ISRCTN78234026 https://doi.org/10.1186/ISRCTN78234026

Treatment of alcohol problems in primary care

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/03/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/12/2023	Mental and Behavioural Disorders	[ ] 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
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Contact information

Type(s)
Scientific

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Additional identifiers

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.

Primary study design
Observational

Study design
Longitudinal observational trial

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 Lärtorget. 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
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Stockholm
Sweden
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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