

Study of Integrated Dual Diagnosis Treatment in the Netherlands.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23336

Source

Nationaal Trial Register

Health condition

Patients with a Severe Mental Illness with co-occurring alcohol or drug abuse.

Sponsors and support

Primary sponsor: Arkin,
Vrije Universiteit Amsterdam

Source(s) of monetary or material Support: Arkin,

A funding application is currently under review at the Fonds Psychische Gezondheid

Intervention

Outcome measures

Primary outcome

1. Type and severity of psychiatric symptoms (BPRS-E);
2. Level of substance abuse (MATE).

Secondary outcome

On a patient level we will use the following secondary outcomes:

1. Patients acceptance and adherence to their treatment (CRS);
2. Quality of life (MANSA);
3. Functioning (GAF);
4. stage of substance abuse treatment (SATS);
5. Therapeutical alliance (HAQ).

To study the effects of IDDT training on professional's therapeutic skills, attitude, knowledge, and fidelity we will use the following secondary outcomes:

1. Mastering of motivational interviewing techniques (MITI);
2. Theoretical knowledge concerning substance abuse (paper test);
3. Team IDDT fidelity (standardized fidelity assessment).

Study description

Background summary

Background:

It is estimated that around 41% of patients in the Netherlands with severe mental illness (SMI) such as schizophrenia and bipolar disorder also suffer from alcohol and/or drug use disorders, also called Substance Use Disorder (SUD). Although a number of studies have sought to establish the outcome of various types of integrated interventions, the literature on efficacy is inconsistent. Positive effects were found with Integrated Double Diagnosis Treatment. This is in concordance with experts who advise to integrate psychiatric and substance abuse treatment. Despite the fact that the effectiveness of IDDT has not yet been studied in the Netherlands, several mental health care institutes already have, or want to implement IDDT.

Research Question:

In this study we want to examine the effectiveness of IDDT on clinical outcomes, and the effects of IDDT training on therapeutic skills, attitude, knowledge, and fidelity.

Method/design:

As IDDT involves collective training of all team members, randomisation will be performed per team. This will also prevent contamination of conditions. Teams will be randomly allocated to condition 1, or to condition 2. In condition 1, IDDT will be implemented after baseline measurement. After 12 months, IDDT will also be implemented in condition 2. The follow up period of both teams will be 24 months. Measurements will be performed at baseline, and after 12 (T1), and 24 months (T2). At baseline, all patients will be screened. Patients who fulfil inclusion criteria will enter the study and followed-up.

Sample size calculation/data analysis:

Power analysis indicates that we need a total sample size of 80 patients if we want to detect a reduction of 20% in patients with DD (power=80%, alpha=0.05). Taken into account an estimated intracluster correlation coefficient of 0.005 (Murray & Blitstein, 2003), this sample size needs to be increased to 96 patients (Murphy et al., 2006).

Study objective

Compared to treatment as usual implementing Integrated Double Diagnosis Treatment (IDDT) in mental health care teams for severe mental illness (SMI) outpatient will improve a. outcomes at psychiatric symptoms and drug or alcohol abuse, and b. will improve therapeutic skills of professionals.

Study design

Baseline measurements will be conducted after randomization and follow-up measurements will be conducted at 12, and 24 months after the baseline measurement.

Intervention

Treatment as usual:

Treatment as usual consists of regular outpatient care according to the principles of FACT.

IDDT:

In collaboration with the Trimbos Institute and Arkin, a comprehensive IDDT toolkit has been developed, based upon the IDDT program and adapted to the Dutch health care context. Further development of the toolkit is recently taken over by LeDD, who also provides the implementation of IDDT through training and supervision. The IDDT toolkit comprises several evidence based interventions, but in this study only the core components will be implemented.

In this study IDDT comprises a standardized assessment of substance abuse. Implementation of IDDT entails that all team members;

1. Have knowledge of substance abuse and addiction;
2. Are trained in standardized assessment of substance abuse;
3. Are familiar with the stages as defined by Prochaska and Diclemente;
4. Will be trained in motivational interviewing techniques.

In each team, one team member will be given the task to monitor, and support the execution of IDDT. Also, an addiction specialist, someone with over 2 years of experience in addiction care, will be added to the team.

Contacts

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Eligibility criteria

Inclusion criteria

All patients in Mental Health Care (MHC) outpatient teams with a SMI defined as:

1. A diagnosis of schizophrenia or major affective disorder;
2. With a duration of at least 2 years;
3. Severe disability in terms of role functioning;
4. A co-occurring Substance Use Disorder (SUD).

Exclusion criteria

Patients will be excluded if they have inadequate mastery of the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2012
Enrollment:	150
Type:	Anticipated

Ethics review

Not applicable

Application type:

Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3034
NTR-old	NTR3182
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A