

# Randomised controlled effectiveness trial of a needs-based psychosocial intervention service for carers of people with schizophrenia

<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> 02/04/2008	<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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

## Study objectives

To test the effectiveness of a needs-based family intervention service for patients recruited as out-patients and their carers, including those of low expressed emotion status.

## 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

Schizophrenia and other psychoses

## Interventions

Intervention group: Needs based intervention service in addition to treatment as usual

Control group: Treatment as usual alone

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome measure

Not provided at time of registration

## Secondary outcome measures

Not provided at time of registration

**Overall study start date**

01/01/1998

**Completion date**

31/12/1998

## **Eligibility**

**Key inclusion criteria**

1. A clinical International Classification of Diseases, Tenth revision (ICD-10) diagnosis of schizophrenia, schizoaffective disorder or delusional disorder
2. Minimum of two years history of illness
3. One relapse of psychotic symptoms requiring hospital admission in the two years preceding the study entry

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

Organic brain disease or learning difficulties

**Date of first enrolment**

01/01/1998

**Date of final enrolment**

31/12/1998

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Academic Department of Clinical Psychology  
Ashton-under-Lyne

United Kingdom  
OL6 9RW

## 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 North West (UK)

## 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	01/06/1999		Yes	No