

Randomised controlled trial (RCT) on qualitative analysis of internal and external care management in severe mental illness

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/12/2010	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RBK99XX8

Study information

Scientific Title

Study objectives

1. To compare two models of care management for patients with severe mental illness. These models involve care management functions being provided
 - i. Internally within a fully integrated NHS team providing a community rehabilitation service (the intervention) and
 - ii. Externally.
2. To formally test the hypothesis that internal care management will deliver enhanced outcomes of reduced hospitalisation and costs and improved clinical outcome and satisfaction with care, when compared to external care management.
3. To identify aspects of the care management process which distinguish internal and external case management and to assess factors which appear to influence the outcomes observed.
4. With reference to the arrangements implemented in a non-experimental setting (Nottingham) to compare this to the experimental setting to explore the differences between the models.
5. To use the results of both experimental and qualitative investigations to develop a multi-site randomised controlled trials. This will test hypotheses developed on the basis of findings from the proposed study and assess the value of an intervention refined on the basis of both qualitative and qualitative insights from the proposed study.

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

Mental and behavioural disorders: Schizophrenia and other psychoses; Mental and behavioural disorders: Depression, anxiety, neuroses

Interventions

To compare two models of care management for patients with severe mental illness. These models involve care management functions being provided:

- i. Internal model of care within a fully integrated NHS team providing a community rehabilitation service (the intervention)
- ii. External model of care

Intervention Type

Other

Phase

Phase I/II

Primary outcome measure

The primary outcome measure will be the duration of psychiatric in-patient care during the six months of the study. This has been found to be a sensitive measure in previous studies and, if integrated care and case management is beneficial, is likely to be demonstrated first in fewer hospital admissions of shorter duration. Secondary outcome measures include number of admissions, improvement in clinical and social functioning, costs and satisfaction with care. Results will be disseminated by workshops and seminars locally in Nottingham and Paddington and more widely at centres in the Trent and North Thames regions: through national conferences; and through publications submitted to peer-reviewed journals covering all mental health disciplines.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/1999

Completion date

28/02/2001

Eligibility

Key inclusion criteria

Phase I - 21 interviews (the "internal" CRAFT care manager, 5 CRAFT case managers, 5 "external" care managers with clients from the experimental study population, 5 care managers and 5 NHS care managers from the non experimental setting).

Phase II - 20 patients will be sampled, 10 from each site and both respective care managers and NHS case managers will be interviewed (i.e. 40 interviews).

- i. RCT - all patients under the care of CRAFT who are referred for care management between 1 August 1999 and 31 July 2000. Referral criteria include: age between 16-65; diagnosis of severe mental illness; at least 2 hospital admissions in last 10 years; known to existing community or in-patient psychiatric services; under the highest level of the Care Programme Approach; to qualify for care management; to reside in the catchment area of North West London Mental Health NHS Trust.

ii. Cases are to be selected purposively to accommodate range and diversity in order to generate robust explanations and to make valid and reliable generalisations.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

20

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/1999

Date of final enrolment

28/02/2001

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Division of Neuroscience & Psychological Medicine

London

United Kingdom

W2 1PD

Sponsor information**Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

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Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive Trent

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?
Results article	results	01/01/2004		Yes	No