Cognitive Adaptation Training in the Netherlands: a nursing intervention to improve daily functioning in people with schizophrenia

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The goal of this pilot study is to (i) investigate which measurements are suitable best for the evaluation of (cost) effectiveness, (ii) investigate whether CAT can be given as a nursing intervention (feasability).

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

Summary

ID

NL-OMON36503

Source
ToetsingOnline

Brief title
CAT-NL

Condition

- Schizophrenia and other psychotic disorders

Synonym
disorder of thought, psychotic disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W,Subsidie is aangevraagd bij UMCG om doelmatigheid te kunnen onderzoeken;verder wordt het onderzoek gefinancierd door GGz Lentis

Intervention

Keyword: cognitive impairment, daily functioning, nursing, rehabilitation and training

Outcome measures

Primary outcome

Prior to the baseline-assessment (T0), patients will be asked to participate in CAT. Effect measurements will be carried out after 4 months (T4) and after 8 months (T8).

It is still unknown which outcome measurements will adress the research questions (mentioned under Objectives) best. Therefore, multiple outcome measures will be included in this study. In a recent study by Velligan et al. (2008), an effect size of Cohen's D > 1.0 was reported. Therefore, we expect the GAF-D to be most sensitive for change in daily functining. Furthermore, the Multnomah Community Ability Scale (MCAS) and the Negative Symptoms Assessment (NSA) will be assessed. These semi-structured interviews are also used in the American CAT-studies. The MCAS contains 17 items on domains interfering with functioning, independence & acceptation, social competence and behavioral problems. From the NSA, only the subscale motivation will be assessed, which contains items on self care, activities and sense of purpose.

To adress the second research question (feasability of CAT as a nursing intervention), the Quality Assurance Measures Form (QAMF) and the Client Satisfaction Questionnaire (CSQ) will be assessed. The QAMF is a treatment fidelity form, also used in the studies by Velligan et al., and is being scored

from supervision sessions and tape recordings of the CAT-session. The patient will be assessed with an amended version of the CSQ, to evaluate client satisfaction.

Furthermore, we expect empowerment to be an important outcome measure. The Mental Health Confidence Scale (MHCS) will be used to adress this, for this scale has proven to be sensitive for change (Castelein et al., 2008).

An overview of all outcome measurements used in this study can be found below, and under 'secondary study parameters'.

Effect measures (T0, T4 en T8)

Total duration: 1* hours

Daily functioning:

1. Global Assessment of Functioning - Disabilities (American Psychiatric Association, 1994), scored by external rater

Secondary outcome

Daily functioning:

2. Multnomah Community Ability Scale (Barker), semi-gestructureerd interview

3. Negative Symptom Assessment, subscale motivation (Alphs), semi-structured interview

4. Social Functioning Scale (Birchwood et al., 1990), self-report and proxy

5. Goal Attainment Scale (Steinbook et al., 1977), semi-structured interview

Well being:

1. Mental Health Confidence Scale (Carpinello et al., 2000), self-report

2. Manchester Short Assessment of Quality of Life (Priebe et al., 1999),

self-report

3. EuroQoL - 5D (König et al., 2007), self-report

Performance based tasks:

1. Mini Mental State Examination (Roper et al., 1996)

2. Frontal Assessment Battery (Dubois et al., 2000)

3. Test of Adaptive Behavior for Schizophrenia, subtest Self-Medication

(Velligan et al., 2007)

Treatment evaluation:

1. Quality Assurance Measures Form (Velligan, unpublished)

2. Client Satisfaction Questionnaire (CAT-version) (de Brey, 1983)

Study description

Background summary

The prevalence of schizophrenia is at least 0.6%. In the Netherlands, there are at least 100.000 people who have got a diagnosis schizophrenia during their life. Fifteen percent of this population are characterized by good remission with full recovery. In 65%, the course is variable, often accompanied with long lasting care dependence. The other 20% have a course that is chonically psychotic, whether or not in combination with institutional dependence.

