Cost effectiveness of a structured treatment for people with long-term severe non-psychotic disorders

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24323

Source
Nationaal Trial Register

Brief title
ICPT

Health condition

severe mental illness
community mental health care
long-term care
cluster randomized controlled trial cost-effectiveness

ernstige psychiatrische stoornissen
sociaal psychiatrische hulpverlening
langdurig psychiatrische zorg
RCT
effectiviteit
kosteneffectiviteit

Sponsors and support

Primary sponsor: Social Psychiatry & Mental Health Nursing, University of Applied Science Arnhem Nijmegen
Source(s) of monetary or material Support: Foundation Innovation Alliance (SIA -

Stichting Innovatie Alliantie) with funding from the ministry of Education, Culture and Science (OCW).

Intervention

Outcome measures

Primary outcome

Quality of life (MANSA)

Secondary outcome

Quality of life (EQ-5D), costs (TiC-P), therapeutic alliance (STAR), professional-perceived difficulty of patient
(DDPRQ), care needs (CANSAS), social contacts (SNM)

Study description

Background summary

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.

STUDY POPULATION

Patients between 18-65 with non-psychotic disorders who are long-term and/or intensive users of specialty mental health care.

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.

OUTCOME MEASURES

Primary: quality of life (MANSA)
Secundary: quality of life (EQ-5D), costs (TiC-P), therapeutic alliance (STAR), professional-perceived difficulty of patient
(DDPRQ), care needs (CANSAS), social contacts (SNM)

SAMPLE SIZE/DATA ANALYSIS

Based on the primary outcome variable, quality of life (MANSA), and assuming 20-25% attrition we need to include 40 clusters
of 6 patients each. Outcomes will be analysed using linear mixed models. All analyses will be performed on the
intention-to-treat set.

CEA/BIA

The economic evaluation will be based on the general principles of a cost-effectiveness analysis. Both the cost-utility and
cost-effectiveness analysis will be performed from the societal perspective. The BIA will be conducted from 3 perspectives: (1)
societal perspective, i.e. including productivity losses, (2) the perspective of the public purse

(VWS) (base case), and (3) the
perspective of the third party payers.

Study objective

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 Care as usual

Study design

Total treatment period for clients is 18 months; the RCT is 4 years. There is a measurement at baseline, an intermediate measurement (6 months after for baseline-measurement), after intervention period (after an intervention period of 12 months), and a follow-up measurement (6 months after end of intervention). Information will be obtained from different sources (client, professional) using multiple methods (interviews, questionnaires). The same questionnaires will be used in both groups, on all four measuring moments.

Intervention

ICPT was developed from an empirical study of so-called 'difficult' patients, in which it became evident that both patient and
professional play an important role in the occurrence of 'ineffective chronic illness behaviour'. A five-stage heuristic model
shows that the 'difficult'-patient label is given by professionals when certain patient characteristics are present and a specific
causal attribution about the patient's behaviours is made [18]. The status of 'difficult' patient is easily reinforced by subsequent patient and/or professional behaviour, turning initial unusual elp-seeking behaviour into 'difficult' or ineffective chronic illness behaviour. Furthermore, a lack of resources in the psychiatric service and the patient's social system negatively influence the
patient-professional interaction [18]. From this theoretical model we conceptualized a number of stages in the intervention
program, each fitting an important step in the theoretical model, resulting in a stage model which fits the patient's level of acceptance of help and cooperation.

Contacts

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Eligibility criteria

Inclusion criteria

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 admission per year) in specialized mental health care.

Exclusion criteria

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

Recruitment

NL
Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	180
Type:	Anticipated

Ethics review

Positive opinion
Date:	13-05-2013
Application type:	First submission

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
NTR-new	NL3822

Register	ID
NTR-old	NTR3988
Other	ICPT : 0001

Study results