Nursing Interventions to Improve Functional Outcome in Patients with Severe Mental Illness (NISMI).

Gepubliceerd: 26-02-2012 Laatst bijgewerkt: 18-08-2022

The goal of the study is to: 1. Improve daily functioning in patients with schizophrenia; 2. To improve behavioral observation in psychiatric nurses; 3. To implement CAT in the usual treatment of patients with severe mental illness.

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

Samenvatting

ID

NL-OMON27298

Bron
Nationaal Trial Register

Verkorte titel
NISMI

Aandoening

Severe mental illnesses encompass schizophrenia, schizo-affective disorders, and major depression. The majority of the patients at the participating clinic are diagnosed with schizophrenia.

Ondersteuning

Primaire sponsor: -University of Groningen, University Medical Center Groningen, The Netherlands
-Lentis research, Linis Mental Health Institute, Groningen, The Netherlands
Overige ondersteuning: Fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The study will include a baseline measurement (T0) and follow-up assessments (T3, T6, T9, T12, T18 en T24; T=assessment month). During all assessments, the primary instruments will be included, consisting of the Personal and Social Performance scale (PSP), and the Multnomah Community Ability Scale (MCAS), both instruments focusing on daily functioning. It is expected that the PSP (the new version of the GAF-D) will be the most sensitive for change in daily functioning. Recent studies by Velligan et al. (2008) have shown effect sizes of Cohen's D > 1.0, on such measures. The MCAS is a semi-structured interview that is also being used during the CAT in America. The MCAS contains 17 items on domains focusing on interference with functioning, self efficacy, social competence, and behavioral problems. Assessment of the MCAS and PSP will take 45 minutes to complete.

25-jun-2014: Instead of with the PSP, we administer the Social and Occupationial Functioning Scale (SOFAS; APA, 2000). Furthermore, we added observational questionnaires to be filled out by the case manager of the participant (the Life Skills Profile and the Social Functioning Scale).

Toelichting onderzoek

Achtergrond van het onderzoek

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. This may also be a major problem in nursing care. 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). In addition, the method seems feasable to be provided by psychiatric nurses, supervised by psychologists. This may lead to improvement of important nursing skills, including the ability to observe behavior that is the result of cogntive impairment.

Doel van het onderzoek

The goal of the study is to:

1. Improve daily functioning in patients with schizophrenia;

2. To improve behavioral observation in psychiatric nurses;

3. To implement CAT in the usual treatment of patients with severe mental illness.

Onderzoeksopzet

The study is a randomized controlled trial, that will have a duration of 2 years. In all patients and nurses, assessments will be conducted at baseline (T0) and follow-up (T3, T6, T9, T12, T18 and T24; T=assessment month). After baseline, nurses and their patients (clustered) will be randomly assigned to one of the following conditions: Cognitive Adaptation Training (CAT), Supportive Training (ST), or Treatment As Usual (TAU). Patients and nurses will be informed on the results of the randomization after the baseline assessment. Patients and nurses cannot be carried over into another condition after randomization. Every condition will have a duration of 12 months (T0-T12). In CAT, nurses will visit their patients each week (45 minutes), and they will receive individual supervision from a psychologist. During the supervisions, the neuropsychological assessment of the patient is being used to further specify the program (see interventions). After T6, the supervisions and home visits will be built off from weekly to montly. After one year (T12), implementation of the CAT method will start for the patients allocated to the CAT at baseline. Assessments from T12-T24 will be used to evaluate the implementation effect of CAT in this study arm. Nurses allocated to ST will visit their patients weekly (45 min.) as well, but will receive plenary supervisions together with other nurses allocated to ST. ST will consist of supportive training, in which activities will be a-specific (eg walking, talking, shopping). The condition is created to control for some of the non-specific effects of CAT. As with the CAT condition, after half a year (T6), supervisions and extra home visits will be built off from weekly to monthly. Nurses and patients allocated to TAU will receive all assessments, but no additional interventions. After T12, patients allocated to ST and TAU will receive CAT as well, and their nurses will also be trained to provide CAT. The design is similar: the first half year (T12-T18), supervisions and extra home visits will be weekly; the second half year (T18-T24), supervisions and extra home visits will be monthly.

25-jun-2014: Primary outcomes are measured in both groups at baseline, 3, 6, 9, and 12 months. For the intervention group follow-up measurements take place at 15, 18, 21, and 24 months. At T18 and T24, all primary outcomes are assessed, at T15 and T21 only

observational questionnaires on everyday functioning are assessed. Secondary outcomes are measured at baseline, 6 and 12 months.

Onderzoeksproduct en/of interventie

Treatment plans that include cognitive adaptation training are based on two dimensions:

1. The patient’s level of apathy versus disinhibition;

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.

The ST condition is created to control for some of the non-specific effects of CAT. This includes direct time of the nurse spent with the patient. Nurses in this condition will also receive weekly supervision by a psychologist, but in a group, together with other nurses. In contrast to the CAT condition, the neuropsychological assessment will not be used in this condition. Furthermore, patients in ST will also receive items, but these will have no direct relevance for their daily functioning (e.g. posters, plants).

Contactpersonen

Publiek

Department of Psychiatry & Rob Giel Research Center
University Medical Center Groningen
P.O.Box 30.001 (CC72)
Piotr J. Quee
Groningen 9700 RB
The Netherlands
+31 (0)50 3612034

Wetenschappelijk

Department of Psychiatry & Rob Giel Research Center
University Medical Center Groningen
P.O.Box 30.001 (CC72)
Piotr J. Quee
Groningen 9700 RB
The Netherlands
+31 (0)50 3612034

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

No inclusion criteria will be held with regard to specific diagnosis. Inclusion criteria are age > 18, suffering from a severe mental illness and living at a long-term clinical health facility.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

N/A

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Cross-over
Toewijzing:	Niet-gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2013
Aantal proefpersonen:	130
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	26-02-2012
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	ID
NTR-new	NL3164

Register	ID
NTR-old	NTR3308
Ander register	NA : NA
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A