Interpersonal Community Psychiatric Treatment: cluster randomized trial into cost effectiveness of a structured outpatient treatment for patients with non-psychotic psychiatric disorders in long-term care

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This study aims for health gain and cost reduction in the care for people with long-term psychiatric disorders. The researchquestions is what the (cost)effectiveness is of Interpersonal Community Psychiatric Treatment (ICPT), compared to care...

Ethical review Approved WMO

Status Pending

Health condition type Personality disorders and disturbances in behaviour

Study type Interventional

Summary

ID

NL-OMON41490

Source

ToetsingOnline

Brief title

ICPT, a cluster RCT

Condition

Personality disorders and disturbances in behaviour

Synonym

difficult behaviour

Research involving

Sponsors and support

Primary sponsor: IQ Scientific Institute for Quality of Healthcare

Source(s) of monetary or material Support: subsidieaanvragen lopen

Intervention

Keyword: community mental health nursing, cost effectiveness, long-term care, RCT

Outcome measures

Primary outcome

Primary: quality of life (MANSA)

Secondary outcome

Secundary: quality of life (EQ-5D), costs (TiC-P), therapeutic alliance (STAR),

professional-perceived difficulty of patient

(DDPRQ), care needs (CANSAS), social contacts (SNM), general mental health

(HONOS), recovery outcomes (IMR) and treatment outcomes (OQ45.2).

Study description

Background summary

In the Netherlands, as in many other developed countries, many people suffer from psychiatric disorder during their life. Recent

epidemiological data shows that 43.5% of the Dutch are affected by some form of mental illness during their life [1]. Depression

(20.1%), anxiety (19.6%), and substance abuse (19.1%) have the highest lifetime prevalence: the first two appear in the top-4

of diseases with the highest disease burden [2]. Comorbidity with personality disorders, which have a prevalence of 9.1% in the

US [3] but which are not fully studied in a Dutch community sample, results in poorer social functioning and limited recovery.

About 80% of all patients receiving mental health services (MHS) have one or more of the aforementioned non-psychotic

disorders [4]. Particularly for this group long-term treatment or care is

poorly developed.

Study objective

This study aims for health gain and cost reduction in the care for people with long-term psychiatric disorders. The research questions is what the (cost)effectiveness is of Interpersonal Community Psychiatric Treatment (ICPT), compared to care as usual (CAU).

HYPOTHESIS

ICPT is more effective in (1) improving patients* quality of life and social networks, (2) preventing or decreasing professionals* perception of patients as *difficult*, (3) discharging patients to a lower level of care, (4) being less costly in reaching these clinical goals than CAU

Study design

Multi-center cluster-randomized clinical trial: participating professionals will be randomly allocated to either ICPT or CAU for an intervention period of 12 months, and a follow-up of 6 months.

Intervention

ICPT is a structured treatment for people with long-term, often difficult to treat non-psychotic disorders, developed with patients, professionals, and experts. ICPT uses a number of evidence-based techniques and was positively evaluated in a controlled pilot study.

Study burden and risks

Due to the nature of the patient group, frequent suicide attempts are to be expected (we think at approximately 40% of this patient group) and therefore is no specific adverse effects of this research, but the usual symptoms of patients with this particular long-term psychiatric problems. There might be expected suicides, but in the same frequency as before the investigation started. The reason for the ICPT intervention is because in both the intervention group and the control group suicide attempts occur regularly.

This is a study with no adverse effects. People in both the control group and the intervention group might become psychotic or suicidal. If this happens during measurement by the investigators, their professional will be informed. We don*t assume that the intervention group is more suicidal than the control

Contacts

Public

Selecteer

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Cluster inclusion criteria (professionals):

- have an individual caseload of >5 patients with a non-psychotic disorder
- be willing to be randomized to either the present care as usual or the experimental ICPT-condition;* Participants inclusion criteria (patients):
- age between 18-65 years (due to organizational delineations between *adults* between 18 and 65, and *elderly* over 65)
- presence of a non-psychotic psychiatric disorder
- long-term treatment (>2 years) or high care use (>1 outpatient contact per week or >2 crisis contacts per year or >1 inpatient
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Exclusion criteria

- * Cluster exclusion criteria (professionals):
- expressed intention to leave the present service between now and 12 months;* Participants exclusion criteria (patients):
- presence of a psychotic, bipolar I or cognitive disorder
- lack of skill in understanding of, or communication in Dutch language
- IQ below 80

Study design

Design

Study phase: 3

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-05-2014

Enrollment: 180

Type: Anticipated

Ethics review

Approved WMO

Date: 14-03-2014

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 18-09-2014

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 22-12-2014

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 08-07-2015
Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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 NL44744.091.13