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Mobile phone technology for reduced drinking

Submission date
06/04/2018

Recruitment status
No longer recruiting

Registration date
31/05/2018

Overall study status
Completed

Last Edited
01/07/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
It is well known that alcohol causes significant harm. Approximately 70 diseases have been estimated to be wholly or partly caused by alcohol, e.g. cardiovascular diseases, cancers, infectious diseases, neurological diseases, and mental disorders - including alcohol use disorder (AUD). Most people with AUD do not seek treatment. Different studies estimate that fewer than 20% have ever been in treatment. Available treatment in specialized addiction clinics is seen as unattractive and stigmatizing and it appears that it is only when problems become very severe that the barriers to treatment are overcome. Thus, a primary concern within the health care system is to make treatment more accessible as well as attractive for the great majority of alcohol dependent people who feel reluctant to participate in the traditional treatment programs available.
Improving ways of collecting data on alcohol consumption, as well as the treatment system, is important for the clinical practitioner as well as for the public health specialist. Today, there are uncertainties regarding reported levels of alcohol consumption for both total alcohol intake and pattern of drinking, and consequently also in assessing health effects of alcohol and in evaluating possible effects of treatment. Using digital technology has been shown to be effective not only in decreasing barriers for individuals to seek treatment but also with regards to the outcome of treatment, where it has been shown to be as effective as face-to-face alternatives. Mobile phone technology has also been suggested as one means to offer time-efficient support within health care.
In this project we aim to examine two mobile phone applications (apps) “Glasklart” and the combination of a portable breathalyzer with a mobile phone application ”iBAC” in the treatment of AUD. The study aims to examine the effects of using apps as complements to standard treatment on alcohol consumption in adults with AUD. A comparison group will receive standard treatment only.

Who can participate?
Adult aged 18 years or older with alcohol dependence

What does the study involve?
Participants attend an initial treatment session of a psychological program. If eligible, they are randomly allocated to receive one of three treatments.
Those in the first group receive treatment as susual. Those in the second group use the Glaskart mobile phone app which records the number of drinks the participant has and their mood. Those

in the third group use this app, alongside a portable breathalyzer which measures current blood alcohol concentration.
Participants follow this for 12 weeks and are followed up with questionnaires and blood samples at the end.

What are the possible benefits and risks of participating?
Participation in the study is not considered to present any risks for the patients; participation is voluntary and patients have sought treatment for their alcohol consumption, which they may benefit from.

Where is the study run from?
Mottagningen för alkohol och hälsa (Sweden)

When is the study starting and how long is it expected to run for?
January 2017 to June 2023

Who is funding the study?
Swedish Research Council for Health, Working Life and Welfare (Forskningsrådet om Hälsa, Arbetsliv och Välfärd) (Sweden)

Who is the main contact?
Dr Anna-Karin Danielsson (Scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
dnr 2018/174-31

Study information

Scientific Title
”Glasklart" and "IBac" – Improving methods for measuring alcohol consumption and treating alcohol problems

Acronym
MORE

Study objectives
Aiming to improve both collection of alcohol consumption data, and treatment of alcohol problems, a number of technical devices have been developed. In this project we aim to examine two of these: the mobile phone application (app) “Glasklart” and the combination of a portable breathalyzer with a mobile phone application ”iBAC”.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Regional Ethical Review Board in Stockholm, 14/03/2018, ref: 2018/174-31
2. Swedish Ethical Review Authority, 19/04/2021, ref: 2021–01965
3. Swedish Ethical Review Authority, 21/02/2023, ref: 2023-00919-02

Study design
Randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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 use disorder

Interventions
The treatment as usual (TAU) programs involves a psychological treatment program – either ” Guide to better drinking habits” or ”Guide to Controlled drinking”, in combination with pharmacotherapy. All participants attend an initial treatment session, where they are assessed for inclusion and exclusion criteria. If eligible, they receive information about the devices used in the study, and the study procedures, from the counsellor in charge of the psychological treatment. This is a 12-week intervention with 3 months follow-up following baseline randomization.

