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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27298

Source
Nationaal Trial Register

Brief title
NISMI

Health condition

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

Sponsors and support

Primary sponsor: -University of Groningen, University Medical Center Groningen, The Netherlands
-Lentis research, Linis Mental Health Institute, Groningen, The Netherlands
Source(s) of monetary or material Support: Fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

Secondary outcome measures will be assessed at baseline (T0), halfway (T12) and at the end of the study (T24). The measures will consist of (i) observational skills of nurses, (ii) performance-based tasks, (iii) clinical symptoms, (iv) job satisfaction, and (v) empowerment. Observational skills will be assessed in nurses, to investigate whether they are better able to recognize cognitive impairments after being teached how to provide their patients with CAT. During 45 minutes, a number of cases will be presented plenary, by means of video demonstrations. The video's will present cases with differing cognitive profiles, as performed by actors. The Schizophrenia Cognitive Rating Scale (SCoRS), a commonly used international instrument to observe and quantify cognitive deficits, will be used by nurses to rate the cognitive deficits of the cases. Performance-based tasks will consist of measures of cognitive functioning and functional capacity. Cognitive tasks will be assessed using the Brief Assessment of Cognition in Schizophrenia, or a battery with similar measures. Functional Capacity will be assessed using the University of California Performance-based Skills Assessment - Brief version (UPSA-B). Assessment of the BACS and UPSA-B will take 45 minutes to complete. Clinical symptoms will be interviewed using the Positive And Negative Syndrome Scale (PANSS). The PANSS is the most widely used scale to measure current severity of positive symptoms, negative symptoms, disorganization, mania and depression. Assessment will take 40 minutes to complete. Work satisfaction in nurses will be evaluated using the Occupational Stress Indicator (OSI). Empowerment in patients will be assessed using the Dutch Empowerment Questionnaire (Nederlandse Empowerment Vragenlijst or NEL). To test feasibility of CAT, we will assess the CAT therapists with the Quality Assurance Measures Form (QAMF). The QAMF evaluates whether therapists give their interventions in line with the CAT guidelines. The QAMF is also being used in the CAT studies of Velligan et al., and is being scored during the supervision sessions and the audio recorings of home visits.

25-jun-2014: The measures include quality of life (Short Form Health Survey-12), negative symptoms (motivation subscale of the Negative Symptoms Assessment) and empowerment (Dutch Empowerment Questionnaire).

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. 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.

Study objective

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.

Study design

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.

Intervention

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).

Contacts

Public
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
Scientific
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

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

N/A

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	130
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-02-2012
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	NL3164
NTR-old	NTR3308
Other	NA : NA
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A