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How can we improve opioid assisted medical treatment for people with externalizing behavior?

Submission date
03/07/2020

Recruitment status
No longer recruiting

Registration date
04/09/2020

Overall study status
Completed

Last Edited
24/08/2022

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
Opioid use disorder (OUD) is a medical condition with substantial and increasing contribution to the global disease burden. Opioid assisted treatment (OAT) is treatment involving a substitute drug, such as methadone, which allows patients to get on with treatment without having to worry about withdrawing or buying street drugs. However, although treatment for alcohol and drug disorders is free of charge in Denmark, there is an alarming number of people who are hard to reach and retain in OAT, and who often experience low quality of life, continue substance use, and who display criminal behavior and have increased mortality.
This trial evaluates the feasibility, acceptability, clinical, and cost-effectiveness of a combination of the Impulsive Lifestyle Counseling program (ILC) and MOVE-individual versus MOVE individual in OAT in four community-based public treatment centers in Denmark. The primary aim is to test whether an intervention with a combination of ILC and MOVE-individual (i) will improve retention more than MOVE (i) for service users with externalizing behavior enrolled in OAT. A secondary aim is, through registers, to investigate whether ILC and MOVE (i) are superior to treatment as usual in municipalities, where ILC and MOVE have not been implemented in OAT.

Who can participate?
Adult patients (over 18) who are seeking/are enrolled in OAT are eligible for participation in the study. Patients with ongoing delusions or psychosis, severe threatening or aggressive behavior and/or severe cognitive impairment will be excluded from the trial.

What does the study involve?
The trial will take place in four different public municipality treatment centers, and 137 individuals who will seek/are undergoing OAT in these four centers will be offered participation in the study. At each treatment center, participants will be randomized to two conditions (ILC and MOVE (i). Both arms consist of primary treatment (14 sessions). All participants will receive vouchers at every second treatment attendance and at follow-up interviews.

What are the possible benefits and risks of study participation?
Receiving treatment through two interventions (ILC and MOVE (i) that have been tested in RCTs

with promising results and positive evaluations from the participating patients; receiving vouchers worth 200 DKK at every other session attendance throughout the trial; receiving vouchers for participating in the follow-up interviews; supporting the development of OAT in Denmark. There are no known risks of participating in the study.

Where is the study conducted?
Recruitment and treatment will be managed by the four participating treatment centers. Data management and analyses will be carried out by The Center for Alcohol and Drug Research, Aarhus University. Data will be stored in secured servers.

When is the study starting and how long is it expected to run?
Patient intake will begin early October 2020 and will continue for one year. Data management, analyses and development of reports/papers will continue until 1/09/2024.

Who is funding the study?
Trygfonden (Denmark)

Who is the main contact?
Birgitte Thylstrup, Associate professor, bt.crf@psy.au.dk, Centre for Drug and Alcohol Research, Aarhus University
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Multicentre RCT comparing two interventions targeting externalizing behavior in patients enrolled in opioid agonist treatment (OAT)

Acronym
ILC

Study objectives

Intervention with a combination of Impulsive Lifestyle Counseling and MOVE-individual (i) (combination of Motivational Interviewing (MI) and Cognitive behavioral therapy (CBT)) will improve retention more than MOVE (i) for service users with externalizing behavior enrolled in opioid agonist treatment. The primary objective is to investigate whether ILC is superior to MOVE (i). A secondary objective is, through registers, to investigate if ILC and MOVE (i) are superior to treatment as usual in municipalities, where ILC and MOVE have not been implemented in OAT.

Ethics approval required
Old ethics approval format

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

Study design
Clinical multicentre randomized controlled trial with longitudinal case-controls

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Externalising behavior

Interventions
A parallel group, two arm, superiority trial comparing ILC with MOVE individual treatment for opioid use disorder (OUD).
Participants will be recruited at four Danish treatment centers in four large Danish cities and municipalities, where the treatment will take place. In all, 137 individuals who seek/are undergoing treatment for opioid use disorders will be offered participation in the study. At each treatment center, participants will be randomized to one of two conditions: ILC/MOVE or MOVE. Recruitment will continue for one year. An extensive baseline assessment will be made approximately one 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: retention; substance use; every day functioning; illegal activities, social interaction with individuals (family, friends, acquaintances) with non-criminal behavior and/or with no substance abuse; employment/educational activities.

The two interventions that are tested in the trial:
1. The Impulsive Lifestyle program (ILC): Eight sessions targeting externalizing and criminal behavior. The ILC aims to support change in lifestyle, and involves a psychoeducational and motivational approach. The eight sessions will be followed by six MOVE (i) sessions.
2. MOVE: 14 MOVE sessions (a combination of motivational interviewing, cognitive behavioral therapy, and contingency management).
All participants will receive vouchers (200 DKK) at every second session attended, and at participation in follow-up interviews.
Case control: The case-control group will be drawn from The Registry of Drug Abusers Undergoing Treatment (SIB). The trial conditions will be compared using SIB; the Danish National Patient Register (Landspatienregistret); The Danish Registry for Causes of Death (Dødsårsagsregistret); The Psychiatric Central Research Register (Det Psykiatriske Centralregister); The Danish Central Crime Register (Det Centrale Kriminalregister) etc.
Randomization procedure: 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. We 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.
Follow-up: 3 and 9 months post-randomization

Intervention Type
Behavioural

Primary outcome measure
1. Dropout from treatment as defined by being discharged for any reason other than having completed the treatment program

Secondary outcome measures
1. Use of substances other than prescribed medications. Substance use is measured in all attended sessions using TEM screening (Trivsels og Effekt Monitorering). TEM consists of 17 items of which eight are related to substance use and will be used to monitor potential substance use in the last seven days before each counseling session. Further, participants will be asked about substance use within the last month (AdultMap)
2. Everyday functioning (concentration, planning, keeping appointments, sleep, eating habits, cleaning etc.) last month (AdultMap) and last week (TEM screening in counselling session)
3. Illegal activities last month (AdultMap)
4. Social interaction with individuals (family, friends, acquaintances) with non-criminal behavior and/or with no substance abuse (AdultMap) in last month
5. Employment/educational activities (AdultMap) in last month

Overall study start date
01/02/2020

Completion date
01/09/2024

Eligibility

Key inclusion criteria
1. Enrolment in opioid assisted treatment
2. Externalizing behavior assessed with EP6 (AdultMap)
3. Ability to engage in individual treatment sessions

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
137

Key exclusion criteria
1. Current psychosis
2. Severe aggressive and chaotic behavior

Date of first enrolment
01/10/2020

Date of final enrolment
24/08/2023

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

Study participating centre
Køge Municipality Center for Substance abuse treatment
Boholtevej 85
Køge
Denmark
4600

Sponsor information

Organisation
TrygFonden

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Virum
Denmark
2830
+45 4526 0800
info@trygfonden.dk

Sponsor type
Industry

Website
https://www.tryghed.dk/

ROR
https://ror.org/02rcazp29

Funder(s)

Funder type
Industry

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
Planned publication in high-impact peer-reviewed journals.
Planned national report.

Intention to publish date
06/01/2024

Individual participant data (IPD) sharing plan
Raw data will be shared at a later stage on request. In the ILC trial we 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 eligble for participating in the project will be thoroughly informed about what the project implies and will asked to sign an informed consent. We keep the data we 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 pseudomized. Only Statististic 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 pseudomized (in 2021).
After pseudomization 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?
Protocol article		07/04/2021	09/04/2021	Yes	No