SOS-training Social skills and Street skills: Improving strength and reducing vulnerability for victimisation: a randomised controlled trial in addicted patients with psychiatric disorders

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41607

Source
ToetsingOnline

Brief title
SOS-training

Condition

- Other condition
- Psychiatric disorders NEC
- Lifestyle issues

Synonym
addiction and mental illness, dual diagnosis

Health condition

verslavingsproblematiek

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: NWO

Intervention

Keyword: addiction, dual diagnosis, social skills training, victimisation

Outcome measures

Primary outcome

The primary study parameter is the percentage of clients that has been

victimised in the year after the start of the training. All sorts of offenses

will be questioned (violence, property crimes, vandalism).

Secondary outcome

The secondary study parameters of the study are:

- Drugs and alcohol intake (Timeline Followback method, Sobell & Sobell, 1996)

- Severity of alcohol and/or drug use disorder: Alcohol Use Disorders

Identification Test / Drug Use Disorders Identification Test (AUDIT/DUDIT)

- Psychopathology: Brief Psychiatric Rating Scale (BPRS)

- PTSS-signs: Posttraumatic Diagnostic Scale (PDS)

- Emotion Disregulation: Difficulties in Emotion Regulation (DERS)

- Cognitive functioning: Mini-Mental State Examination (MMSE)

- Social functioning: Inventory of Interpersonal Problems (short form) (IIP-32)

- Dimensions of Anger Reactions (DAR).

- Quality of Life EuroQol (EQ-5D)

- Manchester short assessment of quality of life (MANSA)

- Self Esteem Rating Scale (SERS-SF 20)

- Kessler psychological distress scale (K10)

- Client Satisfaction Questionnaire (CSQ-8)

Other measures: Costs efficacy (Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (TiC-P)

Other information: moderators en mediators

Client's files will be checked on previous treatments and psychiatric disorders, to examine if the effect of this intervention can be (partly) due to previous treatment and to examine if co-morbid psychiatric disorders interfere with the effect of this intervention.

Study description

Background summary

Addiction and chronic psychiatric disorders often occur together. This vulnerable group of duall diagnosis patients has more chance of being victimised, especially concerning severe violent victimisation. Up until now there is only limited evidence of interventions proven to be effective for this target group. This research is aimed to develop and investigate a training to reduce vulnerability, to improve social skills and assertiveness and therefore lower the chance of being victimised and improve the sense of safety.

The main hypothese of this research is:
- 'SOS-training' is an intervention that reduces the chance of being victimised. There will be a lower frequency of victimisation and a higher sense of safety 12 months after the training, compared to before.

Study objective

The goal of this study is obtaining knowledge about the effectiveness of a training that aims to decrease victimisation of dual diagnosis patients.

The primairy research question is:
- What is the effect of the SOS-training on the frequency of victimisation of dual diagnosis patients?

Study design

The design contains a randomised, open study: Participants will be assigned to a condition randomly. The researchers as well as the participants themselves will be informed about the condition they are assigned to.

Intervention

The SOS-training will contain 12 group meetings of 60 minutes. The goal of this training is to improve psychological strength and to reduce vulnerability for victimisation. The training will consist of different components. One component will focus on counselling on what clients can do themselves to avoid or decrease risks concerning victimisation. A second component will focus on acquiring skills to increase personal safety and becoming more able to handle interpersonal conflicts. We will make use of techniques like brainstorming, group discussion, exercises and role-playing.

Study burden and risks

Burden:
Participants will have to invest time to participate in this research. Participants in the experimental condition will invest more time for participation. On the other hand, they will participate in an intervention of which we assume that it improves strength and reduces vulnerability for victimisation. A more specific overview of time investment can be found in section E2.
Participants will be filling in questionnaires at baseline, 2, 8 and 14 months. An overview of these questionnaires can be found in section K1 'secondary study parameters'. Fifty participants will be filling in the Safety Monitor again one week after the 14-months follow-up.

Risks:
There are no anticipated risks involved in participating in this research.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- In treatment for addiction and chronic psychiatric disorders
- Aged 18 years or older
- Being capable of giving informed consent and participating in the training

Exclusion criteria

- Acute psychotic problems that interfere with participating in the training
- High score on anti-social personality traits, to prevent patients from disturbing the group training.
- High level of psychopathy (score >30 on Psychopathy Checklist)
- Legally incapable

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-04-2014
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	16-01-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-01-2016
Application type:	Amendment

Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24122
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL46081.018.13
OMON	NL-OMON24122