

Metacognitive training: A randomized controlled trial.

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Metacognitive training is more effective than the standard treatment (TAU) for changing paranoid thinking in patients with psychotic disorders.

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

Samenvatting

ID

NL-OMON25876

Bron

Nationaal Trial Register

Aandoening

psychosis
paranoid schizophrenia

Ondersteuning

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Overige ondersteuning: ZON MW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome: Paranoid ideas and ideas of social reference. The GPTS was chosen as primary outcome. The GPTS is a questionnaire that measures paranoid ideas and ideas of social reference with 32 items on a 5-point Likert-scale. The internal consistency is good, with a Cronbach alpha > 0.70 and the test is considered valid.

Toelichting onderzoek

Achtergrond van het onderzoek

State-of-the-art treatment of psychoses and delusions consists of antipsychotic medication prescribed by a psychiatrist, with or without therapist-administered cognitive-behavioral therapy (CBT). In CBT, delusions are examined and challenged in order to bring about a reduction of symptoms and to improve interpersonal relationships. Behavioral experiments are also directed toward testing concepts and towards the adaptation of beliefs based on the outcome of behavioral experimentation. This is the case for all DSM Axis I disorders. However, a delusion is not simply an incorrect interpretation such as occurs with anxiety and mood disorders. Recent findings in fundamental research however suggest that several cognitive biases in schizophrenic patients play an important role in the etiology and maintenance of positive symptoms (hallucinations and delusions). In an effort to translate findings about cognitive biases into clinical practice a groupwise training called Metacognitive Training (MCT) was developed by Moritz and Woodward. The intention of these authors was to fill a gap in order to create a more effective treatment for this population. The purpose of MCT is two-fold: 1) to educate the patient about these cognitive biases and 2) to highlight the negative consequences of these cognitive tendencies. Since the training focuses mostly on the form in which thoughts arise more than on the content of these thoughts it is expected to be a less intrusive and more playful way of gaining effects. This form-based training (versus content-based) might be cost-effective because it is also more suitable for groupwise training because of the fact that patients will not discuss the content of their hallucinations and delusions. Metacognitive training consists of 8 group sessions in which two therapists explain and train patients to overcome the most common cognitive bias (such as memory bias, jumping-to-conclusions bias, attentional bias) with attractive visual aids. In the period following the session patients are encouraged to complete their homework assignments to make generalization possible. It is hypothesized that Metacognitive therapy is more effective than the standard treatment (TAU) for changing paranoid thinking and ideas of social reference.

Method: The first two pilot studies show stimulating results on subjective and objective outcome measures. In a Dutch multi-centre randomized controlled trial (RCT) sixty-four subjects receiving the training additional to the treatment as usual will be compared with sixty-four subjects receiving only treatment as usual (TAU) in terms of paranoid thinking and ideas of social reference (primary outcome), quality of life, effect on several cognitive biases and effect on metacognitions before and after the intervention and with a 4-month follow-up. Patients between the ages of 18-65 with overt psychosis and suffering from an axis-I disorder

in the schizophrenia spectrum (295-codes) will be included.

Results: Results will be stated in terms of efficacy and cost-effectiveness (a CEA will be conducted by a HTA-specialist).

It is expected that there are no risks for the patients involved. Patient will make 12 visits to their local mental health institution. Four of the visits consist of screening and measurements and will take about 90 minutes. The other 8 visits consist of the MCT-sessions en will take a maximum of 90 minutes.

Doel van het onderzoek

Metacognitive training is more effective than the standard treatment (TAU) for changing paranoid thinking in patients with psychotic disorders.

Onderzoeksopzet

In a Dutch multi-centre randomized controlled trial (RCT) sixty-four subjects receiving the training additional to the treatment as usual will be compared with sixty-four subjects receiving only treatment as usual (TAU) in terms of paranoid thinking and ideas of social reference (primary outcome), quality of life, effect on several cognitive biases and effect on metacognitions before and after the intervention and with a 4-month follow-up. To summarize, there's three timepoints for all measurements:

1. $t(0)$ = Before the intervention;
2. $t(1)$ = Right after the intervention;
3. $t(2)$ = 4 month follow-up.

Onderzoeksproduct en/of interventie

Metacognitive Training (MCT): MCT is a group intervention intended for 3-10 patients. Sessions are typically conducted either by a clinical psychologist, psychiatrist, occupational therapist or psychiatric nurse. Each of the eight sessions lasts 45-60 minutes and deals with specific cognitive aberration. In each module, patients are first familiarized with the target domain (e.g., attributional style, jumping to conclusions, theory of mind) by means of a number of everyday examples and illustrations. To emphasize the relevance of the modules for psychosis and to ensure a lasting impact on patients, the linkage of these biases with psychosis formation/maintenance is repeated at the end of each session an eventually elucidated with anecdotal accounts of psychosis. Exercises form the core of the modules.

Patients practice to counteract cognitive biases such as jumping to conclusions. Leaflets with

homework and discussions about symptoms of the participants personalize and generalize the practiced skills into the daily life of the patients.

Treatment as usual (TAU): Concerns standard treatment for psychotic patients, which consist of medication prescribed by a psychiatrist and outpatient treatment by a social-psychiatrist nurse and/or psychologist.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with schizophrenia and/or another psychotic disorder (established with SCAN);
2. With delusional symptoms (PANSS P1>3 & PSYRATS DRS 5>1 & PSYRATS DRS 6>1);
3. Aged between 18-65.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Primary addiction;
2. Insufficient understanding of the Dutch language;
3. IQ<70.

Onderzoeksopzet

Opzet

| | |
|------------------|-------------------------|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blinding: | Open / niet geblindeerd |
| Controle: | Actieve controle groep |

Deelname

| | |
|-------------------------|----------------------|
| Nederland | |
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-01-2010 |
| Aantal proefpersonen: | 128 |
| Type: | Verwachte startdatum |

Ethische beoordeling

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|-----------------|------------------|
| Positief advies | |
| Datum: | 28-04-2010 |
| 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 | NL2183 |
| NTR-old | NTR2307 |
| Ander register | ZONMW : 171001010 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

Resultaten

Samenvatting resultaten

N/A