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Is treatment of alcohol dependence equally effective when carried out in primary care as in a specialized alcohol dependence clinic?

Submission date
09/01/2013

Recruitment status
No longer recruiting

Registration date
09/07/2013

Overall study status
Completed

Last Edited
30/01/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In Sweden 4 % of the population is estimated to fulfill criteria for alcohol dependence. A majority of these individuals with good social and psychiatric conditions suffer from mild to moderate severity of dependence. There are effective treatment methods for alcohol dependence today. However, only 20% of the dependent population receives treatment today, and the treatment facilities are mostly adjusted for the more severely affected patients. Several research studies indicate that a larger proportion of individuals with alcohol dependence would seek treatment for their problems if they found suitable treatment facilities. For individuals with mild to moderate alcohol dependence, primary care and occupational health services may be ideal treatment facilities. Historically, treatment within primary care has mainly been in the form of screening and brief intervention (1-2 advisory sessions) for individuals with a hazardous alcohol consumption. However, recent research has shown that structured and moderately extensive treatment programs can be carried out by doctors and nurses with no specialized competence within the field of dependence treatment. In the present study, the effectiveness and feasibility of implementing a treatment model for alcohol dependence within primary care is studied.

Who can participate?
Male and female, >18 years of age with alcohol dependence.

What does the study involve?
300 alcohol dependent patients are treated either within a primary care unit or within a specialized treatment facility. The treatment method is an extended brief intervention model comprising any or a combination of the following: 1) Assessment (biological markers and questionnaires plus follow up session; 2) Pharmacological treatment (treatment with the medicinal drugs acamprosate, naltrexone, disulfiram, nalmefene) and a manualized psychosocial treatment comprising four sessions covering the following topics: goal with alcohol consumption (no consumption or controlled consumption), handling risk situations, setting up a coping skills plan and implementation/maintenance. Pharmacological and psychosocial treatment can be provided either alone or in combination.

What are the possible benefits and risks of participating?
No specific benefits or risks will be expected from participating in the study.

Where is the study run from?
The study is carried out within 15 primary care units in the Stockholm municipality and a specialized unit within Addiction Centre Stockholm.

When is the study starting and how long is it expected to run for?
The study will take place between mid 2013 and June 2016.

Who is funding the study?
The study is funded by the Swedish Council for Working Life and Social Research (FAS) and by the regional agreement on medical training and clinical research (ALF) between Stockholm County Council and Karolinska Institutet.

Who is the main contact?
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Study website
http://www.riddargatan1.se/tap

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
Treatment of Alcohol dependence in Primary care - implementation and effects

Acronym
TAP

Study objectives
Current hypothesis as of 23/08/2013:
For patients with mild to moderate severity of alcohol dependence, participating in an extended brief intervention (psychosocial and/or pharmacological treatment) carried out within primary care will be equally effective as when carried out within a specialized treatment facility for alcohol dependence measured by change in participants´ alcohol consumption (grams per week)

Previous hypothesis:
For patients with mild to moderate severity of alcohol dependence, participating in an extended brief intervention (psychosocial and/or pharmacological treatment) carried out within primary care will be equally effective as when carried out within a specialized treatment facility for alcohol dependence as measured by number of days with any alcohol consumption and number of days with heavy drinking during 6 and 12 months after inclusion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional ethics board in Stockholm, 07/11/2012, ref: (Dnr 2012/1760-31/1)

Study design
Single-centre non-inferiority randomized controlled trial between-groups design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Alcohol dependence

Interventions
Extended brief intervention (psychosocial and/or pharmacological treatment) conducted by either primary care or a specialized clinic for a dependence treatment.

Patients are treated for 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 23/08/2013:

Change of weekly alcohol consumption measured in grams of alcohol at baseline, defined as 30 days before inclusion, compared to 12 months after start of treatment, defined as 30 days before the 12-month follow-up visit. Comparisons will be made between participants treated in primary care and specialist care.

Previous primary outcome measures:

1. Proportion of days with any drinking during treatment and follow-up
2. Proportion of days with heavy drinking during treatment and follow-up

Measured at 6 and 12 months following inclusion in study

Secondary outcome measures
Current secondary outcome measures as of 23/08/2013:

All with baseline measures compared with measures at follow-up 6 and 12 months after start of treatment in the study, except for the first measure with follow-up 6 months after inclusion in the study.

1. Change of weekly alcohol consumption measured in grams of alcohol
2. Change of days with heavy drinking (cut off women > 3/men >4 standard units with 12 grams of alcohol) per week
3. Change of hazardous and harmful drinking
4. Change of degree of alcohol dependence
5. Change of consequences of drinking
6. Change of symptoms of anxiety and depression
7. Change of quality of life
8. Change of levels of carbohydrate-deficient transferring (CDT)
9. Change of levels of aspartate aminotransferase (AST)
10. Change of levels of alanine aminotransferase (ALT)
11. Change of levels of gamma-glutamyltransferase (GGT)

Measure at follow-up 6 and 12 months after start of treatment in the study.
12. Satisfaction with treatment

Comparisons will be made between participants treated in primary care and specialist care.

Previous secondary outcome measures:

1. Severity of dependence
2. Psychiatric health
3. Percieved quality of life
4. Biological markers

Measured at 6 and 12 months following inclusion in study

Overall study start date
01/04/2013

Completion date
01/06/2016

Eligibility

Key inclusion criteria
1. Alcohol dependence according to ICD-10 criteria
2. Male and female, >18 years of age
3. Housing in Stockholm municipality

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Extensive social problems
2. Withdrawal symptoms
3. Abuse or dependence of other substances apart from alcohol and/or nicotine
4. Severe psychiatric and/or somatic illness
5. Non-Swedish speaking

Date of first enrolment

28/10/2013

Date of final enrolment
04/03/2015

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institutet
Stockholm
Sweden
11435

Sponsor information

Organisation
Addiction Centre Stockholm (Beroendecentrum Stockholm) (Sweden)

Sponsor details
Folkungagatan 44
Stockholm
Sweden
11895

Sponsor type
Hospital/treatment centre

Website
http://www.beroendecentrum.com

ROR
https://ror.org/04g380834

Funder(s)

Funder type
Research council

Funder Name

Swedish Council for Working Life and Social Research (Sweden) (2012-0567)

Alternative Name(s)
Swedish Council for Working Life and Social Research, FAS

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Sweden

Funder Name
Swedish Research Council funding for clinical research in medicine (Sweden) (20120273)

Results and Publications

Publication and dissemination plan
We are planning on publishing the results from the 6-month follow-up and the 12-month follow-up (in two separate papers) during 2016. Further analysis of the data to be confirmed at a later date.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results of 6-month follow-up	01/07/2018	30/01/2019	Yes	No