

Treatment of alcohol problems in primary care

Submission date 20/12/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/03/2022	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/12/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Excessive alcohol consumption is a significant risk factor for several major health problems. Early detection and treatment can have an important impact on reducing the health burden of high alcohol intake, but studies in several countries have documented low levels of implementation in primary care. An important reason why the implementation of screening and brief intervention programs has failed is the reluctance among practitioners to raise questions within a field where they lack competence. By providing practitioners with simple but effective tools to treat alcohol dependence they will be more competent and ready to raise alcohol questions. The 15 method is specifically designed to overcome these limitations and increase the effectiveness of alcohol prevention in primary care. It is a stepped-care program, including brief intervention, assessment and psychological and pharmacological treatment. The aim of this project is to study the effects of a combination of sticks, carrots, and sermons (using the terminology of Evert Vedung) in the implementation of alcohol prevention in primary healthcare.

Who can participate?

Primary health care clinics in the Stockholm Region that have a care agreement with the Region.

What does the study involve?

A new policy initiative is now in force in the Stockholm Region, where the management of alcohol use disorders is mandated in new health care agreements with all primary health care clinics (200+ clinics) in the region. In this study the researchers will evaluate the effects of requirements and training separately and in combination. They will study changes in key alcohol-related activities performed by the staff at five timepoints, before and after the policy shift. Data for these analyses will be extracted from the central electronic case files system.

What are the possible benefits and risks of participating?

None

Where is the study run from?

The Stockholm Centre for Dependency Disorders (Sweden)

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

November 2020 to August 2023

Who is funding the study?

1. Swedish Research Council for Health, Working Life and Welfare, FORTE
2. The Swedish Council for Information on Alcohol and Other Drugs

Who is the main contact?

Prof Sven Andreasson
sven.andreasson@ki.se

Contact information

Type(s)

Scientific

Contact name

Prof Sven Andreasson

Contact details

Riddargatan 1
Alkohol och hälsa
Stockholm
Sweden
11435
+46 (0)812345780
sven.andreasson@ki.se

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Treatment of alcohol problems in primary care: a novel approach combining policy and training in the 15 method

Study objectives

The overarching aim of this project is to generate new knowledge on the effective implementation of a method for prevention of and treatment for alcohol use disorders in primary healthcare. We use the terminology of Vedung, analysing a combination of sticks, carrots, and sermons, three different types of strategies to facilitate the implementation of evidence-based practices. Sticks are regulations in the form of rules and directives which mandate receivers' actions, carrots either involve the handing out or the taking away of material

resources and sermons involve the transfer of knowledge to achieve the desired goals. In the proposed research project, sticks are the new health care agreement for primary care in the Stockholm region which includes treatment of mild or moderate alcohol use disorder that does not require specialist care. Carrots are financial incentives for the adoption and delivery of alcohol interventions and sermons is Internet-based training for identifying and treating hazardous and harmful use of alcohol as well as alcohol dependence.

The project will address the following research questions:

1. To what extent does primary healthcare professionals' delivery of alcohol interventions in primary healthcare change after the use of sticks, carrots, and sermons?
2. What proportion of change can be attributed to the new directives (sticks and carrots) and training (sermons) respectively?
3. To what extent is alcohol disorder management affected in terms of case finding, assessment, and treatment?

Ethics approval required

Old ethics approval format

Ethics approval(s)

An application was submitted and assessed by the Regional Ethics Review Board in Stockholm 29 /06/2021 ; Dnr 2021-03562. The Regional Ethics Review Board concluded that the study does not require ethics approval as data and analyses are based on existing registry information and patients or professionals will not be contacted for data collection. In their advisory opinion, the Ethics Review Board stated that they have no ethical objections to the research project.

Study design

Longitudinal observational trial

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Healthcare professionals' delivery of alcohol interventions in primary care

Interventions

The Health Care Management of the Stockholm Region (HSF) has decided on a new healthcare agreement for primary care in the Stockholm Region, in force from Feb 1, 2021, where primary care is designated as the front line for psychiatric care, including harmful use and dependence of alcohol. As a result, the region is planning a training and support program for primary care. This includes training on how to identify and treat harmful use and mild to moderate alcohol dependence. The training in the "15-method" is planned to be offered to all primary care centres in Stockholm and is based on Motivational Enhancement Therapy (MET) and Cognitive Behavioural Therapy (CBT).

We will study indicators of professional management of alcohol use disorders at five time points: The baseline will be prior to the new agreements between the Region and the primary health care (PHC) clinics. Data on indicators of alcohol management at 3 months after the new agreement has been in force, but no training has yet occurred, will measure the impact of the

new agreements. Data at different time-points after the training has been made available (preliminary in Jan 2022) will measure the impact of training, as a growing number of PHC clinics are trained. In this way, each primary care clinic becomes its own control.

Training will consist of an e-learning education, which all 200+ PHC clinics in Stockholm county will be offered, with the main learning objective to support PHCs to practice the 15-method in their daily work. The education is based on the 15-method manual. The participants will get the opportunity to train different interventions with the use of representative fictitious patients.

The research plan involves obtaining data from the primary care electronic case files that indicate change in each of the three steps in the 15 method: raising the topic of alcohol, assessing the severity of alcohol disorder and treatment of alcohol dependence. The choice of seven indicators is dictated by the information available in the electronic case files.

Intervention Type

Behavioural

Primary outcome(s)

Data on all participants from the PHC clinics that register for alcohol management training is obtained from Läratorget. This will include the time when the training was obtained, it will give age and gender of all trainees, as well as their profession (heads of units, physicians, nurses, psychologists, and others).

1. Raising the topic, enquiring about alcohol consumption. This is measured by the frequency of structured documentation on alcohol habits: weekly alcohol consumption and heavy drinking occasions.

Assessing the severity of alcohol disorder:

2. Use of the AUDIT instrument
3. Ordering of blood tests for alcohol biomarkers (the consumption measures CDT or PEth).

Treatment of alcohol dependence:

4. Prescription of drugs for harmful use and dependence (naltrexone, acamprosate, disulfiram)
5. Registered alcohol-related diagnoses
6. Completed brief advice and extended advice regarding hazardous use, harmful use and dependence of alcohol (KVÅ-coded)
7. Referrals to specialized addiction care

Data are collected from registers that compile alcohol-related activities that the different PHC clinics perform. The timepoints are baseline, 9, 18, 24 and 30 months.

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

31/08/2023

Eligibility

Key inclusion criteria

Primary health care clinics in the Stockholm Region that have a care agreement with the Region

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

129

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/02/2022

Date of final enrolment

01/06/2023

Locations**Countries of recruitment**

Sweden

Study participating centre

Karolinska Institutet

Riddargatan 1

Stockholm

Sweden

11435

Sponsor information**Organisation**

The Stockholm Centre for Dependency Disorders

Funder(s)

Funder type

Research council

Funder Name

Forskningsrådet om Hälsa, Arbetsliv och Välfärd

Alternative Name(s)

Swedish Research Council for Health, Working Life and Welfare, Forskningsrådet om Hälsa, Arbetsliv och Välfärd, FORTE

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Funder Name

The Swedish Council for Information on Alcohol and Other Drugs

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