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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

Registration date
27/06/2023

Overall study status
Ongoing

Last Edited
05/02/2025

Condition category
Mental and Behavioural Disorders

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
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), ref: 2021-01959

Study design
Randomized controlled trial between-groups design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

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

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

Secondary outcome measures
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

Overall study start date
01/01/2021

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

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

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.beroendecentrum.se/

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
25/12/2031

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