Societal participation and overcoming adversity

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26346

Source
NTR

Health condition

victimization
societal participation
severe mental illness
victimisatie
maatschappelijke participatie
ernstige psychische aandoeningen

Sponsors and support

Primary sponsor: Tilburg University
Stichting Rehabilitatie '92
GGz Eindhoven
Dijk & Duin
Source(s) of monetary or material Support: The Netherlands Organisation for Scientific Research (NWO)

Intervention

Outcome measures

Primary outcome

The primary study parameters will be safety and societal participation.

Secondary outcome

The secondary study parameters will be self-confidence and quality of life.

Study description

Background summary

Background
People with severe mental illness (SMI) in the Netherlands are more often victims than perpetrators of violence, and are also more often victimized than other Dutch citizens. This victimization appears to be one of the risks that these service users of mental health care have to deal with in their efforts to participate in the community. Other risks in societal participation are rejection, failure, loss and social stigma with possible adverse consequences.

Objective of the study
The main objective of the study is to gain insight in the effectiveness of the Victoria modules, in terms of acknowledgement for these experiences and risk awareness. These experiences and insights can be used to take acceptable risks in rehabilitation process. The focus is on increasing societal participation, reducing victimization and other forms of adversity.

Intervention
The first part of the module aims at exploring victimization experiences or other forms of adversity that service users have experienced in societal participation. The second part focuses on the evaluation of rehabilitation crises, with specific attention to the social context in which the crisis has occurred and environmental triggers that brought the service user off balance.

Study design and methods
The research will be carried out as a multicentre RCT, in which 346 outpatients will be included at baseline. Randomization is at a team level. A total of 8 FACT-teams of 2 institutes for mental health care are included. There are three moments of measurement: at the start (T0), after 9 months (T1), and after 18 months of intervention (T2).
Generalized linear mixed modelling is used to examine whether there is an effect on primary and secondary outcome parameters (societal participation, victimization, self-confidence,

stigmatization and discrimination, and quality of life).

Study objective

The Victoria modules are thought to have a positive effect on acknowlegdement for adversities and risk awareness. This can be used to take acceptable risks in rehabilitation process. This will then lead to more societal participation and less victimization and other forms of adversity.

Study design

T0 = no intervention, starts Feb. 2016.

training in Victoria.

T1 = experiment and control group, 9 months after T0.

T2 = experiment and control group, 9 months after T1.

Intervention

Victoria is a methodology to explore victimization (risks) attached to societal participation with severe mental illness, in the form of a conversation module.

The experimental teams receive the Victoria modules, and the control groups receive care as usual.

Contacts

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Eligibility criteria

Inclusion criteria

- having a Severe Mental Illness

- receiving care from a Flexible Assertive Community Treatment team of the Mental Health Care Centres Dijk en Duin or Eindhoven

- Older than 17 years of age

- Willing to participate in the research

Exclusion criteria

- younger than 18 years of age

- insufficient command of the Dutch language

- incapable to answer questions due to cognitive impairments, severe symptomatology, or psychoorganic disorders

- prolonged admission to psychiatric hospital, or staying in prison

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-02-2016
Enrollment:	346
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion Date:	11-01-2016
Application type:	First submission

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	NL4172
NTR-old	NTR5585
Other	CCMO NL53845.028.15 : NWO 432-12-808

Study results