Collaborative care program for patients with treatment resistant schizophrenia.

Published: 23-08-2019
Last updated: 19-08-2024

- Identifying phenomena and relationships/patterns through in-depth study of a limited number of cases and get insight in the impact of CCP for TRS on functioning, psychotic symptoms, quality of life, recovery, self-management, shared decision-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON52870

Source
ToetsingOnline

Brief title
Collaborative care for patients with treatment resistant schizophrenia.

Condition

- Schizophrenia and other psychotic disorders

Synonym
long-lasting psychosis, treatment resistant schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Reinier van Arkelgroep (Den Bosch)
Source(s) of monetary or material Support: eigen financiering door deelnemende GGZ organisaties

Intervention

Keyword: Collaborative care program, Recovery, Treatment resistant schizophrenia

Outcome measures

Primary outcome

Improving social functioning

Secondary outcome

Reduce psychotic symptoms

Improve quality of life

Improve recovery

Improve shared decision making

Enhance self management

Reduce and/or early identifcation of somatic co-morbidit

Study description

Background summary

Over the past decades, several effective interventions have been developed for the treatment of patients with TRS, but it is uncertain whether it is possible to offer this integrated in practice to offer these available interventions in an integrated manner in clinical practice. To treat patients with TRS according existing guidelines (in medical psychiatric and psychosocial field) we introduce a collaborative care program for patients with TRS (CCP for TRS).

The CCP for TRS is a structured treatment program for patients with TRS that will be integrated in Early Psychosis Intervention Teams (EPIT) and Flexible Assertive Community treatment (FACT). The program is based on the principles of collaborative care. Similar programs for patients with bipolar disorder or a personality disorder who are treated in Dutch FACT teams showed improvements in symptoms, quality of life and functioning. The CCP for TRS consists of: optimal clozapine treatment, lifestyle interventions, a

peergroup and work with informal caregivers. The program focuses on promoting empowerment and recovery of patients. Also, effective coordination and continuity of care get special attention in this program.

CCP for TRS will be investigated in a quasi-experimental study with the following outcome measures: functioning, psychotic symptons, quality of life, recovery, the degree of shared decision making, patient self-management and somatic co- morbidity. We also investigate the patients' experiences and satisfaction with the CCP for TRS.

Study objective

- Identifying phenomena and relationships/patterns through in-depth study of a limited number of cases and get insight in the impact of CCP for TRS on functioning, psychotic symptoms, quality of life, recovery, self-management, shared decision-making and somatic co-morbidity.
- Get insight into experiences of patients and caregivers with CCP for TRS and identify elements that contribute to satisfaction

Study design

Quasi-experimental research

Intervention

Collaborative care program for patïents with treatment resistant schizophrenia

Study burden and risks

For the intervention study patients are required to visit their own mental health organization 5 times for the data collection. Usually each visit will take about 60 to 75 minutes, but if desired by the patient this could also be 2 visits. If necessary, this meeting can even take place at the patient's residence. At the end of the study patients and caregivers are asked to participate in a focus groupinterview, which takes about 90 minutes.

Contacts

Public
Reinier van Arkelgroep (Den Bosch)

Hinthamerstraat 205
Den Bosch 5211 MN
NL

Scientific
Reinier van Arkelgroep (Den Bosch)

Hinthamerstraat 205
Den Bosch 5211 MN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The intervention study includes patients over 18 years of age with treatment resistant schizophrenia and who receive treatment from participating EPIT and FACT (these patients were identified in the cross-sectional study). These patients do not use clozapine at the time of inclusion.

Exclusion criteria

- Patients who not master the Dutch language to complete in questionnaires and giving an interview.
- Patients without informed consent.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-11-2020
Enrollment:	3
Type:	Actual

Ethics review

Approved WMO Date:	23-08-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-02-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-02-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-06-2022
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

No registrations found.

In other registers

Register	ID
Other	AsPredicted (#62738), pre-registration titled 'Collaborative care for patients with treatment-resistant schizophrenia', registered 13 april 2021. https://aspredicted.org/gk958.pdf
CCMO	NL64469.029.18