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Internet treatment of alcohol dependence in primary care

Submission date
17/11/2017

Recruitment status
No longer recruiting

Registration date
07/06/2018

Overall study status
Completed

Last Edited
17/02/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Alcohol dependence is a common disorder and has a continuum regarding severity. Most alcohol dependent persons have a moderate level of dependence and live under socially orderly conditions. Treatment seeking in this group is low however, mainly due to stigma and because treatment options are seen as unappealing. Alcohol is relevant to discuss in many primary care (PC) consultations and PC is less stigmatizing than addiction care units. But general practitioners (GPs) are reluctant to engage in treating alcohol problems due to time constraints and lack of knowledge about how to ask about and how to treat alcohol problems. Screening and brief interventions are effective for high consumers but there are few studies on dependence. Internet based interventions are attractive to and are shown to reach people with alcohol problems. Yet there are no internet studies on alcohol dependence in PC. The aim with this study is to broaden the base for treatment of alcohol dependence by lowering the threshold for treatment seeking and to reach a larger part of the target group with evidence based treatment. In the present project, the aim is to study the effectiveness of an Internet based Cognitive Behavioral Therapy (iCBT) when added to treatment as usual (TAU) for alcohol dependence in PC, and compare treatment outcome with TAU only.

Who can participate?
Adults aged 18 and older who have a dependence on alcohol.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive TAU from their GPs. Those in the second group receive TAU as well as the iCBT therapy for two months. All participants are then answering questionnaires, take blood samples again at 3 and 12 months which they are given computerized feedback on.

What are the possible benefits and risks of participating?
Participants may benefit from receive extra treatment. All participants will be given what GPs provide patients according to the routines in primary care so there is no added risk.

Where is the study run from?
Karolinska Institutet Stockholm (Sweden)

When is the study starting and how long is it expected to run for?
January 2016 to March 2021

Who is funding the study?
1. Swedish Research Council for Health, Working Life and Welfare (Sweden)
2. Swedish Research Council Funding for Clinical Research in Medicine (Sweden)

Who is the main contact?
Professor Sven Andréasson
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Study website
https://www.alkoholohalsa.se

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Internet-based Treatment of Alcohol Dependence in primary care - a randomised controlled trial

Acronym
iTAP

Study objectives
Internet based treatment (iCBT), when added to treatment as usual (TAU) for patients with alcohol dependence in PC, improves treatment outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Review Board in Stockholm, 07/12/2016, 17/10/2017, ref: Dnr 2016/1367-31/2.

Study design
Randomized controlled trial between-groups design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
The participants will first do an application and read information about the study. After this the participants will provide their concent and answer a number of questionnaires. If inclusion criteria are fulfilled and exclusion criteria are checked, the study coordinator will contact the participant and do the randomization. All participants then provide a blood sample and are scheduled for an appointment to the GP. Participants are randomly allocated to one of two groups.

The Treatment as usual (TAU) receive care from the general practitioners provide treatmnt according to local routines and the training given on feedback on assessment questionairs and biomarkers in blood, offer mediciaton for treatment if applicable.

The iCBT groups receive of adaptation of motivational enhancement therapy and CBT, for two months added to TAU (treatment as usual). In the intervention arm iCBT is added to TAU and will run for two months. Participants are reminded to start work with a new task every week in iCBT.

The treatment duration depends on what the GP finds applicable and will probably differ in duration and in content. TAU is given in both study arms. Follow up in both study arms (as described before) are 3 and 12 months from baseline and involves providing blood samples and answering questionnaires.

Intervention Type
Mixed

Primary outcome measure
Change of weekly alcohol consumption and number of heavy drinking days measured by the Time line follow back instrument.

Secondary outcome measures
1. Change of degree of alcohol dependence ICD 10 criteria is measured using questionnaires at baseline, 3 and 12months
2. Change of consequences of drinking AUDIT scores is measured using questionnaires at baseline, 3 and 12 months
3. Change of symptoms of anxiety and depression HAD scores is measured using questionnaires at baseline, 3 and 12 months
4. Change of quality of life EQ5D is measured using questionnaires at baseline, 3 and 12 months
5. Change of levels of phosphatidylethanol (PEth) are measured using bloodsample at baseline, 3 and 12 months
6. Change of levels of aspartate aminotransferase (ASAT) are measured using bloodsample at baseline, 3 and 12 months
7. Change of levels of alanine aminotransferase (ALAT) are measured using bloodsample at baseline, 3 and 12 months
8. Change of levels of gamma-glutamyltransferase (GGT) are measured using bloodsample at baseline, 3 and 12 months
9. Patients' satisfaction with treatment CSQ is measured using questionnaire at 3 months

Overall study start date
01/01/2016

Completion date
31/03/2021

Eligibility

Key inclusion criteria
1. Alcohol dependence according to ICD-10 criteria, hazardous alcohol consumption
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
260

Total final enrolment
264

Key exclusion criteria
1. Severe mental illness
2. Severe dependence in need of specialist treatment
3. Abuse or dependence of other substances apart from alcohol and/or nicotine
4. Severe somatic illness
5. Non-Swedish speaking

Date of first enrolment
24/08/2017

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institutet Stockholm
Riddargatan 1
11435 Stockholm
Sweden
11435

Sponsor information

Organisation
Addiction Centre Stockholm (Beroendecentrum Stockholm)

Sponsor details
Finsens väg 8
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Sponsor type
Hospital/treatment centre

Website
www.beroendecentrumstockholm.se

ROR
https://ror.org/04g380834

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, FORTE

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Swedish Research Council Funding for Clinical Research in Medicine

Results and Publications

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

Intention to publish date

30/06/2022

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/12/2019	16/12/2020	Yes	No
Other unpublished results			10/05/2022	No	No
Results article		23/02/2023	11/07/2023	Yes	No
Other publications	Moderation analysis	14/02/2025	17/02/2025	Yes	No