Following the first treatment session, the counsellor informs the study coordinator about the new study participant. The coordinator records baseline data in a study data base and initiates the randomization procedure. This procedure is conducted by an administrator with no other role in this study. Randomization is done by a computer program, where participants are randomized (in blocks of ten) either to TAU, or TAU + Glasklart, or TAU +iBAC. Each study participant is given a study number, 1-375. Only the administrator has access to the code key.

Glaskart is a mobile phone app in which the participant records the number of drinks consumed, when and where, in what mood, and whether alone or together with others.
The iBAC group also use the app, and also have a portable breathalyzer that gives a biologic measure of the current blood alcohol concentration at different time points. Both these devices can be viewed on a daily, weekly or monthly basis. The Glasklart app enables instant registration while alcohol is being consumed and the iBAC will be programmed to contact the user and ask for registration at several occasions daily

Instruments:
• Timeline follow back – structured interview for assessment of alcohol consumption during the last 30 days.
• Alcohol Use Disorder Identification Test (AUDIT) questionnaire.
• Severity of alcohol dependence is measured by the number of fulfilled diagnostic criteria for the diagnosis alcohol dependence, according to ICD-10.
• Short Alcohol Dependence Data (SADD). This instrument is currently undergoing Swedish validation and will be published in spring of 2018.
• Client Satisfaction Questionnaire (CSQ).
• Phosphatidylethanol (PEth). Blood samples will be collected by staff at Karolinska Universitetssjukhusets Laboratorium (KS Lab) in Stockholm and will be analysed at KemLab/LS Laboratorium. The results will be delivered through the electronic patient record system (Take Care) within 2-3 days. The results will be printed and anonymised by the study coordinator and then placed in the CRF.

Validation study:
Correlation of registered consumption in the Glasklart app and iBAC respectively, with results from TLFB, AUDIT and Peth.

Qualitative study:
Focus group interviews and individual interviews focusing on study participants' perceptions of these technological tools (e.g. Are Glasklart or iBAC easy to use? Are they perceived as good support/help in the treatment?).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
Number of days with heavy drinking, defined as 4 or more standard drinks (12 grams/drink), during a 12-week intervention period is measured by the timeline follow back instrument (TLFB) and Alcohol Use Disorder Identification Test (AUDIT).

Secondary outcome measures
1. Weekly alcohol consumption is measured by TLFB, AUDIT and Phosphatidylethanol in blood (PEth)-values, at 3 and 6 month follow-up.
2. Number of days during the 12-week intervention with BAC-levels exceeding 60 mg per 100 ml.

Overall study start date
01/01/2017

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Fulfill diagnostic criteria for alcohol dependence according to ICD-10
2. 18 years of age or older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

375

Total final enrolment
175

Key exclusion criteria
1. Severe physical or mental disorder
2. Pregnancy
3. Currently undergoing other treatment for alcohol problems
4. Recent treatment for severe alcohol problems, e.g. alcohol withdrawal

Date of first enrolment
15/09/2020

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Sweden

Study participating centre
Mottagningen för alkohol och hälsa
Riddargatan 1
Stockholm
Sweden
11435

Sponsor information

Organisation
Karolinska Institutet

Sponsor details
Karolinska Institutet
Stockholm
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17177

Sponsor type
University/education

Website

www.ki.se

ROR
https://ror.org/04hmgwg30

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Intended publication of a detailed study protocol during 2018. Results of the trial will be reported during the fall of 2020 with planned publications in peer reviewed journals.

Intention to publish date
01/09/2024

Individual participant data (IPD) sharing plan
All collected data will be managed in a manner that is compatible with the security and personal data law; data will be kept in a secure room accessible only by research personnel. No personal data will stored by Glasklart or iBAC, only a study number. To protect the patient's personal integrity, the datasets generated and/or analysed during the current study are not publicly available but are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/12/2018		Yes	No
Other publications	Patient perceptions	28/12/2023	08/05/2024	Yes	No