

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

Submission date 31/03/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/06/2023	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/12/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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Additional identifiers

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), 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