

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

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24323

Bron

Nationaal Trial Register

Verkorte titel

ICPT

Aandoening

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

Ondersteuning

Primaire sponsor: Social Psychiatry & Mental Health Nursing, University of Applied Science Arnhem Nijmegen

Overige ondersteuning: Foundation Innovation Alliance (SIA - Stichting Innovatie Alliantie) with funding from the ministry of Education, Culture and Science (OCW).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Quality of life (MANSA)

Toelichting onderzoek

Achtergrond van het onderzoek

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)

Secondary: 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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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 help-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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2013
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	13-05-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register

NTR-new

NTR-old

Ander register

ID

NL3822

NTR3988

ICPT : 0001

Resultaten