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Testing an aftercare mobile application for relapse prevention to alcohol and cannabis use among young adults

Submission date
30/11/2022

Recruitment status
No longer recruiting

Registration date
06/12/2022

Overall study status
Completed

Last Edited
06/12/2022

Condition category
Mental and Behavioural Disorders

[ ] 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
Alcohol and illicit drugs constitute massive health and societal problems among young adults in Denmark, but treatment is challenged by low rates of enrollment and engagement and high rates of relapse. Mobile apps may support treatment engagement and help young adults cope with high-risk situations related to relapse. Studies are needed that involve clients and researchers with technical knowledge.

Who can participate?
Young adults aged 18-30 years old enrolled in substance use disorder (SUD) treatment

What does the study involve?
Researchers will test the app among participants who meet the study intake criteria and provide informed study consent. They will be randomly assigned to “Immediate App Access” or “Delayed App Access”. Both groups will be assessed at 6- and 12-week follow-ups. The focus will be on whether the app will prevent relapse to problematic use.

What are the possible benefits and risks of participating?
Study participation has the potential to increase client empowerment and does not have negative side effects.

Where is the study run from?
Aarhus University (Denmark)

When is the study starting and how long is it expected to run for?
January 2021 to December 2023

Who is funding the study?
1. Trygfonden (Denmark)
2. Helsefonden (Denmark)
3. Centre for Alcohol and Drug Research and Orbit Lab, Aarhus University (Denmark)

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Pilot testing an aftercare mobile application for relapse prevention to alcohol and cannabis use among young adults: protocol of a feasibility and randomized pilot study

Acronym
MARPAC

Study objectives
Study hypotheses has two foci 1) the clinical effect of the mobile app (AfterCare) that is tested, 2) regarding feasibility and usability of the app.

Clinical effect: Compared to study participants randomized to 6 weeks later access to the mobile app, study participants randomized to immediate access to the mobile app will report fewer days of alcohol and/or cannabis use in the follow-up assessments after controlling for their substance use at baseline.
Hypothesis #1: Study participants who gain immediate access to the mobile app will report fewer days of cannabis and/or alcohol use in the prior 7 days compared to study participants who gain access to the mobile app 6 weeks later.
Hypothesis#2: Study participants who gain immediate access to the mobile app will report fewer days of cannabis and/or alcohol use in the last month compared to study participants who gain access to the mobile app 6 weeks later.

Feasibility and usability: We expect to find variations among study participants in both study conditions in regards with frequency and preference of the app functions.
Hypothesis#1: Study participants who gain immediate access to the mobile app will use it more than study participants who gain access to the mobile app 6 weeks later.
Hypothesis#2: Study participants who use the specific functions in the mobile app independently (e. g., personalizing the app by entering personalized data in strategies, calendar, or high-risk situations) within the first week after they gain access to the mobile app will be more likely to continue using the app compared to study participants who don’t use the specific functions functions in the app.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/11/2022, Scientific Ethics Committee – Region Mid-Jutland [De Videnskabsetiske Komitéer For Region Midtjylland] (Skottenborg 26, 8800 Viborg, Denmark; +45 78410189; komite@rm.dk), ref: 1-10-72-110-22

Study design
Multicentre randomized pilot study with follow-up

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Alcohol, cannabis, and other illegal drug substance use disorder

Interventions
The aim of the study is to assess the feasibility of using the final version of the AfterCare app in clinical contexts, and to obtain preliminary data on clinical effectiveness for preventing relapse to substance use. The study will test the AfterCare app as an add-on to outpatient treatment. Study participants will be newly enrolled patients who are deemed eligble for study participation. All study participants will receive treatment as usual and go through the same procedures at the participating treatment centers. These procedures include intake assessment and screening (using the Danish monitoring system MapPlan), study recruitment, and randomization to one of the two conditions. The two conditions are the Immediate App Use (IAU; n = 45) and the Delayed App Use (DAU; n = 45) conditions. In the IAU condition, study participants will gain full access to the app the same day that the app is installed on the mobile phone at the third treatment session and for the next 12 weeks. In the DAU condition, study participants gain access to the installed app 6 weeks after the third treatment session and for the next 6 weeks. Thus, during the first 6 weeks after the third treatment sessions, the DAU will function as a control condition.
Block randomization will be used to allocate eligible patients to one of the two treatment conditions. The blocks will be based on seven variables: sex, age, prior treatment for substance use disorder, having a diagnosis for a psychological disorders, frequency of binge drinking in the last month, cannabis use days in the last month, and use of other illicit drugs. The information will be collected online at the site by practitioners involved in the study and sent to the researchers on a secure server

