# Cost-effectiveness of cognitive behaviour therapy of cognitive behaviour therapy for recent onset schizophrenia patients with persistent and recurrent psychosis.

Submission date	Recruitment status  No longer recruiting	Prospectively registered	
20/12/2005		☐ Protocol	
Registration date 20/12/2005	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited	Condition category	Individual participant data	
07/01/2021	Mental and Behavioural Disorders		

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Dr M van der Gaag

#### Contact details

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#### Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

#### Secondary identifying numbers

ZonMW 945-04-406

# Study information

#### Scientific Title

Cost-effectiveness of cognitive behaviour therapy of cognitive behaviour therapy for recent onset schizophrenia patients with persistent and recurrent psychosis.

#### Acronym

COCOS

#### Study objectives

To determine the cost-effectiveness of CBT compared to care as usual in patients with a recent onset of schizophrenia, who suffer from persistent and recurrent symptoms of psychosis.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

**Not Specified** 

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Schizophrenia

#### **Interventions**

Please note that, as of 30/07/2008, the end date of this trial has been updated from 01/12/2007 to 01/04/2008.

#### Interventions:

- 1. CBT by a cognitive therapist and a nurse therapist
- 2. CAU

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

Days functioning in normal range based on PSYRAYS and SFS: minimal suffering and functional restrictions by delusions and/or hallucinations and SFS normal social functioning.

#### Secondary outcome measures

- 1. Medication compliance
- 2. Number of relapses
- 3. Psychiatric symptoms
- 4. Quality of life

#### Overall study start date

01/12/2004

#### Completion date

01/04/2008

# Eligibility

#### Key inclusion criteria

- 1. Schizophrenia patients in the first five years after onset
- 2. Age 18-64
- 3. Treatment resistant or recurrent psychosis

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Upper age limit

64 Years

#### Sex

Both

#### Target number of participants

230

#### Key exclusion criteria

- 1. IQ<80
- 2. Severe addiction

- 3. No competence of Dutch language
- 4. 4 or more CBT sessions in the last year

#### Date of first enrolment

01/12/2004

#### Date of final enrolment

01/04/2008

#### Locations

#### Countries of recruitment

Netherlands

# Study participating centre Parnassia & Groninen University

Den Haag Netherlands 2552 ES

# Sponsor information

#### Organisation

University Medical Center Groningen (Netherlands)

#### Sponsor details

Hanzeplein 1 Groningen Netherlands 9713 GZ

#### Sponsor type

Hospital/treatment centre

#### **ROR**

https://ror.org/03cv38k47

# Funder(s)

#### Funder type

Research organisation

#### **Funder Name**

ZonMw

#### Alternative Name(s)

Netherlands Organisation for Health Research and Development

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Other non-profit organizations

#### Location

Netherlands

### **Results and Publications**

#### Publication and dissemination plan

Not provided at time of registration

#### Intention to publish date

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2011	07/01/2021	Yes	No