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Evaluation of a carers' support programme

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/09/2012	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
PSI12-11

Study information

Scientific Title

Study objectives
The major aim of the study was to evaluate the effectiveness of a carer's support programme of intermediate intensity and duration. A secondary aim was to evaluate the adequacy of a stress-appraisal-coping model of caregiving.

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)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Schizophrenia and other psychoses

Interventions
1. Carers' support programme of intermediate intensity and duration, comprising of 6 individual family sessions in the carers' home followed by 12 fortnightly relatives' groups.
2. 'Standard care'.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. General Health Questionnaire (GHQ)
2. Assessment of physical status
3. Experience of Caregiving Inventory (ECI)
4. Involvement Evaluation Questionnaire (IEQ)

5. Brief Psychiatric Rating Scale (BPRS)
6. Health of the Nation Outcome Scales (NoNoS)
7. Camberwell Assessment of Needs (CAN)
8. Life Skills Profile (LSP)
9. Ways of Coping (WOC)
10. The Positive and Negative Affects Scale (PANAS)
11. Provision of Social Relationships (PSR)
12. Family Environment Scale (FES)

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/1996

Completion date
01/09/1999

Eligibility

Key inclusion criteria
Carers were relatives of patients suffering from a psychotic illness - schizophrenia, schizoaffective disorder, bipolar affective disorder or psychotic depression - under the care of the mental health services. All eligible carers in a defined catchment area of inner southeast London were identified and offered participation in the project.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/03/1996

Date of final enrolment
01/09/1999

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Institute of Psychiatry
London
United Kingdom
SE5 8AZ

Sponsor information

Organisation
Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Primary and Secondary Care Interface National Research and Development Programme (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?
Results article	results	01/08/2003		Yes	No