The Medical Psychiatric Unit (MPU) of the Erasmus MC: a randomized study of effectiveness and costs

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Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46312

Source
ToetsingOnline

Brief title
protocol RCT MPU

Condition

- Other condition

Synonym
a behavioral problem together with a physical illness, a psychiatric problem together with physical suffering

Health condition

elke mogelijke psychische aandoening in combinatie met elk soort somatische aandoening

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MPU, protocol, RCT

Outcome measures

Primary outcome

The primary outcome measure is a decrease in disruptive behavior as measured by a newly developed observation list, the Inpatient Disruptive Behavior Index (InDiBI).

Secondary outcome

* Costs and care use: file research and 'micro-costing' methods.

* Quality of life: EQ-5D-5L.

* Perception and safety of the care provided: patients and caregivers are given a single question with the responses on a three-point scale. In addition, there is a qualitative evaluation among nursing and medical staff, caregivers and patients using semi-structured interviews.

* Burden for informal carers: caregiver strain index

* Quantity and quality of the interventions used: adherence to treatment protocols suicidality and delirium, freedom-limiting interventions, medication

use, calamities / incidents as described under Serious Adverse Events ((S) AEs, section 10.2 of the protocol

* Physical and mental health: morbidity and mortality: file research, modified early warning score, Charlson Comorbidity Index, Global Assessment of Functioning (GAF score), Clinical Global Impression (CGI) and the Suicidal Affect Behavior Cognition Scale (SABCS).

* Disruptive behavior as experienced by evaluation among nursing and medical staff: qualitative interviews.

* Interference of the somatic treatment by the psychiatric condition or behavioral problems: four-point scale to be completed by medical and nursing staff.

Study description

Background summary

Many hospitalized patients have psychiatric comorbidity or behavioral problems. Behavioral problems can hinder somatic treatment and are a burdenfor caregivers, staff and other patients. These behavioral problems can be called 'disruptive behavior'. Medical Psychiatric Units (MPUs) are departments that treat patients with combined severe somatic and psychiatric suffering. Important goals of MPUs are 1) improving quality and safety of care and 2) effective care. Research into the effectiveness and cost-effectiveness of MPUs is scarce, often observational in nature and concerns the quantity and quality of the care process. Research into the outcomes of care is also scarce. In particular, there is no research into one of the primary goals of an MPU, namely a decrease of 'disruptive behavior'. It is therefore still an open question whether disruptive behavior can indeed be treated more effectively in

an MPU.

The MPU at Erasmus MC focuses on the short-term treatment of disruptive behavior in patients who have been hospitalized because of a serious physical illness. In a randomized study, this MPU will be compared with care as usual (CAU): a 'consultative psychiatric team' either in consultation or as co-therapist in a medical ward. This CAU is the current form of treatment for these patients at Erasmus MC. The hypothesis is that 'disruptive behavior' at the MPU is dealt with more effectively and that therefore the disruptive behavior in the MPU condition will decrease earlier and / or more than with CAU.

Study objective

The primary goal is to investigate whether treatment on the MPU leads to a reduction of 'disruptive behavior' compared to CAU. Secondary goals are: to investigate whether treatment at the MPU influences the costs of care for patients, quality of life, experience and safety of the care provided, as preceived by patients and their environment, the burden for caregivers, the quantity and quality of the interventions used by practitioners regarding the behavioral problems and the effects on the physical and psychological health of the patients, disruptive behavior as perceived by nursing and medical staff.

Study design

Phased, randomized clinical trial. The randomization is adjusted to the demand: only when a waiting list is created, patients will be randomized. This prevents the frustration that patients are rejected for the MPU while there are beds available.

Intervention

The study design is a randomized clinical trial, where treatment in the MPU is compared with CAU.

Study burden and risks

Risks

Moving patients to the MPU could cause an increase in psychiatric or behavioral discomfort because the patients are moved, and because the environment is less 'normal'. That is conceivable, but also unlikely: The MPU is designed to manage behavioral and psychiatric disruptions. The expectation is therefore that this risk will be minimal and that not only the psychiatric or behavioral symptoms will decrease compared to CAU.

A second risk is that patients do not receive the optimal somatic treatment because they are no longer in the somatic ward in question. That is also conceivable, but unlikely: at the MPU, the internist is the main physician, regardless of the specialist treatment that the patient undergoes. The referring specialist remains in co-treatment and is therefore always involved. In addition, the MPU is designed to provide complex somatic care.

Benefits

It is expected that patients, caregivers and employees will experience greater satisfaction with treatment of patients in the MPU, because this unit is better equipped to handle disruptive behavior. Therefore, patients will probably feel more 'understood' and ,as a result, can be treated better.

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 who are eligible for inclusion in the study are:
Patients with a somatic indication for admission and a psychiatric or behavioral problem that hampers the treatment of the somatic condition, making treatment in a regular department in the hospital or psychiatric hospital difficult

Exclusion criteria

* Patients without indication for somatic treatment
* Patients with somatic problems that can only be treated at a high or intensive (coronary) care unit
* Patients who require strict isolation in a slothed box. Such a facility is not present on the MPU.
* Minors

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	146
Type:	Anticipated

Ethics review

Not approved

Date:	02-08-2019
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	NL68431.078.18