Schizophrenia is associated with a high suïcide risk.
Partial recovery and care dependency in schizophrenia often lead to social disfunctions. To assist patients in this process, an intervention is needed that leads to more activities, less social isolation and maximum degree of social participation.
A fundamental problem in schizophrenia is the cognitive impairment, which is a better predictor of functional outcome, compared to positive symptoms. In schizophrenia, cognitive impairment can be regarded the core of the disorder. Unfortunately, the Dutch care for individuals with schizophrenia has no intervention which bridges the gap between neuropsychology and everyday living. Therefore, studies are needed in which treatment programs are being evaluated that have proven their efficacy elsewhere.

Cognitive Adaptation Training (CAT, developed by prof dr Dawn Velligan in 1996) is a series of manual-driven compensatory strategies and environmental supports designed to diminish the negative consequenses cognitive dysfunctions have on daily functioning. CAT particularly bypasses impairments in executive abilities (planning and goal directed behavior). In the United States, CAT leads to improvements on daily functioning, quality of life, motivation and medication adherence. Treatment plans for CAT can be targeted at multiple areas of daily functioning, such as self care, household tasks, mobility, leisure activities and social network. This makes the training program suitable for patients in residential care (APZ/RIBW), as well as outpatients (BZW/poliklinisch).

Study objective

The goal of this pilot study is to (i) investigate which measurements are suitable best for the evaluation of (cost) effectiveness, (ii) investigate whether CAT can be given as a nursing intervention (feasability).

Study design

A non-randomized pilot study with blind rating (planned analysis: Repeated Measures ANOVA).

The study concerns a pilot, in which only patients will be included that receive either CAT or TAU. Prior to the study, potential candidates will be approached with the question whether they agree with being assessed with a number of questionnaires about daily functioning and related matters. When the candidate meets the inclusion criteria, he/she will get information about CAT, and will be asked to participate. Participants in TAU will get the opportunity to participate in a future CAT study. Informed consent will be obtained after 2 weeks.
During CAT, patients are seen weekly during sessions of 45 minutes, in their home environment (or their own living room in the residential facility), for 8 months. During the end of the program, sessions can be given once in 2 weeks.

Intervention

Treatment plans that include cognitive adaptation training are based on two dimensions: 1) the patient*s level of apathy versus disinhibition, and 2) the patient*s level of impairment in executive functions. Behaviors characterized by apathy can be altered by providing prompting and cueing that help the patient initiate each step in a sequenced task. Individuals who exhibit disinhibited behavior respond well to the removal of distracting stimuli and behavioral triggers and to redirection. Individuals with mixed behavior (both apathy and disinhibition) are offered a combination of these strategies. Individuals with greater degrees of executive impairment are provided a greater level of structure and assistance and more obvious environmental cues (larger, more brightly colored, and more proximally placed cues). Individuals with less impairment in executive function can perform instrumental skills adequately with less structure and more subtle cues.
These general plans are adapted for individual strengths or limitations in verbal/visual attention, memory, and fine motor coordination. Interventions are explained and maintained or altered as necessary by means of brief weekly visits from a cognitive adaptation training therapist. From the clinical experience of CAT-therapists it can be suggested that patients enjoy the contact with the therapist, appreciate the environmental supports, and look forward to each visit. Because CAT also has a positive effect on motivation and quality of life, we expect the burden of this intervention on the patient to be low. Environmental supports that will be used in the study will be calenders, watches, agenda's, electronic devices, signs, household utensils and supports for mobility and leasure activities.

Study burden and risks

There are a number of reasons to assume that burden on the patient is low:
- the patient is seen on a weekly basis in the home environment, and does not need to visit the institution
- the training is individually tailored. The pace of the training program and area's of focus are defined by the results of the baseline assessment and in collaboration with the patient
- the patient is not only provided with environmental supports, these are also introduced and evaluated/adjusted during the training.
- patients in the control condition will be informed that they will receive CAT, but that this will be in the future, when funds are available.

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

Schizophrenia or schizo-affective disorder according to DSM-IV criteria, age between 21 and 65 years old, fluent in Dutch, cognitive impairment, problems in daily functioning (GAF-D < 60), being to receive CAT on a weekly basis (one session of 45 minutes every week)

Exclusion criteria

Premorbid IQ < 75, cognitive impairment due to neurological disorder, agressive behavior, alcohol- or substance dependency within 6 months prior to inclusion.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2009
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	04-09-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-11-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL27675.042.09