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Youth drug abuse treatment project (YouthDAT project)

Submission date
19/08/2016

Recruitment status
No longer recruiting

Registration date
29/08/2016

Overall study status
Completed

Last Edited
18/09/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Substance use disorder (SUD) in young people is a growing problem in Denmark as well as in many other countries. SUD stunts normal development in the sense that many young users do not get a good education and therefore risk becoming marginalized with little or no attachment to work life. They can also suffer from social and/or psychological problems that can be hard to detect initially and are therefore not attended to in a timely manner during the course of treatment. In Denmark, SUD treatment is provided by independent municipal treatment centers and the treatment offered varies considerably. There is no evidence regarding what works and what doesn't. This study is investigating which approaches work best when treating young people for SUD comparing four different treatments on offer.

Who can participate?
Young people (aged 15-25) entering drug treatment.

What does the study involve?
The participants are randomly allocated to one of four treatment groups, or a fifth "control" group groups. Participants in the control group receive treatment as usual. All participants in the treatment groups receive cognitive behavioral therapy (CBT) once a week for 12 weeks, attend motivational interviews (MI) and use something called Transtheoretical Model of Behavior Change (TTM) to assess how ready they think they are to work on specific goals. Six months after this initial treatment, they are also followed up using what is called a Recovery Management Check-up (RMC). Participants in the second treatment group are also given a dkr200 voucher every time they attend a session. Participants in the third and fourth treatment group receive 6 months of follow up treatment after the initial 12 weeks. They also receive regular text messages reminding them of upcoming sessions, and also offering encouragement. Participants in the fourth group also get the same vouchers as those in the second whenever they attend a session. All participants in all groups are asked to complete a questionnaire before they start treatment in order for the counsellors treating them to identify their potential strengths and potential risk factors that may stop the participant from completing their treatment.

What are the possible benefits and risks of participating?
All participants in the treatment groups offered 12 sessions of CBT and MI by trained

counsellors every week, which is above the standard in Danish drug treatment. The sessions will be targeted on individual problems that may behind the substance abuse rather than just working on reducing or stopping the drug use. This also means that the goal of treatment is determined by the counseller and the drug user working together. During the course of treatment, the young person will have the same opportunities with regards to receiving other non-SUD treatments (i.e. psychiatric screening, medical treatment, acupuncture etc.). However, in order to secure that the groups will not differ with regards to the kind of SUD treatment delivered, the participants will not be offered alternative SUD treatments, such as group-therapy. Moreover, all participants in the treatment groups will get a six-month recovery management check-up (RMC), regardless whether they complete the treatment or not. The purpose of the RMC is to assess if a young person is in need of further treatment and to offer such treatment when necessary.

Where is the study run from?
A total of nine drug treatment centers in Denmark.

When is the study starting and how long is it expected to run for?
May 2014 to February 2018

Who is funding the study?
Ministry of Social Affairs and the Interior (Denmark)

Who is the main contact?
Professor Mads Uffe Pedersen
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

1-10-72-177-14

Study information

Scientific Title
A comparison of the efficacy of four treatment modalities for substance abuse in youth

Acronym
YouthDAT

Study objectives
The primary aims of the proposed research are to
1. Compare the efficacy of four treatment modalities in the treatment of youth with Substance use disorder (SUD);
1.1. Short-term intensive CBT&MI
1.2. Short-term intensive CBT&MI + vouchers
1.3. Short-term intensive CBT&MI + follow-up treatment + reminders
1.4. Short-term intensive CBT&MI + follow-up treatment + reminders + vouchers
2. Examine the effect of using reminders between sessions on treatment retention
3. Examine the effect of using vouchers to reinforce treatment retention
4. To examine if there were differences in how youth with different problem-profiles, as identified by the YouthMap, benefitted from the four treatment modalities

Ethics approval required
Old ethics approval format

Ethics approval(s)
Danish Research Ethics Committee, 02/09/2014, ref: 1-10-72-177-14.

Study design
Multicentre randomized case control follow-up study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Substance abuse

Interventions
Study Design:
The participants are randomly allocated into one of four groups. All four groups receive 12 weekly sessions of cognitive behavioral therapy (CBT) and motivational interviewing (MI) and all four groups will be using Prochanska & DiClemente's Transtheoretical Model of Behavior Change (also known as stages of change or TTM) to assess readiness to work on specific goals, lastly all four groups will get a six-month Recovery Management Check-up (RMC). This is also the outline of the treatment provided in the first group. The second group will additionally use voucher-based contingency management, i.e. the youth will be given a voucher in the amount of dkr200

(approx. €30) every other time he or she attends a therapy session. The third and fourth group will receive 6 month of follow-up treatment after the initial 12 week CBT & MI treatment is completed. In addition, the counsellors in group three and four will stay in contact with the youth between the 12 sessions (sending SMS reminders, encouragement and letters of current status), as well as create a contract between counsellor and youth. Lastly, the fourth group will also use voucher-based contingency management, i.e. the youth will be given a voucher in the amount of dkr200 (approx. €30) every other time he or she attends a therapy session.
The four groups are as such:
1. 12 sessions of manual-based CBT & MI & TTM & RMC
2. 12 sessions of manual-based CBT & MI & TTM & RMC + vouchers
3. 12 sessions of manual-based CBT & MI & TTM & RMC + 6 month. follow-up + contract + reminders + letters of status
4. 12 sessions of manual-based CBT & MI & TTM & RMC + 6 month. follow-up + contract + reminders + letters of status + vouchers
Lastly, there will be a fifth case-control group consisting of a gender, age and drug of choice matched group of youth who entered treatment in the respective treatment centers before the study began. This group will be identified through journals after intake is completed in order to match the group with the participants in each of the nine municipalities.
5. Case-control group who received treatment as usual.

Throughout the study an online log will be used by the counsellors to record different variables relating to the sessions and of actions between sessions. Each session will begin with the youth completing a questionnaire on well-being, drug- and alcohol-use, and cognitive functioning since last session (WOM: Wellbeing and Outcome Monitoring). The results of these will also be recorded in the log.

Before treatment is initiated, the youth will complete a YouthMap questionnaire in collaboration with the counsellor to be used to identify potential strengths of the youth as well as potential risk factors with regards to completing the treatment course. This initial screening is planned to take place at the first appointment, which is not part of the 12 sessions, while the youth is to be given feedback on the YouthMap profile in the first of the 12 sessions, where the goal of treatment is also to be established in collaboration with the youth.

All sessions in the 12-week program will be videotaped, with the camera focusing on the counsellor. These videos will be used in an analysis of the degree to which the methods have been implemented during the trial. The analysis will assess a) the degree to which the counsellor uses the manual and the techniques of CBT & MI, and the quality of the therapy using the MD3 Screening, Brief Intervention, and Referral to Treatment (SBIRT) coding scale. And b) the YouthMap feedback with a focus on the method of delivery (one-way communication or dialogue) and the degree to which the profile is utilized in setting goals.

The study can be divided into three overall phases:

1. A pre-trial phase.
Initially, data on practice as usual i.e. the organizational structure of the treatment centers, the type of therapy delivered, level of data registration as well as counsellor level-of-training was collected. The counsellors also videotaped a session with a youth before the trial began, to have baseline data on the type and quality of therapy pre-trial. Following this, the counsellors participated in an intensive eight-day course on CBT & MI, and the other therapeutic elements included in the study. They were subsequently randomly assigned to one of the four groups and each given the treatment manual that applied to the group they had been randomized to. Researchers at the Center for Alcohol and Drug Research (CRF) visited the each treatment

center for a 1-day information meeting, where the study, the manual and the YouthMap questionnaire were reviewed and discussed with the counsellors.

2. A trial phase.
Intake begins and the youth are randomly assigned to one of the four groups. Randomization is based on four variables: age, gender, number of days using cannabis last month and number of days using drugs other than cannabis last month. Before treatment is initiated each youth completes a YouthMap questionnaire with their respective counsellor. The results of these have two functions: a) to supply the counsellor with a profile of the youth that will form the basis for the youth and counsellor to set goals for treatment and b) to be used as baseline-data in the study. Throughout the study, the counsellors receive supervision from two trained and experienced psychologists (who were also responsible for the initial CBT & MI course). The counsellors are offered guidance in interpreting the individual YouthMap profiles by Professor Mads Uffe Pedersen and they also participate in a one-day course on the interpretation of the YouthMap profile. Researchers at CRF will do a total of four follow-up interviews with each participant during the project (3 m, 6m., 9m. and 21 m. after baseline). These are conducted either online by the youth him- or herself or over the telephone by a researcher.

3. A post-trial phase.
Intake ceases when at least 400 of the randomized youth have completed at least one CBT/MI session.CRF will collect data on an age/gender and drug of choice matched group of youth who were enrolled in each treatment center before the trial began in order to conduct a cost-effect analysis as well as to serve as a case-control group. Researchers at CRF will during this phase also conduct an analysis of level of adherence to the CBT/MI methods. Two videos from each counsellor, recorded at an allocated time during the trial, as well as the baseline video, will be analyzed using SBIRT. In addition, researchers at CRF will conduct the afore mentioned analysis of how the YouthMap profile is communicated to the youth, as well as the extent to which the result of YouthMap is used to set treatment goals in collaboration with the youth. Lastly we will conduct statistical analysis, comparing the outcome of the four groups on variables such as drug use, treatment retention and well-being. Furthermore, we will analyze if there are differences in how the four profiles respond to the four treatment modalities.

Interventions:
1. Cognitive behavioral therapy is a highly structured and focused approach to substance use treatment that is based on a collaborative and active relation between the counsellor and the youth. It is collaborative in the sense that the therapist’s role is to help the youth discover the erroneous thinking and maladaptive behaviors that underlie the addiction through open-ended questioning and by making the youth reflect upon the benefits and disadvantages of using substances. In addition, the youth is taught different cognitive and behavioral techniques that can reduce emotional discomfort and negative affect in order to learn alternative ways of coping with these. Psychoeducation also plays a big part in CBT for SUD, both with regards to how the drugs affect people on an emotional and cognitive level, but also with regards to cravings and the peak in cravings they may experience, before it declines. The relationship between cognition, emotion, and behavior, which lies at the heart of the cognitive understanding of maladaptive behaviors, is also presented to the youth. Different high-risk situations are identified and strategies are planned for how to deal with these situations. Homework between sessions are planned and these can be of various tasks that applies to the problems discussed in the session. The tasks are to be determined in collaboration with the youth and they should be of a kind that increases the likelihood of success and of fulfilment.
2. Motivational interviewing (MI) is a client-centered non-judgemental counseling style that aims to elucidate and resolve the ambivalence that the youth may have towards their drug use. Youth who enter treatment do so at various levels of motivation and readiness to change. The

therapist's role is to increase the youth's awareness of the problems drug use create in their lives. This is accomplished through open-ended questioning, reflective listening, and through summary statements. By meeting the youth in a non-confrontational and non-judgmental style the therapist picks up on and explores statements that expresses problems relating to the drug use and the therapist also attempts to elicit change-talk from the youth. While the therapist is focusing on eliciting motivation to change, he or she is never directional in their approach. While MI is present throughout the treatment course, it is especially applied at the beginning of treatment.
3. The Transtheoretical Model of Behavior Change (TTM) is used to determine the level of readiness for change and to set realistic goals. According to the TTM, change is acquired through a process that entails the following stages: Precontemplation (not considering making changes or acknowledging problems), contemplation (recognizing problems relating to substance use and considering making changes), preparation (making plans to change behavior), action (making changes, cutting down or stopping all together), maintenance (sustaining change and preventing relapse), and relapse (slips are dealt with quickly, whereas fullblown relapses require a regression to one of the initial stages of the TTM). The TTM is also used throughout the therapy to assess progress with regards to the goals of therapy.

The sessions: each session begins with a review of the agenda. In this project, the agenda is predetermined with the exception, that the youth can add a theme if they want. In the two groups that use vouchers, these are given to the youth in the beginning of the session, otherwise the Wellbeing and Outcome Monitoring (WOM) is always the first task on the agenda. WOM examines the current state of well-being in three areas: personal, relational and social, as well as the current state of every-day functioning, and use of drugs and alcohol since last session. The answers given by the youth are discussed in relation to the previous WOM and current concerns and problems are discussed when necessary. This flows easily in to the next point on the agenda which deals with changes since last session, current problems or positive experiences since last session and reviewing the goals. Homework is then reviewed and high-risk situations are discussed. Coping strategies are planned and potential slips are dealt with. In all these discussions, the counsellor and the youth collaboratively examine the thinking pattern of the youth and the counsellor offers psychoeducation, when appropriate. Coping skills are rehearsed and trained using various CBT techniques. New homework is assigned and the session ends with an assessment of the session itself.

Intervention Type
Other

Primary outcome(s)
Use of illicit drugs (measured pre-treatment, during treatment, and 3, 6, 9 and 21 month after admission)

Key secondary outcome(s))
1.Use of alcohol (measured pre-treatment, during treatment, and 3, 6, 9 and 21 month after admission)
2. Use of cigarettes (measured pre-treatment, and 3, 6, 9 and 21 month after admission)
3. Treatment retention
4. Illegal activities (measured pre-treatment and 3, 6, 9 and 21 month after admission)
5. Psychological wellbeing (measured pre-treatment, during treatment, and 3, 6, 9 and 21 month after admission)
6. Use of drugs in social network (measured pre-treatment, and 3, 6, 9 and 21 month after admission).

7. Social support (measured pre-treatment, and 3, 6, 9 and 21 month after admission)
8. Educational and vocational activities (measured pre-treatment, and 3, 6, 9 and 21 month after admission)
9. Housing conditions (measured pre-treatment, and 3, 6, 9 and 21 month after admission)
10. Income (measured pre-treatment, and 3, 6, 9 and 21 month after admission)

Completion date
01/02/2018

Eligibility

Key inclusion criteria
1. Youth aged 15-25 years entering drug treatment
2. Starting treatment in one of the participating treatment centers
3. Parental consent will have to be provided for those participants who are under the age of 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
460

Key exclusion criteria
1. Youth who are addicted to opioids
2. Youth with threatening behavior
3. Youth with a serious psychiatric disorder including current psychotic condition, current mania or major depression etc
4. Youth with severe cognitive impairment (e.g. IQ< 70)

Date of first enrolment
01/09/2014

Date of final enrolment
01/05/2016

Locations

Countries of recruitment
Denmark

Study participating centre
Center for Drug Treatment Randers
Gammel Hadsundvej 1
Randers
Denmark
8900

Study participating centre
Center for Drug Treatment, Aarhus
Sumatravej 3
Aarhus
Denmark
8000

Study participating centre
Center for Drug Treatment, Odense
Slotsgade 7
Odense
Denmark
5000

Study participating centre
Center for Drug Treatment, Holbæk
Kasernevej 6, 1. sal
Holbæk
Denmark
4300

Study participating centre
Center for Drug Treatment, Svendborg
Nyborgvej 4 1. sal
Svendborg
Denmark
5700

Study participating centre
Center for Drug Treatment, Herning
Tietgensgade 5
Herning

Denmark
7400

Study participating centre
Center for Drug Treatment, Fredericia
Vendersgade 46-48
Fredericia
Denmark
7000

Study participating centre
Center for Drug Treatment, Aabenraa
Reberbanen 3
Aabenraa
Denmark
6200

Study participating centre
Center for Drug Treatment, Silkeborg
Færgevej 1
Silkeborg
Denmark
8600

Sponsor information

Organisation
Aarhus University, Centre for Alcohol and Drug Research

ROR
https://ror.org/01aj84f44

Funder(s)

Funder type
Government

Funder Name

Ministry of Social Affairs and the Interior

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Post Hoc Secondary Analysis	21/07/2021	22/07/2021	Yes	No
Results article		31/08/2021	18/09/2023	Yes	No
Basic results		26/03/2019	26/03/2019	No	No
Participant information sheet		25/08/2016	20/09/2016	No	Yes
Participant information sheet		25/08/2016	20/09/2016	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes