Collaborative Care for patients with severe personality disorders: a comparative multiple case study on process and outcomes.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON34680

Source
ToetsingOnline

Brief title
Collaborative Care for patients with severe personality disorders.

Condition

- Personality disorders and disturbances in behaviour

Synonym
cluster B personality disorders, personality disorders

Research involving
Human

Sponsors and support

Primary sponsor: De Geestgronden (Bennebroek)

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Collaborative care, multiple case study, personality disorders, suicidality

Outcome measures

Primary outcome

Outcome indicators are the following variables:

- no show/drop out

- suicidality

- self harm

- addiction

- quality of life

- psychosocial functioning

Secondary outcome

Process indicators are the following variables:

- quality of the therapeutic alliance

- patient or family satisfaction

- fostering or hampering factors

- (organisational) preconditions

Study description

Background summary

A personality disorder is a severe and complex psychiatric disorder. The lifetime prevalence of personality disorders is 9-14% in the general population, whereas as much as 60% of patients in specialized mental health care and 56% of patients with an addiction have at least one personality

disorder (Multidisciplinaire Richtlijn Persoonlijkheidsstoornissen, 2008; Tyrer & Mulder, 2006).
Structured psychotherapy is recommended as the preferred treatment of personality disorders since studies mainly report modest positive results (Bateman & Fonagy, 2008, 2001; Linehan e.a., 2006; Binks e.a., 2006; Giesen-Bloo e.a., 2006; Van de Bosch, 2005; Leichsenring & Leibing, 2003; Verheul e.a., 2003). Although these therapies are aimed at the complex problems of personality disorders, a substantial group of patients does not benefit. These patients have a chronic and unstable course of illness with disruptive behaviour and addiction problems. They experience severe suffering, especially those who have been treated with several (unsuccessful) therapies and with an elevated risk of suicide (van Luyn, 2007; Paris, 2007). They often receive long lasting care in specialized mental health care institutes (Koekkoek e.a., 2007; van Meekeren, 2009).
However, these patients may benefit from Collaborative Care; a structured approach, with a central role for the nurse, with emphasis on the quality of the communication and the reduction of health care needs, problems and problematic behaviour. We expect that this intervention strategy will improve quality of life and coping with (chronic) suicidal behaviour, psychiatric illness, addiction and daily problems (De Bie e.a., 2009; Koekkoek e.a., 2009).

Study objective

The objective of this study is to describe the process of application as well as the outcomes of a Collaborative Care program provided for patients with severe personality disorders in specialized mental health care.
The following research questions are formulated:
A. What are the results of a Collaborative Care program for patients with a personality disorder with regard to suicidality, self harm, addiction, psychosocial functioning and quality of life?
B. What are the experiences of patients, family members and nurses with the Collaborative Care program?
C. Which factors hamper or foster the application of a Collaborative Care program, as described by patients, family and nurses?

Study design

The present study is a comparative multiple case study conducted within the specialized mental health care institute GGZ inGeest, located in Amsterdam and surrounding areas, and contains an experimental group in which the Collaborative Care program is provided and a control group in which Care as Usual is provided. A distinctive feature of a multiple case study is, that data are collected and analyzed at the individual level as well as the group level. Different types of data collection will be used: questionnaires, dossier research and interviews. By means of data triangulation a profound

understanding will be obtained of the results and the processes of the Collaborative Care program.

Intervention

Collaborative Care is a care arrangement in which a collaborative care manager (nurse) has a central role in optimizing coordination and continuation of care. The strong emphasis on collaboration in all stages of the care process * with the active involvement of the patient * should empower the patient in coping with his illness and life in general. *Contracting* is used to reach a shared decision on treatment goals and working methods. The treatment components which are provided within Collaborative Care enhance problem solving skills regarding rumination, impulsivity and emotion-management. (Para) suicidal behaviour will be systematically registered and discussed with the patient. The mental condition of the individual patient will be monitored by means of Routine Outcome Monitoring (ROM).
Nurses in the experimental group will be trained in their role as collaborative care manager and in the application of these special Collaborative Care interventions. The application of the intervention will be supported with intervision and coaching.

Study burden and risks

Possible advantages of participation in this study
We expect that patients will be better able to cope with their problems and illness. We do not know for sure that this outcome will be obtained: that is the reason to conduct this research.

Disadvantages of participation in this study
Patients will be asked to complete questionnaires three times during the study. This will cost 4 hours during the first session, during the second (after 6 months) and third session (after 12 months) this will cost 1,5 hours. Partly the questionnaires will be completed with the help of a research assistent, partly the patient can complete the questionnaires in their home setting in their preferred time. In the experimental group a questionnaire will be completed every session, this will cost a very limited amount of time and effort.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- patients with cluster B personality disorder (DSM-IV-TR2 criteria)
- patients who receive specialized mental health care for more than 2 year
- patients with a minimum score of 20 on the Borderline Personality Disorder Severity Index
- patients aged between 18-65

Exclusion criteria

- patients who participate in a specialized psychotherapeutic program for their personality disorder at the moment of the study
- patients with insufficient command of the Dutch language for completing questionnaires
- patients without informed-consent statement

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2010
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	09-06-2010
Application type:	First submission
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
CCMO	NL30245.029.09