: 241/08

Study design
Multicentre observational longitudinal panel study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Can be found at http://www.cedar-net.eu

Health condition(s) or problem(s) studied
Severe mental illness

Interventions
Before the start of recruitment, specific instruments were developed to measure CDM style, key elements of CDM in routine care, as well as CDM involvement and satisfaction from patient and therapist perspectives. Together with established instruments to assess outcome, these are being put to use in the longitudinal study in order to examine the study hypothesis. Total duration of observation per subject is 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Needs (Camberwell Assessment of Need Short Appraisal Schedule [CANSAS]), measured at timepoints t0 - t6

Secondary outcome measures
1. Quality of life (Manchester Short Assessment of Quality of Life [MANSA]), measured at timepoints t0 - t6
2. Service use (Client Sociodemographic and Service Receipt Inventory - European version [CSSRI]), measured at timepoints t0 and t6
3. Symptomatic impairment (Health of the Nation Outcome Scales [HoNOS] and Outcome Questionnaire [OQ-45]), measured at timepoints t0 and t6

Overall study start date
01/11/2009

Completion date
31/10/2011

Eligibility

Key inclusion criteria
1. Adult, aged 18 - 60 years at intake, either sex
2. Main diagnoses mental disorder of any kind established by case notes or staff communication using Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) (SCID) criteria
3. Presence of severe mental illness based upon validated criteria including symptom severity (Threshold Assessment Grid [TAG] greater than or equal to 5) and illness duration (greater than or equal to 2 years)
4. Expected contact with mental health services (excluding inpatient services) during the time of study participation
5. Sufficient command of the host country's language
6. Capable of giving informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
560

Key exclusion criteria
1. Main diagnosis of mental retardation, dementia, substance use or organic brain disorder
2. Cognitive impairment severe enough to make it impossible to give meaningful information on study instruments
3. Treatment by forensic psychiatric services

Date of first enrolment
01/11/2009

Date of final enrolment
31/10/2011

Locations

Countries of recruitment
Denmark

Germany

Hungary

Italy

Switzerland

United Kingdom

Study participating centre
Ulm University
Günzburg
Germany
89312

Sponsor information

Organisation
European Commission (Belgium)

Sponsor details
Research Directorate General
Directorate F2 - Public Health
CDMA 2/30
Brussels
Belgium
1049

Sponsor type
Government

Website
http://cordis.europa.eu/fp7/health/

ROR
https://ror.org/00k4n6c32

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme (HEALTH-2007-3.1-4) (ref: 223290)

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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?
Protocol article	protocol	10/11/2010		Yes	No
Results article	results	04/02/2013		Yes	No
Results article	results	01/02/2015		Yes	No
Results article	results	01/03/2015		Yes	No
Results article	results	01/05/2015		Yes	No
Results article	results	23/01/2017		Yes	No