Cognitive Behavioural Therapy - Social Functioning In Adolescence with recent onset schizophrenia

Published: 03-04-2014
Last updated: 23-04-2024

To evaluate the applicability and (cost-) effectiveness of a shortened, partly group based, Cognitive Behavioural Therapy (CBTsa) focussing on social activation in patients with recent onset schizophrenia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON41291

Source
ToetsingOnline

Brief title
SOFIA

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychosis, schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Psychiatrie, afdeling Vroege Psychose
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW

Intervention

Keyword: CBT, Negative symptoms, Recent onset schizophrenia, Social withdrawal

Outcome measures

Primary outcome

Negative symptoms, social withdrawal behavior / inactivity

Secondary outcome

Social functioning, Quality of life, cost, Positive and General symptoms, Need

for Care

Study description

Background summary

Cognitive Behavioural Therapy (CBT) is one of the most commonly provided forms of therapy in the Netherlands. It is a short-term, structured therapy that is sometimes offered groupwise and sometimes individually. In CBT it is assumed that not the events themselves, but rather thoughts, interpretations and expectations about these events evoke negative feelings. CBT focuses on changing both thinking patterns (cognitions) and behaviors. The effectiveness of cognitive behavioral therapy has often been studied in people with a psychotic disorder, but research to date has focused mainly on reducing symptoms such as hallucinations or delusions.

Aaron T. Beck, founder of Cognitive Behavioural Therapy (CBT), and colleagues have developed and investigated a new CBT approach, in which they target inactivity in a chronic schizophrenia population with severe negative symptoms The therapy is based on accumulating evidence that dysfunctional beliefs in conjunction with neurocognitive impairments can impede functioning. These results suggest that CBT can be highly successful in establishing clinically meaningful improvements. However, the therapy has not yet been investigated in a recent-onset population.

In this study, we particularly focus on maintaining social activities and reducing symptoms such as a lack of initiative or diminished interest. We expect that CBT focused on social withdrawal behavior will be effective in reducing negative symptoms, improving the performance, cost and quality of life

of patients with recent-onset schizophrenia.

Study objective

To evaluate the applicability and (cost-) effectiveness of a shortened, partly group based, Cognitive Behavioural Therapy (CBTsa) focussing on social activation in patients with recent onset schizophrenia.

Study design

Single blind randomized controlled trial with 6 month-follow up.

Intervention

Individual and group-based CBT intervention targeting social withdrawal.

Study burden and risks

Patients will undergo a 2-hour during testbattery and will carry along a mobile device with which participants are prompted by a beep at random intervals throughout the day (for a 6-day period) to report about their current experiences and withdrawal behaviour. These assessments will be repeated post-treatment and at 6-month follow-up. No risks are attached to this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

(1) recent onset schizophrenia (start antipsychotic medication <2 yr);
(2) Social withdrawal (> 3 moderate severity on the PANSS N4; Passive/apathic social withdrawal);
(3) Aged 18-35 years;
(4) Fluent in Dutch
(5) IQ>70;
(6) Able and willing to give informed consent

Exclusion criteria

- Neurological disease or damage that would compromise cognitive functioning
- Negative symptoms as a consequence of positive symptoms, or as a consequence of a physical handicap

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-05-2014
Enrollment:	112
Type:	Actual

Ethics review

Approved WMO Date:	03-04-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL46776.018.13