

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

☒ 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

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