Study on Cost-Effectiveness of Personality Disorder Treatment.

No registrations found.

Ethical review Positive opinion **Status** Recruitment stopped

Health condition type -

Study type Interventional

Summary

ID

NL-OMON25384

Source

Nationaal Trial Register

Brief title SCEPTRE

Health condition

Personality disorder

Sponsors and support

Primary sponsor: N/A

Source(s) of monetary or material Support: Psychotherapeutic Centre De Viersprong

Intervention

Outcome measures

Primary outcome

- 1. Structural improvement of personality pathology (assessed with oq-45, sipp);
- 2. Quality Adjusted Life Years (QALYs).

Secondary outcome

- 1. Symptomatic improvement (assessed with the SCL-90);
- 2. Functional improvement (assessed with, amongst others, questions regarding work situatin and care consumption);
- 3. Quality of life.

Study description

Background summary

SCEPTRE stands for Study on Cost-Effectiveness of Personality Disorder Treatment. The project was launched on 1st September 2003 at six mental health care institutes in the Netherlands (PTC De Viersprong, CvP De Gelderse Roos, Altrecht, ZMC De Heel, Mentrum, GGZ WNB).

For three years the project will follow more than 800 patients with personality disorders undergoing a variety of different psychotherapeutic treatments. Project SCEPTRE embraces three tracks: effectiveness, cost-effectiveness and treatment selection. Each is briefly explained below.

Effectiveness

We already know that psychotherapy is the treatment of first choice for personality disorders. However, what is the optimum dose? Does a difference exist between outpatient, day hospital and inpatient psychotherapy? Are there only symptomatic gains or also structural and functional improvements? Which features of patients predicts the outcome of treatment? These are central questions in this part of SCEPTRE. The research is unique for its innovative quasi-experimental design, which combines the benefits of the experiment and the naturalistic study and thus optimises the study's feasibility and external validity (representativeness). SCEPTRE is the largest study ever conducted into the effectiveness of psychotherapy among patients with personality disorders. It is also an initial attempt to compare the different settings and intensities of treatment with each other.

Cost-effectiveness

Without exception, all studies so far published under the banner of "cost-effectiveness of psychotherapy" have applied ad-hoc methodology and presented costs and effects independently of each other. At best these studies can be categorised as "cost-minimisation" analyses. SCEPTRE is one of the first studies to use state-of-the-art methodology to examine cost-effectiveness. SCEPTRE does not regard costs and effects as stand-alone outcomes, but explicitly creates a relationship between them by means of a cost-effectiveness ratio. The ratio establishes the connection between direct medical costs, production costs, costs of patients and the generic outcome criterion of "Quality Adjusted Life Years" (QALYs). The number of QALYs is determined using the EuroQol EQ-5D, a generic measurement instrument developed especially for economic evaluations in health care. The QALY analysis allows the effects of different psychotherapeutic treatments to be compared with the effects of other treatments. By adopting this approach, the cost-effectiveness of long-term psychotherapy can become an important argumentation in decision-making and in allocating health care

budgets. The quasi-experimental research design of SCEPTRE in a naturalistic setting is ideal for solid research into cost-effectiveness. The naturalistic character increases external validity, which is an essential quality for any economic analysis.

Treatment selection

Health care would be ideal if it were to be patient-focused (demand-driven), evidence-based and cost-effective. All too often, however, the reality is different. Within care institutes, the type of therapy is determined not infrequently by the institute's own range of treatments. In the absence of consensus on matched care, the decisive factor is often the individual preference of the intaker or patient. This project aims to develop a tool to support treatment selection for personality disorders. The envisaged tool consists of decision-making trees or decision-making rules that provide pointers to answer to the following questions: Is psychotherapy possible with this patient?

What should the primary targets and goals of treatment be?

What is the optimum dose for this patient in terms of setting, duration/frequency and theoretical frame of reference?

The innovative nature of this development process lies in the systematic and step-by-step integration of clinical, empirical and experiential knowledge. An initial prototype is being modelled based on best clinical expertise in conjunction with existing scientific knowledge. The next step will be to perform retrospective and prospective case analyses to examine to what extent the prototype reflects existing practice. The model will then be checked against empirical data from SCEPTRE. Finally, model-consistent and model-inconsistent indications will be compared in terms of their effectiveness and efficiency.

Study objective

- 1. Effectsizes of the psychotherapeutic treatments vary between 0.5 and 2.0;
- 2. A lower dosage of psychotherapeutic treatment is mainly related to symptomatic improvement, while a higher a dosage is also related to structural and functional improvement;
- 3. The dosage for an optimal cost-effectiveness is lower than the maximum dosage;
- 4. When compared to cluster B personality disorders, for cluster C personality disorders a lower dosage is required to reach optimal cost-effectiveness;
- 5. A lower level of psychological mindedness and/or ability for a positive working alliance with the therapist is related to a lower level of (cost-)effectiveness.

Intervention

Psychotherapeutic treatment programs for patients with personality pathology that will be distinguished from one another according to the following dosages:

- 1. Short (maximum of 6 months) outpatient;
- 2. Short day hospital;
- 3. Short inpatient;
- 4. Long (at least 6 months) outpatient;
- 5. Long day hospital;
- 6. Long inpatient.

Contacts

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Eligibility criteria

Inclusion criteria

- 1. At least one DSM-IV axis-II diagnosis;
- 2. An indication for psychotherapeutic treatment aiming at structural improvement of the personality pathology (besides symptomatic and/or functional improvement).

Exclusion criteria

- 1. Insufficient command of Dutch language;
- 2. Severe cognitive impairments;
- 3. Mental retardation;
- 4. Axis-I schizophrenia.

Study design

Design

Study type: Interventional

Intervention model: Parallel

Masking: Open (masking not used)

Control: N/A, unknown

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-09-2003

Enrollment: 821

Type: Actual

Ethics review

Positive opinion

Date: 23-11-2006

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 NL8

NTR-new NL812 NTR-old NTR825

Other : N/A

ISRCTN ISRCTN73817429

Study results

Summary results

N/A