

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

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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

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)

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications

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?
Results article		01/06/2004		Yes	No
Results article		01/05/2006		Yes	No