ISRCTN55274820 https://doi.org/10.1186/ISRCTN55274820

The effectiveness and cost effectiveness of screening and stepped-care intervention for alcohol use disorders in the primary care setting

Submission date
15/08/2006

Recruitment status
No longer recruiting

Registration date
04/12/2006

Overall study status
Completed

Last Edited
09/12/2010

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
N/A

Study information

Scientific Title

Acronym
STEPWICE

Study objectives
1. Screening and stepped care interventions for alcohol use disorder are as effective as minimal interventions in primary care.
2. Screening and stepped care interventions for alcohol use disorder are as cost-effective as minimal interventions in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Iechyd Morgannwg Health Local Research Ethics Committee approval gained on 5th July 2000.

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

Health condition(s) or problem(s) studied
Alcohol Use Disorders

Interventions
Stepped Care Intervention (SCI):
This consists of three care steps:
a. All SCI subjects receive one 40-minute session of Brief Motivational Intervention (BMI) in the general practice setting conducted by a trained Practice Nurse (PN). This intervention will be manual-guided using the method of Rollnick et al. All SCI subjects will then be followed-up by the PN with a phone call at two weeks, and face-to-face interview at one month post intervention in the primary care setting to assess response to the intervention. Subjects not improved will be referred to Step b.
b. Manual-guided, outpatient Motivational Enhancement Therapy (MET) (four one hour sessions

over two weeks) adapted from the Medical Research Council (MRC) funded UK Alcohol Treatment Trial intervention protocol (similar to the MET intervention used in Project MATCH), conducted by a trained Addiction Prevention Practitioner (APP) attached to the collaborating practices. The APP model has been described by Ghodse et al. This will be followed by a further phone call at two weeks and a follow-up face-to-face interview at one month post-MET by the PN to assess response to intervention.
c. Subjects not improved will be referred to a specialist Community Alcohol Team (CAT) to receive specialist treatment (including, as necessary, inpatient care, outpatient counselling, group therapy, relapse prevention treatment, medication) with no limit on duration or intensity of Intervention.

Control intervention:
Minimal intervention will consist of one five minute session of advice to cut down drinking conducted by the trained PN and provision of an information leaflet on services available locally for problem drinkers, and a self-help booklet. The minimal intervention will also be manual guided.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Alcohol consumption obtained using the Time Line Follow-Back interview method (TLFB). This method will be used to provide two measures identical to the primary outcome measures used in project MATCH (Project MATCH Research Group, 1997), namely:
1. Mean number of Drinks per Drinking Day (DDD)
2. Percentage of Days Abstinent (PDA)

Secondary outcome measures
1. Alcohol-related problems: Alcohol Problems Questionnaire (APQ)
2. Blood investigations (Gamma-GlutamylTransferase [GGT], Carbohydrate-Deficient Transferrin [CDT-Axis], Mean Corpuscular Volume [MCV])
3. Health related Quality of Life (Euroqol questionnaire [EQ-5D], Short Form health surveys [SF-36, SF-12])
4. Health economic measures
5. Patient compliance (using attendance records)
6. Patient and clinician satisfaction using scales developed by the Kings College Group.

Alcohol consumption and secondary measures 1, 2, & 3 will be included in the baseline assessment to:
a. test the adequacy of matching between groups, and
b. to act as covariates in subsequent analyses to control for baseline values.

The Severity of Alcohol Dependence Questionnaire (SADQ), the Situational Confidence Questionnaire (SCQ) and the short Readiness to Change Questionnaire will also be administered at baseline and later investigated as predictors of outcome and care step utilisation.

Overall study start date
01/06/2000

Completion date
31/05/2003

Eligibility

Key inclusion criteria
1. Male
2. Age 18 to 65 (the reason for limiting the age range is that patients above and below this range are catered for by different services in Step 3)
3. Alcohol Use Disorders Identification Test (AUDIT) score more than or equal to eight
4. Diagnosis of an Alcohol Use Disorder according to the Internation Classification of Diseases (ICD-10) (hazardous or harmful drinking, alcohol dependence) as assessed by the baseline research interview
5. Consent to participate in either treatment, and follow-up
6. Willing to nominate an independent informant who the research team can contact to obtain information at baseline and during follow-up, and to nominate a locator who will be able to assist in tracing the subject at follow-up (the independent informant and locator may be the same person)
7. Stable place of residence
8. Living within commuting distance of the practice
9. No treatment for substance misuse in previous 30 days

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
236

Key exclusion criteria
1. Current severe mental illness
2. Primary drug dependence (except nicotine and cannabis)
3. Severe physical illness that would preclude participation
4. Current legal problems likely to interfere with follow-up
5. Severe brain damage or mental impairment

Date of first enrolment
01/06/2000

Date of final enrolment
31/05/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor information

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Funder(s)

Funder type
Government

Funder Name

Wales Office of Research and Development (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2009		Yes	No