

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

Submission date
11/08/2010

Recruitment status
No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date
15/09/2010

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
25/01/2017

Condition category
Mental and Behavioural Disorders

☐ 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

Contact name

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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