

# A double-blind randomised placebo-controlled trial of symptom-triggered alcohol detoxification on a general psychiatric ward

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/11/2015	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

N0151123769

# Study information

## Scientific Title

A double-blind randomised placebo-controlled trial of symptom-triggered alcohol detoxification on a general psychiatric ward

## Study objectives

To test the null hypothesis that there is no significant difference in length of hospital stay between subjects administered symptom-triggered alcohol detoxification and those receiving a detoxification according to usual clinical practice.

## 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)

Treatment

## 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

Mental and Behavioural Disorders: Alcohol dependence

## Interventions

Double blind randomised control trial of two methods of alcohol detoxification. Randomised to 'symptom-triggered alcohol detoxification' or detoxification according to 'usual clinical practice'.

## Intervention Type

Other

## Phase

Not Specified

### **Primary outcome measure**

1. Description of demographics: means, confidence intervals, medians, ranges.
2. Duration of detoxification: means, confidence intervals, t-tests.
3. Rates of completion of detoxification: percentages, chi-square.
4. Intensity of withdrawal symptoms: repeated measures analysis of variance (ANOVA).
5. Overall patient satisfaction: means, t-test.
6. Occurrence of complications of withdrawal: qualitative analysis for physical complications; repeated measures ANOVA for psychiatric symptoms.
7. Total medication used: means, t-tests.
8. Prognostic indicators for various outcomes: ANOVA, analysis of covariance (ANCOVA), linear and logistic regressions.

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

01/04/2003

### **Completion date**

30/03/2004

## **Eligibility**

### **Key inclusion criteria**

70 patients admitted to one ward and who are identified by staff as requiring alcohol detoxification at the point of admission, and who meet International Statistical Classification of Diseases and Related Health Problems - tenth revision (ICD10) criteria for alcohol dependency.

### **Participant type(s)**

Patient

### **Age group**

Not Specified

### **Sex**

Not Specified

### **Target number of participants**

70

### **Key exclusion criteria**

Does not meet inclusion criteria

### **Date of first enrolment**

01/04/2003

### **Date of final enrolment**

30/03/2004

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**CDAT**

Harlow

United Kingdom

CM20 1DL

## **Sponsor information**

**Organisation**

Department of Health

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

North Essex Mental Health Partnership NHS Trust (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