Intervention Type
Behavioural

Primary outcome(s)
Clinical effect:
1. Seven-day alcohol use measured using the Time Line Follow Back questionnaire (TLFB), at baseline, and 6, and 12-week follow-ups
2. Thirty-day alcohol use measured using a single-item question (How many days have you drank alcohol in the last month?), at baseline, and 6, and 12-week follow-ups
3. Seven-day cannabis use measured using the Time Line Follow Back questionnaire (TLFB), at baseline, and 6, and 12-week follow-ups
4. Thirty-day cannabis use measured using a single-item question (How many days have you used any cannabis products in the last month?), at baseline, and 6, and 12-week follow-ups

Feasibility and usability:
Average use of app measured using the number of clicks on different app functions in the first 6 weeks of use

Key secondary outcome(s))

1. Seven-day illicit drug use measured using a single-item question (How many days have you used any illicit drugs, except for cannabis, in the last 7 days?), at baseline, and 6, and 12-week follow-ups
2. Thirty-day illicit drug use measured using a single item question (How many days have you used any illicit drugs, except for cannabis, in the last month), at baseline, and 6, and 12-week follow-ups
3. Depressive symptoms in the last 2 weeks measured using the Patient Health Questionnaire-2 (PHQ-2) and anxiety symptoms in the last 2 weeks measured using the Generalized Anxiety Disorder 2-item (GAD-2), at baseline, and 6, and 12-week follow-ups

Completion date
01/12/2023

Eligibility

Key inclusion criteria
1. Aged 18 – 30 years old
2. Own a mobile with a data plan
3. Enrolling in outpatient treatment for alcohol or cannabis use at one of the participating sites
4. Provision of informed consent to study participation
5. Attends the third treatment session after enrollment in treatment for the provision of the app

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Severe mental illness (e.g., psychosis) or dangerous behavior (e.g., aggression)
2. Severe neuropsychological disorder or cognitive dysfunction
3. Not willing or able to give informed consent to participate in the study
4. Does not speak or understand Danish in a way that makes it possible to participate in the project
5. Took part in a prior stage of the project that focused on the app development

Date of first enrolment
01/12/2022

Date of final enrolment
01/10/2023

Locations

Countries of recruitment
Denmark

Study participating centre
Brydehuset Rusmiddelbehandling
Brydehusvej 12
Ballerup
Denmark
2750

Study participating centre
KABS City, Ambulant behandling med fokus på stofmisbrug
Kirsten Walthers Vej 2, 2nd floor
Valby
Denmark
2500

Study participating centre
CAS - Center for Alkohol- og Stofbehandling
Ringstedgade no14, 16, and 22
Roskilde
Denmark
4000

Study participating centre
Rusmiddelrådgivning Horsens Kommune
Vesterled 1
Horsens
Denmark
8700

Sponsor information

Organisation
Aarhus University

ROR
https://ror.org/01aj84f44

Funder(s)

Funder type
Research organisation

Funder Name
TrygFonden

Alternative Name(s)
Tryg Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Denmark

Funder Name
Helsefonden

Alternative Name(s)
Health Foundation, Helsefonden (Health Foundation)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Denmark

Funder Name
Aarhus Universitet

Alternative Name(s)
Aarhus University, Universitas Arhusiensis, AU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Denmark

Results and Publications

Individual participant data (IPD) sharing plan
We prepared a consent form that would increase trust and engagement with the target population concerning data collection, and thus stated that the collected data is only sharable among members of the research group.

IPD sharing plan summary
Stored in non-publicly available repository, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.0	14/09/2022	06/12/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes