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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

Registration date
23/01/2004

Overall study status
Completed

Last Edited
01/11/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] 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
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?
Results article		01/06/2004		Yes	No
Results article		01/05/2006		Yes	No