The effects of relapse prevention plan

Published: 13-06-2007
Last updated: 08-05-2024

This experimental study addresses the question of whether the use of relapse prevention plans in nursing practices will reduce the usage and the average duration of seclusions with at least 30% in comparison with the control *care-as-usual*condition...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON31144

Source
ToetsingOnline

Brief title
Relapse prevention plan

Condition

- Psychiatric disorders NEC

Synonym
personality disorders, psychoses

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Westelijk Noord-Brabant (Halsteren)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: psychiatry, reducing, Relapse prevention plan, seclusion

Outcome measures

Primary outcome

The primary study parameters are the number of seclusions and the average duration of seclusions registered during the stay at the hospital.

Secondary outcome

The secondary study parameters are the number of psychical crises, registered with *Social Dysfunction and Aggression Scale* (SDAS-11) and the number of aggression accidents, registered with *Social Observation and Agression Scale* (SOAS).

In addition, the following mediating relations between the relapse prevention plan and the primary and the secondary study parameters will be explored: (1) the insight of the patient into the illness, (2) the working alliance between the patient and the nurse, (3) the locus of control, (4) the acceptance of the patient of the illness, (5) the satisfaction of the patient with the quality of care and (6) the patient*s compliance with the therapy.

Study description

Background summary

The psychiatric hospital GGZ Westelijk Noord-Brabant has received a grant for the project "Do not leave a serious sick alone ", aiming to reduce the number and the average duration of seclusions. Seclusion is a controversial issue in the mental health care, having provoked debate for several decades. It is associated with neglect and emotional abuse of psychiatric patients. Seclusion is an intrusive experience for both the patients and the staff. The Dutch tradition in using seclusion as a method of restrain, has been criticized a lot the last years, because of the higher usage and duration of seclusion, compared with other European countries. The surrounding countries do not use seclusion as a coercive method anymore or they are trying to reduce it significantly.

Although seclusion practices are becoming less popular the last years, there is still lack of knowledge on alternative successful interventions to prevent seclusion. Therefore it is important to research scientifically the effectiveness of different implementation strategies. This is one of the reasons for the significant practical relevance of this study. In addition, the effect of the relapse preventions plans in preventing psychical crises and seclusions in mental health institutions has not been until now investigated.

Study objective

This experimental study addresses the question of whether the use of relapse prevention plans in nursing practices will reduce the usage and the average duration of seclusions with at least 30% in comparison with the control *care-as-usual*condition. Early recognition and early intervention in psychiatric patients using prevention relapse plans strive for preventing psychical crisis, which in consequence may serve as prevention of seclusion.

Study design

The objective of this study will be investigated through randomized controlled trial (RCT) with a follow-up of 3 months. After being informed about the research, patients will get one-week to decide if they want to participate. Patients will be included in the study only after signing an informed consent. They have to be stabilized to the extent that he or she could collaborate in the preparation of the relapse prevention plan. After the first data collection, the patients will be divided at random between de experimental and the control condition. For the participants of the experimental condition individualized relapse prevention plans will be prepared, while the participants of the control condition will receive care-as-usual. After the completion of the relapse prevention plans in the experimental group, and after a comparable period of time of care-as-usual in the control condition, the first posttest will be conducted. The same measurement takes place three months later, if the participants are still staying at the hospital. The participants in the study will receive 10 euro for each measurement. The primary and the secondary study parameters will be registered for the both experimental and control group until the patients* stay at the hospital is ended. In addition, the mediating variables between the relapse prevention plan and the primary and the secondary study parameters will be investigated.

Intervention

The relapse prevention plans focus on early recognition and early intervention directed to prevent psychical crises by psychiatric patients. The preparation of a relapse prevention plan takes about a week, in conjunction with the patient and the members of his of her social network. This plan includes the early signs of psychical crises that are worked out as well as the actions that

could be taken when psychical crises threaten. A detailed intervention protocol for the preparation of relapse prevention plans will be submitted together with this research protocol.

Study burden and risks

Self-registration scales will be administrated three times during the study. Each measurement takes about 40 minutes. This means that totally 2 hours will be enough to complete the three measurements. The time necessary for the preparation of the relapse prevention plan depends on the individual needs of the patient. Therefore a concrete estimation of the time is difficult to be made in advance.

Contacts

Public
GGZ Westelijk Noord-Brabant (Halsteren)

Hoofdlaan 8
4661 AA Halsteren
Nederland
Scientific
GGZ Westelijk Noord-Brabant (Halsteren)

Hoofdlaan 8
4661 AA Halsteren
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Readiness to participate in the study.

Exclusion criteria

geen

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2007
Enrollment:	210
Type:	Actual

Ethics review

Approved WMO

Date:	13-06-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL17027.078.07