

# The importance of one initial month of abstinence in the treatment of alcohol dependence with a goal of controlled drinking: effects on alcohol consumption and health at short- and long-term follow-up

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/06/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 04/12/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Many patients with alcohol problems wish to reduce their drinking without abstaining totally. It is unclear whether it would be beneficial for these patients to start treatment with a month of abstinence. The aim of this study is to test whether a month of abstinence before treatment with an aim of controlled drinking results in better treatment outcomes.

### Who can participate?

Patients aged over 18 years with alcohol dependence seeking treatment with a goal of controlled drinking

### What does the study involve?

Participants are randomly allocated to 1 month of initial abstinence or to treatment as usual without such initial abstinence. All participants have a treatment goal of controlled drinking. They are offered the same treatment options: cognitive behavioural therapy (CBT) combined with pharmacological treatment.

### What are the possible benefits and risks of participating?

One month of sobriety may be beneficial for health. Both treatments are likely to reduce alcohol consumption. The risks of participating are small as participants are alcohol-dependent with long-standing heavy drinking.

There is now good evidence that treatment aiming for controlled drinking, as opposed to abstinence, has good effects for persons with mild to moderate dependence severity, while persons with severe dependence are recommended abstinence. There are however several good reasons to abstain from alcohol for a period for this group as well. There is evidence that a month of sobriety is beneficial for mental, cardiovascular and metabolic health, after 1 and 6 months of follow-up. These studies however have been performed with moderate drinkers,

where dependence has been an exclusion criterion. What the outcomes are for alcohol-dependent persons with higher levels of consumption has not been investigated. Even when the treatment aim is controlled drinking, an initial month of abstinence is frequently recommended. The assumption here is that the toxic effects of alcohol, which often manifest in high levels of craving, are reduced after a month of sobriety, and that this improves the prerequisites for the following treatment. This seems reasonable for persons with long-standing heavy drinking. Whether it also applies for the larger group with mild to moderate dependence has not been studied however.

Where is the study run from?

Stockholm Centre for Dependency Disorders (Sweden)

When is the study starting and how long is it expected to run for?

January 2021 to October 2025

Who is funding the study?

1. ALF medicin (Sweden)
2. Swedish Research Council (Sweden)

Who is the main contact?

Dr Sven Andréasson, sven.andreasson@ki.se

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Sven Andreasson

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

Nil known

# Study information

## Scientific Title

The importance of one initial month of abstinence in the treatment of alcohol dependence with a goal of controlled drinking: effects on alcohol consumption and health at short and long term follow-up

## Acronym

VM (Vit Månad - "white month")

## Study objectives

This study will test the hypothesis that 1 month of abstinence will improve treatment outcomes for patients with a goal of controlled drinking.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 27/05/2021, The Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 75002 Uppsala, Sweden; +46 (0)10 475 08 00; [registrator@etikprovning.se](mailto:registrator@etikprovning.se)), ref: 2021-01959

## Study design

Randomized controlled trial between-groups design

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Alcohol dependence

## Interventions

All study participants have a treatment goal of controlled drinking. They are offered the same treatment options: cognitive behavioural therapy (CBT) combined with pharmacological treatment. In addition to this, they will be randomized to either start their treatment with 1 month of abstinence or start with controlled drinking treatment right away.

Randomisation is done through computer-generated randomization in blocks of 10; allocation 1:1. Randomisation is performed for each inclusion, where the study participant is given a study ID which conforms to the number of inclusion. The allocation is unknown to the study coordinator and other study staff up until the point of study inclusion and the start of treatment.

## Intervention Type

Behavioural

## Primary outcome(s)

Alcohol consumption measured by the Timeline Follow Back method, where drinks per week can be calculated, at baseline, 1, 6 and 12 months

### **Key secondary outcome(s)**

Heavy drinking days measured by the Timeline Follow Back method, where the number of days per week with heavy drinking, defined as 5 or more Swedish standard drinks for men and 4 or more for women can be calculated, at baseline, 1, 6 and 12 months

### **Completion date**

31/12/2025

## **Eligibility**

### **Key inclusion criteria**

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

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

18 years

### **Upper age limit**

99 years

### **Sex**

All

### **Total final enrolment**

217

### **Key exclusion criteria**

1. Severe mental illness
2. Abuse or dependence of other substances apart from alcohol and/or nicotine
3. Severe somatic illness
4. Non-Swedish speaking

### **Date of first enrolment**

01/04/2023

### **Date of final enrolment**

28/02/2025

## Locations

### Countries of recruitment

Sweden

### Study participating centre

Stockholm Centre for Dependency Disorders

Riddargatan 1

Stockholm

Sweden

11435

## Sponsor information

### Organisation

Beroendecentrum Stockholm

### ROR

<https://ror.org/04g380834>

## Funder(s)

### Funder type

Research council

### Funder Name

ALF medicin

### Funder Name

Vetenskapsrådet

### Alternative Name(s)

Swedish Research Council, VR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

**Location**

Sweden

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Sven Andreasson (sven.andreasson@ki.se).

**IPD sharing plan summary**

Available on request