ISRCTN14539251 https://doi.org/10.1186/ISRCTN14539251

Is controlled drinking a viable goal for alcohol-dependent patients?

Submission date
05/06/2018

Recruitment status
No longer recruiting

Registration date
04/09/2018

Overall study status
Completed

Last Edited
22/07/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Excessive drinking of alcohol is one of the biggest risks to health worldwide. In Sweden, about 1 in 7 men and 1 in 10 women drink too much alcohol, which can lead to increased physical and mental illness. Over 1 in 20 people in Sweden drink heavily or are considered alcoholic. Most of them have a stable life and reasonable mental health, but even moderate reductions in alcohol intake can reduce the risk of illness, death and other negative consequences. This means that treatment for excessive drinking could improve public health. Less than 1 in 10 people who drink excessively seek help with their problem, which is lower than for people with mental health problems. One reason for this might be that they don't want to give up alcohol completely (be abstinent), which is often the goal of treatment for excessive alcohol use. Research has shown that more people would try treatment if the goal was to reduce their drinking, rather than stop it completely.
Controlled drinking is when people reduce their drinking to a stable and non-harmful level. This study aims to investigate using two methods to establish controlled drinking in socially stable alcohol-dependent patients. Behavioural Self-control training (BSCT) aims for controlled drinking through skills training and is based on the principles of cognitive behaviour therapy. Motivational Enhancement Therapy (MET) is a treatment method commonly used to treat addiction and is based on the techniques of Motivational Interviewing.

Who can participate?
People aged 18 to 70 years with stable housing who have drunk alcohol on 30 of the last 90 days and want to reduce their alcohol consumption.

What does the study involve?
The participants will be randomly allocated to receive 5 sessions of BSCT or 4 sessions of MET. At 3, 6, 12 and 24 months after treatment, they will have blood samples taken and will be interviewed about their drinking.

What are the possible benefits and risks of participating?
The potential benefit is that participants might reduce their alcohol consumption to non-harmful levels. The potential risk is that they will keep drinking excessively. All participants in the study are assessed regarding negative consequences of alcohol consumption. Further, liver enzymes

are collected at four times during the study (recruitment, 6, 12, 24 months). If participants are showing damage from drinking, they will be removed from the study and referred for usual treatment.

Where is the study run from?
Karolinska Institutet, Sweden

When is the study starting and how long is it expected to run for?
October 2015 to December 2022

Who is funding the study?
Stockholm County Council, the Research Council of the Swedish Alcohol Retailing Monopoly and the Swedish Research Council for Health, Working Life and Welfare

Who is the main contact?
Anders Hammarberg, Anders.Hammarberg@ki.se

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2016/634-31/2

Study information

Scientific Title

An RCT of Behavioural Self Control Training vs Motivational Enhancement Therapy for alcohol-dependent patients

Acronym

KD-study

Study objectives

Current study hypotheses as of 13/04/2023:
1. Behavioral Self-control Training (BSCT) is superior to Motivational Enhancement Therapy (MET) for the reduction in mean weekly alcohol consumption, at 6, 12 and 24 months after inclusion. BSCT focuses on developing specific skills related to the goal of controlled drinking.
2. A reduction in alcohol consumption will be sustained for a longer period of time (24 months) following a BSCT program for alcohol-dependent patients compared to following a MET program.
3. The degree of alcohol dependence will predict outcome in BSCT.
4. The degree of impaired control over alcohol consumption will predict outcome of BSCT.
5. The level of individual goal for future alcohol consumption will predict treatment outcome.
6. The degree of previous serious consequences of consumption will predict success in treatment for controlled drinking.
7. The degree of adherence to treatment will predict success in BSCT.
8. The level of psychiatric symptoms (anxiety and depression) will moderate outcome of BSCT.
9. A deficit in cognitive functioning at baseline will correlate with the clinical manifestation of impaired control over alcohol consumption.

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Previous study hypotheses as of 04/10/2022:
1. Behavioral Self-control Training (BSCT) is superior to Motivational Enhancement Therapy (MET) in decreasing the mean weekly number of drinks at 6, 12 and 24 months after inclusion, because BSCT focuses on developing specific skills related to the goal of controlled drinking.
2. A reduction in alcohol consumption will be sustained for a longer period of time (24 months) following a BSCT program for alcohol-dependent patients compared to following a MET program.
3. The degree of alcohol dependence will predict outcome in BSCT.
4. The degree of impaired control over alcohol consumption will predict outcome of BSCT.
5. The level of individual goal for future alcohol consumption will predict treatment outcome.
6. The degree of previous serious consequences of consumption will predict success in treatment for controlled drinking.
7. The degree of adherence to treatment will predict success in BSCT.
8. The level of psychiatric symptoms (anxiety and depression) will moderate outcome of BSCT.
9. A deficit in cognitive functioning at baseline will correlate with the clinical manifestation of impaired control over alcohol consumption.

