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A randomised comparison of two levels of an intervention to work with relatives of alcohol and drug users in primary care

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
14/01/2009

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

RGC00393

Study information

Scientific Title

Study objectives
To establish the effectiveness of an intervention designed to be used with patients in the primary care setting who are affected by the alcohol or drug problem of a relative. Each approach will be developed from existing evidence and based on the stress-coping-health model. The research aims to establish the most cost effective service for this client group within the primary care setting and by comparing the two approaches establish the key components of the intervention that lead to a positive outcome.

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)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Alcohol/drug addiction

Interventions
The approaches will differ in the extent of input provided by the primary care professional
1. Self-help manual with minimal input
2. Self-help manual with a five step structured package including discussion on stress, coping and social support

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The main outcome measures are:
For the relatives:
1. Total score on the Symptom Rating Test
2. Total and subscale scores on the Coping Questionnaire (Subscales: Engaged, Tolerant and Withdrawal)
3. In addition, categorical data on the engagement in treatment of the person with the alcohol /drug problem during the period of the intervention including whether the person engages in treatment (i.e. new episode) or remains in treatment (in cases where the person is already in contact with a service)

For the PHCPs:
Total and subscale scores on the adapted version of the Alcohol and Alcohol Problems Perception Questionnaire

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2000

Completion date
01/04/2002

Eligibility

Key inclusion criteria
Relatives of people with alcohol/drug problems are included if:
1. The relative considered that the drinking or drug taking of another member of the family had been a major source of distress
2. The relative with the alcohol/drug problem had been drinking or consuming drugs at some time during the last six months
3. The alcohol/drug user and relative had been living under the same roof at some point during the last six months

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
143

Key exclusion criteria
Those relatives of alcohol/drug users experiencing alcohol and drug problems themselves will be excluded from the study as it would be difficult to clearly separate the problems caused by their own use of substances as opposed to that of their relatives.

Date of first enrolment
01/04/2000

Date of final enrolment
01/04/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Psychology
Birmingham
United Kingdom
B15 2TT

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 West Midlands (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	01/01/2009		Yes	No