

# A randomised controlled trial of the effectiveness and cost-effectiveness of nurse-led screening and brief alcohol interventions (SBI) in primary health care (PHC)

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 01/11/2022	<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**

rctc122 RES2301/7001

## **Study information**

### **Scientific Title**

A randomised controlled trial of the effectiveness and cost-effectiveness of nurse-led screening and brief alcohol interventions (SBI) in primary health care (PHC)

### **Study objectives**

Pragmatic cluster randomised controlled trial aiming to evaluate the impact of nurse-led screening and brief alcohol intervention compared to current standard practice in primary care. Hypothesis was that brief intervention would be more effective at reducing risky alcohol consumption than routine advice.

### **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)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

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

Alcohol dependence

### **Interventions**

This is a pragmatic trial with cluster randomisation of practices. Nurses from the randomly selected practices will screen patients to identify excessive drinking and carry out baseline assessments with excessive drinkers who consent to the trial. Thereafter, SBI nurses provide brief intervention according to a structured protocol whilst controls provide advice as per

standard treatment. Study outcome measures are assessed at 12 months after intervention. Longer term follow-up of patients is planned for 36 months after intervention but will be contingent on finding effects at 12 months.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Weekly alcohol consumption (units), assessed at 12 months after intervention.

**Secondary outcome measures**

1. Drinking problems index, assessed at 12 months after intervention.
2. Screening score, assessed at 12 months after intervention.
3. Quality of life (12-item short form health survey [SF12]), assessed at 12 months after intervention.

**Overall study start date**

01/01/1999

**Completion date**

31/12/2002

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

1. Patients (male and female) aged 16+ years
2. Attending primary care nurses (practice nurses, district nurses, health visitors, midwives and community psychiatric nurses [CPNs]) in practices from the former Yorkshire Regional Health Authority area
3. Men scoring 8+ and women scoring 7+ on the AUDIT screening questionnaire
4. Consent

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

127

**Total final enrolment**

127

**Key exclusion criteria**

1. Current major physical or psychiatric illness
2. Severe alcohol dependence
3. Severe brain damage or mental impairment

**Date of first enrolment**

01/01/1999

**Date of final enrolment**

31/12/2002

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

England

United Kingdom

**Study participating centre**

**The Department of Primary Health Care**

Newcastle upon Tyne

United Kingdom

NE2 4AA

**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 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

Not provided at time of registration

## 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>		01/06/2004		Yes	No
<a href="#">Results article</a>		01/05/2006		Yes	No