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Efficacy of physician-delivered brief counselling intervention for binge drinkers: randomised controlled trial in primary care practice

Submission date
30/07/2008

Recruitment status
No longer recruiting

Registration date
21/08/2008

Overall study status
Completed

Last Edited
24/11/2008

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
binger01

Study information

Scientific Title

Efficacy of brief interventions (BI) for binge drinkers

Acronym
BINGER

Study objectives
To test the effect of brief interventions (BI) in a sample consisting exclusively of binge drinkers.

Please note that, as of 24/11/2008, the following amemndments were made to this trial record due to errors in inforamtion provided at time of registration:

1. Start and end dates were amended from 01/11/2008 and 01/11/2008 to 01/03/2003 and 01/03/2006, respectively
2. The target number of recruitment was changed from 2,433 to 752. The former is the number of participants who screened positive (i.e. binge drinking pattern and Alcohol Use Disorders Identification Test [AUDIT] score 15 or lower), whereas the latter is the number of participants who were randomised to the trial arms

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University Hospital "12 de Octubre" (Hospital Universitario 12 de Octubre). Date of approval: 23/04/2008 (ref: 2008-45-2)

Primary study design
Interventional

Study design
Multi-centre, randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
High-risk alcohol drinkers

Interventions
This is a randomised controlled trial with a 12-month follow-up period conducted by 74 physicians in 20 primary care centres in Spain.

The brief intervention by the physician consisted of 2 short counselling sessions 4 weeks apart. Each 10 to 15-minute face-to-face counselling session was offered within the context of routine patient care by a physician using a scripted workbook. The intervention workbook included a review of alcohol-related health effects, a pie chart displaying the frequency of different types of at-risk drinkers, a list of methods for cutting down drinking, a treatment contract, and cognitive behavioural exercises.

Subjects assigned to the control group received a booklet on general health issues and were followed up at 6 and 12 months. They were instructed to address any health concerns in their usual manner.

Please use the following contact details to request a patient information sheet:
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Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Change in alcohol use: number of binge episodes (>5 drinks for men and >4 drinks for women on a single occasion) in the previous month and the percentage of bingers, assessed at baseline, 6 and 12 months.

Key secondary outcome(s)
Changes in weekly alcohol consumption and rates of excessive drinking in the previous 7 days (more than 18 drinks per week for men and more than 13 drinks per week for women), assessed at baseline, 6 and 12 months.

Completion date
01/03/2006

Eligibility

Key inclusion criteria
All adults patients aged 18 to 65 years of age will be asked to undergo alcohol use disorders screening (Alcohol Use Disorders Identification Test [AUDIT]) (Rubio et al., 1998) by their primary care physicians (PCPh). All patients who screen positive will be contacted and invited to participate in a face-to-face interview to determine their eligibility for the trial. Patients will be eligible for the randomised trial if they report a pattern of binge drinking and score 15 or lower on the AUDIT (scores above 15 were referred to the Drug Abuse Programme for Treatment). Patients eligible for the study will be binge drinkers, defined as men who had drunk 5 or more standard drinks per occasion (12.8 g of alcohol per drink) on 1 or more occasions in the previous month. Women will be included in the study sample if they had drunk 4 or more standard drinks per occasion on 1 or more occasions in the previous month.

Rubio, G., Bermejo, J., Caballero, C., Santo-Domingo, J. Validación del test de identificación de trastornos por uso de alcohol (AUDIT) en atención primaria (Spanish validation of the Alcohol Use Disorders Identification Test [AUDIT] in primary care). Rev Clin Esp 1998; 198: 11-14.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pregnant women
2. Plan to move out of the area within the year
3. Do not have a telephone
4. Those who are already participating in an alcohol intervention programme
5. Those who have an Axis I psychiatric disorder (American Psychiatric Association [APA] 2000) other than substance abuse that, in the judgment of the PCPh, prevents them from participating
6. Unable to complete the informed consent

Date of first enrolment
01/03/2003

Date of final enrolment
01/03/2006

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitario 12 de Octubre
Madrid
Spain
28047

Sponsor information

Organisation
Brain and Mind Foundation (Fundacion Cerebro y Mente) (Spain)

ROR
https://ror.org/025e2dr05

Funder(s)

Funder type
Research organisation

Funder Name
Brain and Mind Foundation (Fundacion Cerebro y Mente) (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration