

# COFI - Comparing Functional and Integrated systems of mental health care

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| <b>Submission date</b><br>16/03/2015   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
|  |   | <input checked="" type="checkbox"/> Protocol         |
| <b>Registration date</b><br>25/03/2015 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>25/04/2023       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> 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?

Professor Stefan Priebe

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**Protocol serial number**

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# 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

## **Study type(s)**

Treatment

## **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(s)**

Re-hospitalisation rates

## **Key secondary outcome(s)**

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.

## **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

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## 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

United Kingdom

England

Belgium

Germany

Italy

Poland

**Study participating centre**

**Queen Mary University of London**

Mile End Road  
London  
United Kingdom  
E1 4NS

**Study participating centre**

**Universite Catholique De Louvain (UCL)**

Place De L'Universite  
Louvain-La-Neuve  
Belgium  
1348

**Study participating centre**

**Technische Universitaet Dresden (TUD)**

Fetscherstrasse  
Dresden  
Germany  
01069

**Study participating centre**

**Università Degli Studi Di Verona (UNIVR)**

Via Dell' Artiglierie 8  
Verona  
Italy  
37129

**Study participating centre**

**Institute Of The Psychiatry And Neurology (IPIN)**

Sobieskiego  
Warsaw  
Poland  
-

**Study participating centre**

**King's College London (KCL)**

Strand

London

United Kingdom

SE5 8AF

## Sponsor information

### Organisation

Queen Mary University of London

### ROR

<https://ror.org/026zzn846>

## 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

### 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? |
|--------------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>      | results  | 01/02/2018   |            | Yes            | No              |
| <a href="#">Results article</a>      |          | 18/12/2018   | 25/04/2023 | Yes            | No              |
| <a href="#">Results article</a>      |          | 14/05/2020   | 25/04/2023 | Yes            | No              |
| <a href="#">Protocol article</a>     | protocol | 25/11/2015   |            | Yes            | No              |
| <a href="#">HRA research summary</a> |          |              | 28/06/2023 | No             | No              |