

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	☐ Prospectively registered
Registration date 23/01/2004	Overall study status Completed	☐ Protocol
Last Edited 14/01/2009	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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

United Kingdom

England

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

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive West Midlands (UK)

Results and Publications

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