

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

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 01/12/2010	<b>Condition category</b> 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

### Contact name

Prof Peter Tyrer

### Contact details

Division of Neuroscience & Psychological Medicine  
Mental Health & Liaison Services Research Group  
Imperial College School of Medicine  
Paterson Centre  
20 South Wharf Road  
London  
United Kingdom  
W2 1PD  
+44 (0)171 886 1648/1655  
p.tyrer@ic.ac.uk

## 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

Richmond House

79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

**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?
<a href="#">Results article</a>	results	01/01/2004		Yes	No