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

Submission date
11/08/2010

Recruitment status
No longer recruiting

Registration date
15/09/2010

Overall study status
Completed

Last Edited
25/01/2017

Condition category
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

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Observational

Study design
Multicentre observational longitudinal panel study

Study type(s)
Diagnostic

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(s)

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

Denmark

Germany

Hungary

Italy

Switzerland

Study participating centre
Ulm University
Günzburg
Germany
89312

Sponsor information

Organisation
European Commission (Belgium)

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

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	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
Protocol article	protocol	10/11/2010		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes