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Understanding your vulnerabilities

Submission date	Recruitment status	[ ] Prospectively registered
13/11/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/11/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/11/2023	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Many young adults with substance use disorder experience internalizing symptoms such as anxiety and depression in addition to their substance use. Comprehensive integrated treatments may not be feasible for practical reasons, or because patients are not well-prepared to engage in such treatment. Brief psycho-education may help prepare patients for more comprehensive care, or to benefit from treatment that focuses on only substance use disorder or only mental health problems, in spite of the comorbidity. This study aims to assess the acceptability and feasibility of brief psycho-education.

Who can participate?
People aged 18 to 30 years old enrolled in treatment for substance use disorder at the participating site

What does the study involve?
The study involves receiving either standard treatment with cognitive behavioral counselling and motivational interviewing or standard treatment with six sessions of integrated psycho-education. All patients will have access to the same pharmacological and wrap-around services in addition to counselling, regardless of randomization.

What are the possible benefits and risks of participating?
The potential benefits of participating are to have a better treatment experience and improved outcomes. While any study carries risks, the Ethics Committee for the Central Jutland Region has not identified significant risks.

Where is the study run from?
The Municipality of Gladsaxe (Denmark)

When is the study starting and how long is it expected to run for?
January 2021 to June 2025

Who is funding the study?
Trygfonden, a Danish research fund

Who is the main contact?
Morten Hesse (Associate Professor at the Centre for Alcohol and Drug Research, Aarhus University), mh.crf@psy.au.dk

Contact information

Type(s)
Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
38967

Study information

Scientific Title
Brief psychoeducation for comorbid alcohol and other drug use disorders and internalizing symptoms

Acronym
PsyCom

Study objectives
Brief psychoeducation on internalizing problems will be acceptable and feasible in the context of outpatient treatment for substance use disorders

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/12/2022, The Scientific Ethics Committees for the Central Jutland Region (Skottenborg 26, Viborg, 8800, Denmark; +45 7841 0183; komite@rm.dk), ref: 1-10-72-113-22

Study design
Two-arm pilot feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community, Other therapist office

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet in Danish, or a translation into English

Health condition(s) or problem(s) studied
Substance use disorder and internalizing symptoms

Interventions
This study will investigate treatment as usual plus psychoeducation versus treatment as usual alone for comorbid substance use disorders and internalizing symptoms.

For both interventions, the municipality is responsible for providing psychosocial and pharmacological treatment for substance use disorders. In the experimental arm, the clients are offered six sessions of psychoeducation focusing on the overlap between internalizing symptoms and substance use.

Many emerging adults (18-30 years old) with alcohol and other drug use disorders (AOD) suffer from concurrent symptoms of anxiety or depression, often referred to as internalizing disorders. However, the provision of good care is challenged because of the limited availability of relevant treatment options that can easily be implemented and managed in clinical practice. Considering the high risk of severe consequences across life areas for these emerging adults, it is of great importance to develop innovative brief evidence-based interventions that engage them at an early stage when they enroll in AOD treatment.

There is a flyer to inform participants about the study; informed consent; information material from the National Scientific Ethics Committees (as part of informed consent material); a workbook on the experimental conditions (can be made available by request); standard treatment (can be made available by request).

During the first in-person contact, social workers and/or nurses at the participating treatment site will assess whether an individual is eligible for study participation according to the eligibility criteria. If the individual is deemed eligible, the same employee will verbally inform the individual about the trial and provide a participant information sheet, including material on informed consent and material from the National Scientific Ethics Committees. If the individual accepts the invitation and gives informed consent for study participation, the employee will collect the necessary information for randomization in an online questionnaire, which is forwarded to the Center for Alcohol and Drug Research (CADR), at Aarhus University, via an anonymous and secure email. The research team will ensure the confidentiality of this data by keeping the online questionnaire data and consent forms on secure servers. Information on randomization will be sent by the research team within the same day or the next day by secure mail to the treatment site, which will initiate the start of the treatment sessions in the study arm that is given by the randomization. Treatment will start.

All treatment providers at the participating site have a BA in social work, nursing, or a related field. Two counsellors with an education in social work will provide the experimental condition and have been trained in this by the researchers, who are available for questions throughout the study period. Standard treatment will be provided by all other counsellors at the treatment site. These counsellors also have educational background in social work/nursing and are trained in providing the standard treatment. Supervision is given to all counsellors by a psychologist at the site when needed.

Both interventions are provided face-to-face at the treatment site. Both interventions are individual counselling.

The study takes place at the participating treatment site; an outpatient treatment site in Gladsaxe municipality; Denmark. The intervention occurred in therapy rooms within the community clinic for substance use disorders.

The study is randomized using the minimization method with balancing on gender, age (25<age<30), and employment or training (versus none).

All treatment providers have a BA in social work, nursing, or a related field. For the experimental group, treatment providers practised the psychoeducation using extensive roleplay.

Intervention Type
Behavioural

Primary outcome measure
The expectation of a good outcome measured using the Outcome Expectancies Questionnaire at 1 and 3 months post-randomization

Secondary outcome measures
1. Symptoms of anxiety and depression measured using the Depression, Anxiety and Stress Scale - 21 Items (DASS-21) at 1 and 3 months
2. Level of functioning measured using the WHO Disability Assessment Schedule-5 (WHODAS-5) at 1 and 3 months
3. Knowledge of internalizing symptoms measured using qualitative interviews at the 3-month follow-up
4. Retention and treatment attendance measured using an electronic logbook to assess treatment attendance at each session, including no-shows and cancellations. Retention will be measured using time-to-event models at the time of the latest discharge from treatment, or December 31st 2024, whichever occurs first.
5. Days abstinent measured using the MapPlan at 1 and 3 months
6. Acute psychiatric care measured using both case files and interview data at 1 and 3 months post-randomization

Overall study start date
31/01/2021

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Seeking treatment for substance use disorder
2. Reporting 3 or more points on the Youthmap internalizing problems

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
30 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
Psychotic disorders

Date of first enrolment
17/08/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Denmark

Study participating centre
Gladsaxe Rusmiddelcenter (substance use disorder treatment services in the Municipality of Gladsaxe)
Østmarken 4
Søborg
Denmark
2860

Sponsor information

Organisation
Aarhus University

Sponsor details
Bartholins Allé 10
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Sponsor type
University/education

Website
https://psy.au.dk/en/research/research-centres-and-units/centre-for-alcohol-and-drug-research

ROR

https://ror.org/01aj84f44

Organisation
Gladsaxe Kommune (Gladsaxe Municipality)

Sponsor details
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Denmark
2860
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Sponsor type
Hospital/treatment centre

Website
https://gladsaxe.dk/kommunen/borger/sundhed-og-sygdom/misbrug-af-alkohol-og-rusmidler/gladsaxe-rusmiddelcenter

Funder(s)

Funder type
Research organisation

Funder Name
Danish Foundation TrygFonden

Alternative Name(s)
TrygFonden Kystlivredning

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 publications in high-impact and peer-reviewed journals

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Morten Hesse, mh.crf@psy.au.dk. Data will be stored pseudonymized at Statistics Denmark's servers. Data will be the primary and secondary outcomes from the interviews only, not from the logbook. Data will be made available six months after the study has ended in aggregated format with cells of no less than 5 patients. Consent to share has not been collected. Ethical and legal restrictions mean that only aggregate data will be shared. Changes in legislation up to the request for raw data may influence the sharing of data.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	30/08/2021	14/11/2023	No	No