Reducing relapse and recurrence in depression with continuation Cognitive Therapy.

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25030

Bron
NTR

Aandoening

Recurrence or Relapse of Major Depression Disorder

Ondersteuning

Primaire sponsor: Arkin, mental health care institute Amsterdam,
Department of Psychology of the University of Groningen,
Vanderbilt University, Nashville,
Vrije Universiteit Amsterdam, Faculteit der Geneeskunde Huisarts- en Verpleeghuisgeneeskunde,
Trimbos Instituut, Innovation Centre of Mental Health & Technology,
Vrije Universiteit Amsterdam, Faculteit der Aard- en Levenswetenschappen Gezondheidswetenschappen: Health Economics and Technology Assessment
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is the cumulative proportion of relapses/recurrences in a survival-analysis over a follow-up period of 15 months after the start of the preventive therapy as measured with the ‘Structural Interview for DSM-IV (SCID) using the Longitudinal Interval Follow-up Evaluation (LIFE), which provides a retrospective assessment of depression recurrences since the time of the last evaluation.

Toelichting onderzoek

Achtergrond van het onderzoek

Major depressive disorder (MDD) is projected to rank second on a list of 15 major diseases in terms of burden and is highly recurrent in nature. Accordingly, efforts to reduce the disabling effects of this chronic condition should shift to preventing recurrence after response to a acute treatment. The best established effective psychological intervention is cognitive therapy, with indications for prophylactic effects after remission. In this study (cost-) effectiveness of Continuation preventive cognitive therapy (C-C-PCT) after response to acute CT (A-CT) will be examined in comparison with care as us usual (CAU). In a randomized controlled clinical trial we will compare two parallel groups; (1) C-PCT after A-CT versus, and (2) CAU after A-CT, with follow-ups at 3, 6, 12 and 15 months. Randomisation will be stratified for number of previous episodes and the level of residual symptoms. The study population are patients that responded to A-CT treatment with at least two previous depressive episodes. The primary outcome is cumulative person-time based incidence of depression relapse/recurrence over 15 months using DSM-IV-TR criteria as assessed by the Structural Clinical Interview for Depression. A secondary outcome measure is symptom severity as measured with the Inventory of Depressive Symptomatology (IDS-R). With 85 participants per condition, the trial has a power of 80% to detect a difference of 17,5% in the cumulative incidence rate of relapse/recurrence with a 15 months follow-up (1-tailed test, alpha=0.05). We assume that relapse/recurrence will occur in 40% of the cases. Allowing for a drop-out of 20% we need to include 214 participants in total at baseline. The economic evaluation will be conducted from a societal perspective with a time horizon of 15 months. Primary outcome measure: the number of depression-free days. Resource use and occupation-related costs will be measured using the TiC-P and PRODISQ, and will be valued using Dutch standard prices. Bootstrapping will be used to estimate the uncertainty surrounding these ratios.

Doel van het onderzoek

Major depressive disorder (MDD) is projected to rank second on a list of 15 major diseases in terms of burden and is highly recurrent in nature. Accordingly, efforts to reduce the disabling effects of this chronic condition should shift to preventing recurrence after response to a acute treatment.

The best established effective psychological intervention is cognitive therapy, with indications for prophylactic effects after remission. In this study (cost-) effectiveness of Continuation preventive cognitive therapy (C-C-PCT) after response to acute CT (A-CT) will be examined in comparison with care as us usual (CAU).

This study is a randomized controlled clinical trial in two parallel groups comparing (1) C-PCT after A-CT versus (2) CAU after A-CT.

We expect that offering C-PCT (about €800 per patient) after A-CT, will be party offset by reduced costs due to relapse and recurrences via lesser healthcare consumption, and greater productivity when people are employed. In other words, we expect that the new intervention will be associated with better health gains for additional costs. We also expect that these additional costs will not be excessively high and will, in general, be lower than a willingness-to-pay ceiling of €20.000 per QALY.

Onderzoeksopzet

Assessment interviews will be conducted at baseline, 3, 6, 12 and 15 months after randomization.

Onderzoeksproduct en/of interventie

Short-term continuation PCT (C-PCT) consist of 8 sessions that is offered as sequential treatment after response to A-CT. The effectiveness of C-PCT has been evaluated in earlier trials (Bockting et al., 2005; 2009).

CT is directed at the identification of maladaptive cognitions and the development of a personal prevention strategy. C-PCT (Bockting et al., 2009) is an adapted type of cognitive therapy specifically developed to prevent relapse in recurrent depression and adapted to remitted patients. Like in regular CT, each C-PCT session follows a fixed structure, with agenda setting, review of homework, explanation of rationale of each session, and assignment of homework. A specific manual for the client and therapist has been published describing the structure of the treatment and the intervention used is available (Bockting et al., 2009). Unlike CT for acutely depressed patients, C-PCT is not primarily directed toward modifying negative thoughts. Instead, it starts with the identification of negative thoughts and dysfunctional attitudes, aided by a self report questionnaire with examples of attitudes and specific techniques such as the downward arrow technique. The focus of treatment is then directed on changing these attitudes using different cognitive techniques such as Socratic questioning and identification of positive attitudes. Moreover, patients are encouraged to practice with alternative attitudes in the final sessions. In addition specific

attention will be paid to enhancing the memory and retrieval of positive experiences and making a person prevention plan.

Care As Usual (CAU) consists of the usual care that patients generally receive in primary care (and partially in secondary care) after treatment for acute depression. CAU typically consists of anti-depressant maintenance medication in primary and secondary care, or counseling in secondary care. Often, there is no treatment at all. A comparison of C-PCT with CAU is relevant from a public health perspective since it would help to demonstrate the intervention’s added value over and above CAU. We will not intervene with CAU, but monitor CAU, including type and dosage of AD use, using the TIC-P (Hakkaart-van Roijen et al., 2002).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Two or more previous depressive episodes indicating high risk for relapse/recurrence;

2. In remission according to DSM-IV criteria;

3. A current score of <14 on the Hamilton Rating Scale for Depression;

4. During the acute phase of the last episode, patients received CT at the Arkin Mental Health Care Institute.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Current mania or hypomania or a history of bipolar illness;

2. Any psychotic disorder (current and previous);

3. Alcohol or drug misuse;

4. Predominant anxiety disorder;

5. Insufficient mastering of the Dutch language.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2011
Aantal proefpersonen:	214
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL2482
NTR-old	NTR2599
Ander register	ZonMw : 80-82310-97-11123
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A