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Previous study hypotheses:
1. Behavioral Self-control Training (BSCT) is superior to Motivational Enhancement Therapy (MET) in decreasing the number of heavy drinking days and days with consumption at 6, 12 and 24 months after inclusion, because BSCT focuses on developing specific skills related to the goal of controlled drinking.
2. A reduction in alcohol consumption will be sustained for a longer period of time (24 months)

following a BSCT program for alcohol-dependent patients compared to following a MET program.
3. The degree of alcohol dependence will predict outcome in BSCT.
4. The degree of impaired control over alcohol consumption will predict outcome of BSCT.
5. The level of individual goal for future alcohol consumption will predict treatment outcome.
6. The degree of previous serious consequences of consumption will predict success in treatment for controlled drinking.
7. The degree of adherence to treatment will predict success in BSCT.
8. The level of psychiatric symptoms (anxiety and depression) will moderate outcome of BSCT.
9. A deficit in cognitive functioning at baseline will correlate with the clinical manifestation of impaired control over alcohol consumption.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Review Board in Stockholm, 13/05/2016, 2017/2120-32.

Study design
Multi-centre superiority randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
Individuals who visit the clinics undergo customary diagnostic procedures, and are thereafter asked for participation in the study. Individuals who indicate a positive response are then informed about the study both in written and oral form. After this, they undergo a screening procedure to determine if selection criteria are met. Patients who fulfill selection criteria are included in the study and undergo a baseline assessment. The patients are randomized (block randomization) to one of two treatment arms:
1. BSCT
Individual BSCT treatment is administered in accordance with manual (Hammarberg & Wallhed Finn, 2015) for 12 weeks:
1.1. Session 1: Structured feedback from the screening, motivational factors for change of

alcohol consumption, goal of alcohol consumption. The homework assignment that is given to the patients comprises an alcohol consumption diary and a personal goal sheet.
1.2. Session 2: Identification of risk situations, with homework assignment: Identifying your own risk situations.
1.3. Session 3: Moderation strategies, with homework assignment: practicing personal moderation skills
1.4. Session 4: Strategies for abstaining from alcohol, with homework assignment: personal strategies for abstaining
1.5. Session 5: Maintain altered alcohol consumption and evaluation
The therapist gives feedback on home assignments and introduces a new treatment theme at each session. The treatment is based on cognitive behavioural theory, in which the focus of treatment is to alter behavioural patterns that maintain high alcohol consumption (both high weekly consumption and frequent binge drinking episodes).
2. MET
Individual MET treatment consists of four sessions according to a manual (Hammarberg et al., 2015) for 12 weeks:
2.1. Session 1: Feedback on the screening followed by a motivational interviewing session (Miller & Roll Nick, 2013)
2.2. Sessions 2–4: Motivational interviewing sessions. If applicable, a concerned significant other may take part in one of the sessions. Also, a change plan may be introduced to the patient. Apart from this, the therapist works according to the principles of motivational interviewing (Miller & Rollnick, 2013) with no thematically determined treatment content.

The therapists who conduct BSCT and MET in the study are all licenced psychologists or psychotherapists with adequate training in each treatment method. 10% of the treatment sessions are recorded (random selection). The MET tapes are quality assessed by a certified lab (MIC Lab, Karolinska Institutet (www.miclab.org). The BSCT tapes are assessed by an independent licensed psychologist specialized in cognitive behavioural therapy (CBT), in order to check compliance to BSCT-treatment.

At the inclusion visit, follow-up visits at 6, 12 and 24 months are scheduled. Follow-up visits are conducted by the study coordinator at each clinic. All forms for each participant will be stored in a Case Record Form (CRF). All CRFs are kept in a locked journal archive between study visits.

After screening and inclusion procedures, patients perform a neuropsychological test (CANTAB) for 1.5 h. The tests contain 8 parts that measure executive function in different domains relevant to the patient group, e.g. attention, impulsivity, working memory, decision making. The test is repeated after 12 weeks, and the patients perform the same tests except for one, which is excluded due to learning effects.
The follow-up- assessments are done at 12, 26, 52 and 104 weeks, where the patients meet a study coordinator (who conducts a semi-structured interview) and fill out self-rating scales concerning the outcome variables. Blood samples are collected at baseline, 12, 26, 52 and 102 weeks. One blood sample is stored in a Biobank for genetic analysis. Professor Markus Heilig at the Centre for Social and Affective Neuroscience, Dept. of Clinical and Experimental Medicine at Linköpings University is responsible for the genetic analyses.

