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Towards more effective European Community care for patients with severe psychosis

Submission date	Recruitment status	[ ] Prospectively registered
25/08/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/10/2018	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
QLG5-CT-2002-01938

Study information

Scientific Title
Towards more effective European Community care for patients with severe psychosis

Acronym
MECCA

Study objectives
The MECCA study is a cluster randomised controlled trial following the same protocol in community mental health teams in six European countries. The trial tests the hypothesis that the new intervention as compared to current best standard practice - will lead to a better outcome in terms of quality of life, compliance with medication, needs for care, treatment satisfaction, and the quality of the therapeutic relationship between keyworker and patients with psychotic disorders over a one year period. Changes in psychopathology are not hypothesised to differ between the two groups. The research question regarding costs is purely exploratory.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Psychosis

Interventions
Key workers are randomly assigned to either the intervention or treatment as usual condition. Randomisation of key workers will be stratified by professional background (ASW, CPN, psychiatrist etc.) and by the number of patients within each key worker's caseload consenting to participate. Patients would be asked for informed consent prior to their key worker being randomised. Whilst the control group will receive treatment as usual in line with current best

practice, the intervention group will, in addition to treatment as usual, receive an innovative intervention. The key worker asks patients about their subjective quality of life, treatment satisfaction and wishes for additional/different support using a brief questionnaire. The questionnaire (MECCA) consists of satisfaction ratings with eight life domains (satisfaction with mental and physical health, accommodation, job situation, leisure activities, friendships, relationship with family/partner, personal safety) and three aspects of treatment (satisfaction with practical help, psychological help and medication). Each satisfaction item will be rated on a 1 to 7 rating scale and followed by a question on whether the patient wishes for additional /different support in the given area reflecting subjective needs for change. The assessment is completed by the key worker and patient every two months. Key workers will enter patients answers onto a laptop or palm top computer using software specifically designed for the project, with patients ratings presented in a user-friendly colour display detailing scores on each outcome measure. It is expected that the results will directly feed into the therapeutic dialogue and be discussed by the patient and key worker together. The discussion is intended to address in particular all areas where the patients expressed dissatisfaction and ratings that have changed since the previous assessment.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Outcome in the two groups will be compared in a pre-post-design. The primary outcome is quality of life. To assess objective and subjective quality of life, the Manchester Short Assessment of Quality of Life (MANSA) will be used at baseline and follow-up (12 months).

Secondary outcome measures
Subjective outcome criteria include satisfaction with treatment, needs, treatment compliance, assessment of the therapeutic relationship and patient empowerment. Objective outcome criteria are observer rated psychopathology and costs.

Overall study start date
01/07/2002

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Inclusion criteria for key workers are a professional qualification in mental
health and a minimum of one-year professional experience in an outpatient setting. Out of the caseload of each key worker patients who fulfil the following criteria will be identified: living in the community and treated as outpatients by community mental health teams; a history of at least 3 months of continuous care in the current service; a diagnosis of functional psychosis according to International Statistical Classification of Diseases and Related Health Problems - tenth revision (ICD-10), i.e. schizophrenia and other psychotic disorders; aged between 18 and 65 years of age; having at least one contact with their key worker every two months; capable of giving informed consent; and sufficient knowledge of the language of the host country.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
480

Key exclusion criteria
Living in 24 hour supported hostel type of accommodation; severe physical handicap, organic psychiatric illness or primary substance abuse (however, dual diagnosis as such is not an exclusion criterion); expectation of clinicians to discharge the patient from the service within the next 12 months.

Date of first enrolment
01/07/2002

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Unit for Social and Community Psychiatry
London
United Kingdom
E13 8SP

Sponsor information

Organisation
European Commission

Sponsor details
DGRTD-F5
Brussels
Belgium
B-1049
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Sponsor type
Other

Website
http://www.cordis.lu/fp5/

ROR
https://ror.org/00k4n6c32

Funder(s)

Funder type
Other

Funder Name
European Commission (Contract number: QLG5-CT-2002-01938)

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

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	01/07/2002		Yes	No
Results article	results	01/11/2007		Yes	No