

Managing victimization risks attached to societal participation by people with severe mental illness

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

Summary

ID

NL-OMON46868

Source

ToetsingOnline

Brief title

Societal participation and overcoming adversity

Condition

- Other condition
- Schizophrenia and other psychotic disorders

Synonym

Severe Mental Illness (SMI)

Health condition

mensen met ernstige psychische aandoeningen, met een lange(re) ziekteduur (> 2 jaar in zorg zijn bij de GGz) met beperkingen in het functioneren op meerdere levensterreinen

Research involving

Human

Sponsors and support

Primary sponsor: Tranzo Tilburg University

Source(s) of monetary or material Support: NWO programma 'Geweld Tegen Psychiatrische Patiënten'

Intervention

Keyword: severe mental illness, societal participation, victimization

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

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.

Study objective

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 reducing victimization and other forms of adversity.

Research questions on objective and subjective safety:

- Do the Victoria modules contribute to acknowledgement for victimization experiences?

- Do the Victoria modules contribute to an increase in perceived safety?
- Do the Victoria modules lead to less forms of adversity in societal participation?
- Do the Victoria modules lead to less perceived stigmatization and discrimination?

Research questions on societal participation and rehabilitation

- Do the Victoria modules contribute to more insight in the wishes, needs, and goals of clients in terms of social participation?
- Do the Victoria modules lead to an increase in social/societal functioning?
- Do the Victoria modules contribute to more self-confidence?
- Do the Victoria modules contribute to a higher quality of life?

Study design

The research will be carried out as a multicentre RCT. Randomisation is at a team level, after which a random subsample is taken at a individual level. A total of 8 FACT-teams of 2 institutes for mental health care are included (each institute 4 teams). There are three moments of measurement: at the start (T0), after 9 months of intervention (T1), and after 18 months of intervention (T2). In order to monitor the implementation process in the intervention teams, qualitative interviews will be carried out among clients, mental health professionals, management staff, and trainers with the focus on the practical application of the novel intervention. These interviews will take place during the last measurement period.

Intervention

The module aims at exploring victimization experiences or other forms of adversity that service users have experienced in societal participation (in the field of housing, employment, daily activities, and social relations).

Study burden and risks

The Victoria modules (the intervention) carefully explore whether there are any adversities related to participation and rehabilitation. For this study, a questionnaire will also be administered to the client. Should the client through conversation about these adversities be thrown off balance, the client is embedded in a treatment practice and the multidisciplinary FACT team will act as a safety net. When the client indicates not wanting to talk about victim experiences, this will be respected.

Contacts

Public

Selecteer

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

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 psycho-organic disorders
- prolonged admission to psychiatric hospital, or staying in prison

Study design

Design

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

Primary purpose: Other

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2016
Enrollment:	345
Type:	Actual

Ethics review

Approved WMO	
Date:	18-11-2015
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	24-05-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	22-03-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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
CCMO	NL53845.028.15