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COFI - Comparing Functional and Integrated systems of mental health care

Submission date
16/03/2015

Recruitment status
No longer recruiting

Registration date
25/03/2015

Overall study status
Completed

Last Edited
25/04/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Mental disorders affect 38.2% of the EU population. For reducing the associated burden, countries across Europe have been engaging in costly reforms of mental health care organisation. Reforms focus on one controversial core question: should mental health care systems be functional or integrated? In functional systems, separate clinicians and teams in different services are in charge of either inpatient or outpatient community care. This is also known as specialisation. In integrated systems, the same clinicians and teams are responsible for the patient throughout inpatient and outpatient care. So far, there is no sound research evidence to inform the debate regarding which system is best. This has far reaching implications for policy decisions. The aim of this study is to compare the performance and cost-effectiveness of the functional and integrated systems of mental health care in Europe. It will look at clinical and social outcomes and also the patient quality of life, satisfaction with care, safety and cost-effectiveness of care. We will also establish how patients and clinicians experience integrated and functional mental health care. To help us understand the results of the study, we will analyse policy documents on organisation of mental health care in each country. At the end of the study, guidelines for policy-making will be produced, specifying in what context and for which patient groups functional or integrated systems are preferable.

Who can participate?
Adults (aged at least 18) diagnosed with a mental disorder and hospitalised in a psychiatric inpatient unit.

What does the study involve?
Eligible patients are asked about their experience of hospital care, and provide consent for the researcher to access their medical records. Some of the patients are treated via functional systems of health care. Others are treated using integrated systems of health care. Each patient is contacted again 12 months later to assess the results of their treatment. Throughout the study, we work as a multi-disciplinary team (psychiatrists, psychologists, nurses, sociologists, public health experts, health economists) and follow-up at least 6000 patients with major mental disorders. This includes people with psychosis, depressive and anxiety disorders.

What are the possible benefits and risks of participating?
COFI addresses a research question which is of key importance for shaping the future organisation of mental health services and provision of mental health care. We will be able to establish which system of mental health care works best in terms of reduction of hospitalisation, improvement of social outcomes and safety and quality of care. Patients participating in the study and rating their experience of treatment may benefit as evidence suggests that assessing patient satisfaction with treatment may result in improvements. No risks related to participation are identifiable. COFI is not testing new interventions and does not investigate medicinal products. There will be no additional interventions and routine care will not be altered in any way because of a patient's participation in COFI.

Where is the study run from?
Six different hospitals from Belgium, Germany, Italy, Poland and the UK.

When is the study starting and how long is it expected to run for?
February 2014 to January 2018

Who is funding the study?
European Seventh Framework Programme

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Comparing policy framework, structure, effectiveness and cost-effectiveness of functional and integrated systems of mental health care

Acronym
COFI

Study objectives
Throughout Europe, countries are seeking to improve the organisation of mental health care with often radical reforms. These reforms are associated with far reaching changes for the national health care systems and consume large amounts of funding. Yet, the reforms are inconsistent, and all policies are currently made in the absence of any sound scientific evidence. These reforms focus on one central and controversial issue:
Should mental health care systems be functional or integrated?
The two systems can be summarised as:
1. Functional systems: care is provided by separate staff in distinct services, and the transition between services is coordinated through a network of regulated referrals;
2. Integrated systems: care is provided by the same mental health staff across different services who co-ordinate all interventions.
The overall aim of COFI is to compare the effectiveness and cost-effectiveness of the functional and integrated systems of mental health care in Europe through the use of a natural experiment. The comparison will consider clinical and social outcomes (re-hospitalization rates, symptom levels, social situation) as key performance indicators (KPIs), as well as patients' quality of life, satisfaction with care, safety and cost-effectiveness of care. Different patients subgroups defined by diagnosis, age, gender, socio-economic and migrant status, and physical comorbidities will be investigated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval has been obtained in all five countries where the study is being conducted:
1. England: NRES Committee North East - Newcastle & North Tyneside 2, 04/06/2014, ref: 14/NE/1017
2. Belgium: Comité d'Ethique hospitalo-facultaire des Cliniques St-Luc (Ethical Committee for the hospital and faculty of the St-Lucas Clinic), 29/09/2014
3. Germany: Ethical board at the Technische Universität Dresden (Ethikkommission an der Technischen Universität Dresden), 12/05/2014
4. Italy:
4.1. Comitato Etico per la sperimentazione clinica (CESC) delle provincie di Verona e Rovigo– Ethics committee for clinical research of the districts of Verona and Rovigo, 27/08/2014.
4.2. Comitato Etico per le sperimentazioni cliniche (CESC) della provincia di Vicenza –

Ethics committee for clinical research of the district of Vicenza, 14/10/2014
4.3. Comitato Etico per le sperimentazioni cliniche (CESC) della provincia di Treviso – Ethics committee for clinical research of the district of Treviso, 10/10/2014
4.4. Comitato Etico per le sperimentazioni cliniche (CESC) della provincia di Padova – Ethics committee for clinical research of the district of Padova, 17/12/2014
4.5. Poland: Komisja Bioetyczna przy Instytucie Psychiatrii i Neurologii w Warszawie (Bioethics Committee at the Institute of Psychiatry and Neurology in Warsaw), 04/09/2014

Study design
The study is a multisite (multi-country) natural experiment comparing the effectiveness and cost-effectiveness of integrated and functional systems of mental health care.

Primary study design
Observational

Secondary study design
Natural experiment

Study setting(s)
Hospital

Study type(s)
Treatment

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
Serious mental illness (ICD-10 codes F2 to F4)

Interventions
Two types of mental health systems, co-existing in the participating countries, will be compared in a natural experiment:
1. In integrated systems, after hospital admission the same clinician (psychiatrist, psychologist, nurse, social worker or occupational therapist) is in contact, in face-to-face meetings, with the patient for outpatient treatment after discharge. Thus, there is personal continuity in the treatment of the patient across inpatient and outpatient care.
2. In functional systems, after hospital admission other clinicians are in contact with the patient for outpatient treatment after discharge. Thus, there is no personal continuity in the treatment of the patient across inpatient and outpatient care.

Intervention Type
Behavioural

Primary outcome measure
Re-hospitalisation rates

Secondary outcome measures
1. Clinical outcomes: number of re-hospitalisations, compulsory re-hospitalisations, community treatment orders and yearly inpatient bed days.

2. Social outcomes: employment, accommodation, living situation, friendships, total social contacts, perceived socio-economic status and experienced discrimination.
3. Safety of care: deaths, completed suicides, serious assaults committed by patients, physical violence experienced by patients, suicide attempts, serious side effects from treatment requiring hospitalisation.
4. Costs of care: costs related to the use of inpatient services, outpatient services, day centres and other community health services.
5. Patient reported outcomes: subjective quality of life, satisfaction with care.
6. Quality of care: therapeutic alliance, continuity of care, clinical decision making processes and adherence of interventions received by patients to guidelines.

Overall study start date
01/02/2014

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. 18 years of age or older of any gender
2. Diagnosis of psychotic disorder (F20-29), affective disorder (F30-39) or anxiety disorder (F40-49)
3. Being hospitalised in a psychiatric inpatient unit
4. Sufficient command of the language of the host country to provide written informed consent and understand the questions in the research interviews
5. Capacity to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
6000

Key exclusion criteria
1. Diagnosis of organic brain disorders
2. Too severe cognitive impairment for providing meaningful information on the study instruments

Date of first enrolment
01/10/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Belgium

England

Germany

Italy

Poland

United Kingdom

Study participating centre
Queen Mary University of London
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Study participating centre
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Technische Universitaet Dresden (TUD)
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Study participating centre
Universitá Degli Studi Di Verona (UNIVR)
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Study participating centre
Institute Of The Psychiatry And Neurology (IPIN)
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Study participating centre
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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

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

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/11/2015		Yes	No
Results article	results	01/02/2018		Yes	No
Results article		18/12/2018	25/04/2023	Yes	No
Results article		14/05/2020	25/04/2023	Yes	No
HRA research summary			28/06/2023	No	No