All participants in the study are assessed continuously regarding negative consequences of alcohol consumption. Further, liver enzymes are collected at four times during the study (inclusion, 6, 12, 24 months). In clinically relevant cases, patients are excluded from the study and the usual treatment at each clinic is offered.

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measure as of 04/10/2022:
Mean weekly alcohol consumption during the time period 90 days before inclusion compared with 6 months post inclusion

Previous primary outcome measure:
Percentage of days with binge drinking (men: >60 g alcohol per occasion; women: >48 g alcohol per occasion) during the time period 90 days before inclusion compared with at 6, 12, and 24 months post inclusion.

Secondary outcome measures

Current secondary outcome measures as of 04/10/2022:
1. Percentage of days with binge drinking (men: >60 g alcohol per occasion; women: >48 g alcohol
per occasion) compared with 6, 12, and 24 months post inclusion
2. Percentage of weeks with harmful use (men: >168 g/week; women: >108 g/week) during the time 90 days before inclusion compared with 6, 12, and 24 months post inclusion
3. Percentage of weeks with consumption according to individual goal from the time of inclusion until 6, 12 and 24 months post inclusion
4. Degree of dependence at inclusion compared at 12 and 24 months post inclusion
5. Biological markers of alcohol consumption at inclusion, compared with 6, 12, and 24 months post inclusion
6. Alcohol-related medical, psychological and social consequences of alcohol consumption at inclusion compared with 6, 12 and 24 months post inclusion
7. Self-reported alcohol craving at inclusion compared with 6, 12, and 24 months post inclusion
8. Degree of loss of control of consumption at inclusion compared with 6, 12, and 24 months post inclusion

Previous secondary outcome measures:
1. Percentage of days with drinking during the time 90 days before inclusion compared with 6, 12, and 24 months post inclusion
2. Percentage of weeks with harmful use (men: >168 g/week; women: >108 g/week) during the time 90 days before inclusion compared with 6, 12, and 24 months post inclusion
3. Percentage of weeks with consumption according to individual goal from the time of inclusion until 6, 12 and 24 months post inclusion
4. Degree of dependence at inclusion compared at 12 and 24 months post inclusion
5. Biological markers of alcohol consumption at inclusion, compared with 6, 12, and 24 months post inclusion
6. Alcohol-related medical, psychological and social consequences of alcohol consumption at inclusion compared with 6, 12 and 24 months post inclusion
7. Self-reported alcohol craving at inclusion compared with 6, 12, and 24 months post inclusion
8. Degree of loss of control of consumption at inclusion compared with 6, 12, and 24 months post inclusion

Overall study start date

05/10/2015

Completion date

01/12/2022

Eligibility

Key inclusion criteria
1. Fulfils criteria for alcohol use disorder according to DSM5
2. Aged 18-70 years
3. Has an explicit goal of reducing current alcohol consumption
4. Alcohol consumption during at least 30 of the last 90 days before inclusion
5. Stable housing in the Stockholm region
6. Willingness to give informed consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
250

Total final enrolment
250

Key exclusion criteria
1. Has complete abstinence as target for treatment
2. Severe somatic or psychiatric problems
3. Pregnant
4. Current drug use (during the past 3 months)
5. Harmful use of or dependence on substance other than alcohol (except nicotine)

Date of first enrolment
15/08/2017

Date of final enrolment
01/12/2020

Locations

Countries of recruitment
Sweden

Study participating centre
1. Centre for Dependency Disorders Stockholm, Riddargatan 1- Mottagningen för alkohol och hälsa
Stockholm
Sweden
11435

Study participating centre
Centre for Dependency Disorders Stockholm, Mottagningen för Alkohol och Hälsa Nord
Stockholm
Sweden
18233

Study participating centre
Centre for Dependency Disorders Stockholm, Magnus Huss Clinic
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41328

Sponsor information

Organisation
Karolinska Institutet

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Sponsor type
University/education

ROR
https://ror.org/04hmgwg30

Funder(s)

Funder type

Not defined

Funder Name
Stockholm County Council

Funder Name
The Research Council of the Swedish Alcohol Retailing Monopoly

Funder Name
Swedish Research Council for Health, Working Life and Welfare

Results and Publications

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

Intention to publish date
30/08/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from primary investigator; Anders Hammarberg, anders.hammarberg@ki.se. Raw data with de-identified participant data will be provided for primary and secondary outcome measures. Data will be available for 5 years for meta-analyses if legal restrictions are not violated.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/09/2023	14/11/2023	Yes	No
Results article	Two-year follow-up	21/07/2025	22/07/2025	Yes	No