

# Reducing long-term benzodiazepine use: effectiveness and cost-effectiveness of two minimal interventions and development of guidelines for case management

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<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/04/2012	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## 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

PCC16 T84 8846

# Study information

## Scientific Title

Not provided at time of registration

## Study objectives

Recent studies have shown that two inexpensive interventions (a brief GP consultation and a letter from the patients GP) can be effective in leading to reduced benzodiazepine (BZD) intake in long-term users. In a randomised controlled trial, we will directly compare the effectiveness and cost-effectiveness of these two interventions and search for patient and other variables predictive of successful and unsuccessful response to intervention. We will then use the results to develop a set of guidelines for rational deployment of three levels of intervention against long-term BZD use:

1. A GP letter advising gradual reduction
2. A short GP consultation plus self-help booklet
3. Specialised intervention at a benzodiazepine withdrawal clinic

## 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

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Depression, anxiety, neuroses

## Interventions

1. A brief GP consultation
2. A letter from the GP advising gradual reduction

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Benzodiazepine

**Primary outcome measure**

Effectiveness in curtailing long term use of benzodiazepines and cost-effectiveness of the two interventions.

The main outcome measure was change in BZD intake between the six-month periods before and after the intervention. This was taken from practice prescription records and was available for all 273 patients entering the analysis. BZD intake for each patient was converted to a standard measure of 10 mg diazepam equivalents (Ashton, 1994).

**Secondary outcome measures**

A subsidiary outcome measure was whether or not the patient was a "true reducer", defined as having reduced BZD intake by a quarter or more, including those who had stopped intake completely.

**Overall study start date**

24/03/1997

**Completion date**

23/03/1999

**Eligibility****Key inclusion criteria**

Patients on benzodiazepines.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

284

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

24/03/1997

**Date of final enrolment**

23/03/1999

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****Centre for Alcohol and Drug Studies**

Newcastle upon Tyne

United Kingdom

NE1 6UR

**Sponsor information****Organisation**

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

**Sponsor details**

The Department of Health

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**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

# Funder(s)

## Funder type

Government

## Funder Name

NHS Executive Northern and Yorkshire (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?
<a href="#">Results article</a>	results	01/10/2001		Yes	No