

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

<b>Submission date</b> 09/01/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/07/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/01/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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?  
Professor Sven Andreasson  
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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 transferrin (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. Perceived 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?
<a href="#">Results article</a>	results of 6-month follow-up	01/07/2018	30/01/2019	Yes	No