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Combined drug and alcohol treatment trial

Submission date	Recruitment status	[X] Prospectively registered
30/06/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/09/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
01/03/2021	Mental and Behavioural Disorders	[_] Record updated in last year

Plain English summary of protocol

Current plain English summary as of 29/09/2020:

Background and study aims
In Denmark, treatment for Alcohol and Other Drug Disorder (AODD) is free of charge, and the 98 municipalities nationwide are responsible for offering patients social treatment for AODD within 2 weeks after a patient has made the first request. Still, there is an alarming number of people who are hard to reach and retain in treatment. Furthermore, the fact that drug use disorders (DUD) co-occur with alcohol use disorders (AUD) at high rates among patients enrolled in treatment, and affect long-term abstinence, has strong clinical implications for how to approach AUD and DUD in the interventions offered by treatment facilities. As a consequence, there is a strong need to improve our knowledge about how integrated treatment of AUD and DUD works compared with the individual treatment of AUD and DUD. The aim of this study is to evaluate the feasibility, acceptability, clinical and cost-effectiveness of MOVE group (MOVE-G) treatment versus MOVE individual (MOVE-I) treatment in four community-based treatment centres in Denmark.
Before 2007 drug and alcohol treatment was separated not only by the Act of social Service /drug use treatment (Ministry of Social Affairs) and the Act of Health/alcohol treatment (Ministry of Health) but also organizationally. Today alcohol and drug treatment are still divided by the acts, but about 80% of the municipal alcohol and drug treatment has merged into the same organization. The same counsellors are treating both clients with AOD and DUD and sometimes clients with AOD and DUD are treated in the same counseling groups. The primary purpose of this study is whether this organizational merge of alcohol and drug treatment and the combination of clients with AUD and DUD in the same counselling is just as effective as individual alcohol and drug treatment.

Who can participate?
Adult patients (aged 18 and over) who are seeking either drug use treatment or alcohol use treatment

What does the study involve?
The treatment will take place in four different municipality treatment centers, and 300 individuals who will seek treatment for alcohol/and or drug-related problems in these four centers will be offered participation in the study.
In each treatment center, participants are randomly divided into two groups. For these two

groups the first five sessions will be the same: five weekly individual sessions with the same counsellor. After these five sessions, one group will receive group therapy, whereas the other group continue to receive individual therapy sessions. The groups will include individuals with drug-related as well as individuals with alcohol-related problems.
The treatment course consists of primary treatment (14 sessions) and aftercare (6 months), where contact with the treatment center is gradually reduced. All participants will receive treatment with MOVE (a combination of motivational interviewing, cognitive behavioural therapy and contingency management), and will receive vouchers at every second treatment attendance (only in the primary treatment). The aftercare consists of two phone conversations + two personal conversations per month in the first 3 months. In the next 3 months the aftercare consists of one phone conversation every second week. The after treatment is concluded with an in-person conversation with the counsellor.
To test the feasibility and acceptability of the treatment, the intervention will furthermore include analyses of audio recordings of the treatment sessions, qualitative interviews with participants at nine months follow-up, a quantitative survey of the counselors treatment experiences, and comparisons of treatment data with national registers.

What are the possible benefits and risks of participating?
Benefits of participating in the study are: being part of a treatment course that others have been satisfied with, which has shown promising results; receiving vouchers worth 200 Danish kroner at every other attendance in treatment sessions; receiving vouchers for participating in follow-up interviews supporting the development of drug and alcohol treatment in Denmark. There are no known risks of participating in the study.

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

When is the study starting and how long is it expected to run for?
February 2020 to November 2023

Who is funding the study?
Tryg Foundation (Denmark)

Who is the main contact?
Mads Uffe Pedersen
mup.crf@psy.au.dk

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Previous plain English summary:

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Who is the main contact?
Mads Uffe Pedersen
mup.crf@psy.au.dk

Contact information

Type(s)
Scientific

Contact name
Prof Mads Uffe Pedersen

Contact details
Aarhus BSS
Aarhus University
Bartholin Allé 10, building 1322, room no 214
Aarhus
Denmark
8000
+45 (0)8716 5771
mup.crf@psy.au.dk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ID: 128564

Study information

Scientific Title
Combined Drug and Alcohol Treatment Trial (COMDAT): a two-arm interventional multicentre parallel-group superiority trial

Acronym
COMDAT

Study objectives
The primary objective is to investigate whether MOVE (g) including patients with both DUD and AUD in the same group is non-inferior to MOVE (i) DUD and MOVE (i) AUD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/06/2020, National Committee on Health Research Ethics (Region MidtJylland, Regionssekretariatet - Region Midtjylland, Skottenborg 26, 8800 Viborg, Denmark; +45 (0)7841 0183; komite@rm.dk), ref: 1-10-72-68-20

Study design
Two-arm interventional multicentre parallel-group superiority trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Alcohol and drug use disorders

Interventions
A parallel-group, two-arm, superiority trial comparing MOVE individual treatment (i) with MOVE group treatment (g) for alcohol use disorder and drug use disorder.

Participants will be asked to answer a short screening instrument identifying sex, age and severity of substance use, psychiatric diagnoses, and income. These questions will be used for randomization. The researchers know from other projects that these questions together constitute a very solid outcome predictor (even 21 months after enrollment to treatment).

Randomization will be performed by means of the minimization method using Minim randomization software, which is a biased-coin approach with a probability of 0.7 to 0.8 for allocation of the “best fitting” treatment (Bally et al., 2018). The minimization method is chosen to obtain an overall balanced distribution of participants, as the number of participants would most likely be too small for true randomization.

Both treatment conditions last 14 sessions and are followed by 6 months of follow-up treatment. The primary objective is to investigate whether MOVE (g) is non-inferior to MOVE (i). A secondary objective is, through registers, to investigate if MOVE (i) and MOVE (g) are superior to treatment as usual in municipalities, where MOVE has not been implemented. Participants will be recruited at four Danish treatment centers in four different Danish cities. Participants will be randomized to one of two conditions: Move (i) or MOVE(g). Recruitment will continue for one year, and the expected intake is 300 participants. An extensive baseline assessment will be made

approximately 1 week after randomization (interview by clinician), and follow-up assessments will be conducted at 3 and 9 months post-randomization. The most important outcome measures are drug and alcohol intake, number of sessions attended and psychological wellbeing.

Intervention Type
Behavioural

Primary outcome measure
1. Substance intake (last week and last month) measured in all attended sessions using the TEM screening (Trivsels og Effekt Monitorering) that consists of 17 items of which eight are related to substance use. The eight substance-related items in TEM will be used to monitor substance use in the last seven days before each counseling session. In addition, the client will be asked about substance use within the last month (AdultMap) at enrolment and 3 and 9 months after enrolment
2. Number of sessions attended is measured consecutively by the clinician responsible for the participant's treatment course
3. Dropout from treatment as defined by being discharged for any reason other than having completed the treatment program

Secondary outcome measures
1. Psychological wellbeing within the last month measured at enrolment and 3 and 9 months after enrollment (AdultMap) and last week using three items as part of the TEM screening in every counselling session
2. Everyday functioning (concentration, planning, keeping appointments, sleep, eating habits, cleaning etc) within the last month measured at enrolment and 3 and 9 months after enrolment (AdultMap) and within the last week using TEM screening in every counselling session
3. Illegal activities within the last month at enrolment and 3 and 9 months after enrolment (AdultMap)
4. Employment/education activities within the last month and 3 and 9 months after enrolment (AdultMap)

(added 29/09/2020)
Outcome measures related to feasibility/acceptability:
5. Audio recordings of all treatment sessions
6. Qualitative interviews about participants experiences of treatment at nine months follow-up.
7. Survey of the counselors treatment experiences that focuses on the feasibility of the treatment.
8. Compare reason of discharge from treatment with the two national registers of drug and alcohol users admitted to treatment (Case-control)

Overall study start date
01/02/2020

Completion date
01/11/2023

Eligibility

Key inclusion criteria

1. Participants aged above 17 years seeking treatment for a substance use disorder, who are willing to give consent
2. Participants must be able to speak and read Danish

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Patients with an ongoing or recent (< 1 month) treatment episode for substance use disorders
2. Patients with opioid use disorders
3. Patients with ongoing delusions/psychosis, threatening/aggressive behavior and/or severe cognitive impairment

Date of first enrolment
01/10/2020

Date of final enrolment
01/11/2022

Locations

Countries of recruitment
Denmark

Study participating centre
Aarhus Municipality Center for Substance abuse treatment
Sumatravej 3
Aarhus
Denmark
8000

Study participating centre
Randers Municipality Center for Substance abuse treatment
Gammel Hadsundvej 1
Randers
Denmark
8900

Study participating centre
Aabenraa Municipality Center for Substance abuse treatment
Reberbanen 3
Aabenraa
Denmark
6200

Study participating centre
Herning Municipality Center for Substance abuse treatment
Tietgensgade 5
Herning
Denmark
7400

Sponsor information

Organisation
Aarhus University

Sponsor details
Nordre Ringgade 1
Aarhus
Denmark
8000
8715 0000
au@au.dk

Sponsor type
University/education

Website
https://www.au.dk/

ROR
https://ror.org/01aj84f44

Funder(s)

Funder type
Charity

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

Results and Publications

Publication and dissemination plan
The researchers aim to publish at least two papers and a scientific report based on this study. They plan to publish these two publications in high-impact peer-reviewed journals. A study protocol will be submitted soon.

Intention to publish date
01/01/2024

Individual participant data (IPD) sharing plan
In the COMDAT trial the researchers adhere to the Danish data protection law and regulations and the study has been approved by the Danish data protection agency. Researchers performing data management, analysis and interpretation will, however, be kept blind to participants' randomization status at all times during the trial. All enrolled patients eligible for participating in the project will be thoroughly informed about what the project implies and will be asked to sign an informed consent. The researchers keep the data they obtain confidential. The researchers in the study may not pass information about individuals in the study to people who are not a part of the study. Data will consist of data obtained via screening measures and taped conversations (only audio).
All obtained data will be placed on a safe server at Aarhus University. Data will be encrypted and a two-factor password will be used to get access. It is only researchers involved in the study who will get access to the data. As soon as all data have been collected they are sent to Statistics Denmark and will be pseudonymized. Only Statistics Denmark possess the unique key that can identify specific individuals
The datasets generated during and/or analysed during the current study are/will be available for publication reviewers upon request from Mads Uffe Pedersen (mup@psy.au.dk). Data can be requested after they have been sent to Statistics Denmark and have been pseudonymized (in 2021). After pseudonymization data will be used for analyses in reports/papers.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			23/09/2020	No	Yes
Protocol article	protocol	26/02/2021	01/03/2021	Yes	No