Evaluation of a carers' support programme

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 |