Disrupting the rythm of depression: effectiveness and cost-effectiveness and mediating factors of preventive cognitive therapy, with or without antidepressants and compared to antidepressants alone, in the prevention of recurrent major depressive disorder.

Published: 28-04-2009
Last updated: 24-08-2024

The objective of this study is threefold:1) compare the effectiveness and cost-effectiveness of brief CT added to maintenance AD versus maintenance AD alone versus guided tapering or discontinuation of AD with brief CT.2) examine whether the…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON39379

Source
ToetsingOnline

Brief title
Disrupting the rhythm of depression

Condition

- Mood disorders and disturbances NEC

Synonym
major depressive disorder, melancholia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMw; OOG subsidie

Intervention

Keyword: (cost-)effectiveness, anti-depressants, depression, mediating factors, preventive cognitive therapy

Outcome measures

Primary outcome

Proportion of relapse/recurrence in a survival analysis over a follow up period

of 2 years using DSM-IV criteria as assessed bij the Structural Interview for

DSM-IV (SCID I) at 3, 12 and 24 months (current depressive symptomatology and

previous 3 and 6 months).

Assessment HDSR at screening, 3, 12 en 24 months.

Secondary outcome

Number of Episodes and severity of depression:

SCID-I and Inventory of Depression Symptomatology (IDS-SR 18).

Predictors and mediators:

avoidance of emotions: AAQ II

rumination: RRS-uitgebreide extended version

Dysfunctional attitude scale (DAS-A)

Attribution Style (DASQ and LEIDS)

Every Day Problem Checklist (EPCL 20)

Negative Life Events Questionnaire (NLEQ 21)

Coping (UCL)

Assess medication adherence:

Medication Adherence Questionnaire (MAQ22)

Economic evaluation:

quality adjusted life years (EQ5D)

Implicit attitudes en attentional bias

Impliciete Associatie test (IAT24)

Assess the difficulty to disengage from negative information:

Rapid Serial Visual Presentation (RSVP) task

New addition June 5 2013:

Effect in daily life:

PsyMate

DNA-assessment:

Saliva sample

Study description

Background summary

Disrupting the rhythm of depression: effectiveness and cost-effectiveness and mediating factors of preventive cognitive therapy in the prevention of recurrent major depressive disorder.

Major Depressive Disorder is recognized as a recurrent condition. Previously (ZONPreventieprogramma) we demonstrated the effectivity in a national multicenter randomized controlled trail of preventive cognitive therapy (CT) added to treatment as usual (TAU) compared with TAU alone, in remitted patients with a history of recurrent episodes of major depressive disorder, especially in patients with multiple previous episodes. Maintenance treatment with antidepressants is the leading strategy to prevent relapse and recurrence in patients with recurrent major depressive disorder (MDD) who have responded to acute treatment with AD (Dutch Multidisciplinary Guideline for Depression, 2005). However, previous studies, including ours, indicated that most patients (up to 70-80%) in clinical practice are not willing to take this medication long after remission or take too low dosages (Meijer et al., 2004, Bockting et al., 2008)). Moreover, as patients need to take medication for several years, it may not be the most cost-effective strategy. The best established effective and available alternative is brief cognitive therapy (e.g. Beck, 2004, for a meta-analysis see Vittengl et al., 2007). However, it is unclear whether the combination of AD to brief Ct is beneficial. In addition it is unclear whether brief CT while tapering antidepressants (AD) is an effective alternative for long term use of AD in recurrent depression. Therefore, we will compare the effectiveness and cost-effectiveness of brief CT added to maintenance AD versus maintenance AD alone versus guided tapering or discontinuation of AD with brief CT.
In addition, we examine whether the prophylactic effect of CT was due to CT tackling illness related risk factors for recurrence such as residual symptoms or to its efficacy to modify presumed (psychological) vulnerability factors of recurrence, e.g. rigid dysfunctional attitudes.

Study objective

The objective of this study is threefold:

1) compare the effectiveness and cost-effectiveness of brief CT added to maintenance AD versus maintenance AD alone versus guided tapering or discontinuation of AD with brief CT.

2) examine whether the prophylactic effect of CT was due to CT tackling illness related risk factors for recurrence such as residual symptoms or to its

efficacy to modify presumed (psychological) vulnerability factors of recurrence, e.g. rigid dysfunctional attitudes

3) examine differential predictors of response to the three interventions

Study design

A randomized controlled multi center trail including 3 arms:

1) Continuation maintenance-AD
2) Continuation maintenance-AD + brief CT
3) Intention guided tapering maintenance-AD +brief CT

Intervention

In the treatment arm where AD will be continued GP*s and psychiatrists will be advised to prescribe continuation/maintenance AD as recommended by national guidelines (2005) continuing AD at minimal required adequate used dosage (>=20 mg Fluoxetine equivalent). In the treatment arm including guided tapering of AD GP*s and psychiatrists will be advised to taper AD in 4 weeks to prevent possible withdrawal symptoms. In this arm patients will be asked for an intention to taper AD. The patient is allowed to start AD again at any time during the study (this will be monitored).

For patients randomised to the two CT-arms an 8 sessions preventive cognitive group therapy (2 hours each) will be delivered by a special trained behavioral therapist.

Study burden and risks

The burden associated with participation is not that big and surely not invasive. All patients using antidepressants will be seen by their own GP or psychiatrist. After remission they all continued this medication for at least 8 weeks. Also the group of patients that have the intention of tapering antidepressant will be seen by their own GP's or psychiatrists. We will advise to taper antidepressants in 4 weeks to prevent withdrawal symptoms. All patients and GP/psychiatrist may start medication at any time during the study (this will be monitored).
When one condition is clearly inferior according to an interim analysis conducted by an independent statistician at 12 months follow-up, then the third arm including preventive cognitive therapy and tapering of antidepressants will be aborted, all participants will be informed, and participants from the inferior condition will be advised to start again with AD.

There are some possible advantages associated with participation on

the researchproject:
- during 2 years a screening on a disease which is known for its high percentage of relapse, and
- for 2/3 of the group: a therapy for free.
This cognitive therapy is known to protect against relapse (time to relapse and the severity in case of a relapse, decreased); Bockting et al, 2005). A recent meta-analysis points at a prophylactic effect of CT (Vittengl et al., 2007). The results of this study will give more information about the (costs)effectiveness of preventive cognitive therapy on depression and gives us insight in the mediating variables of relapse. This information can throw new lights in the development of more effective treatment.

Contacts

Public
Universitair Medisch Centrum Groningen

Laan van Nieuw Oost Indië 334
Den Haag 2593 CE
NL
Scientific
Universitair Medisch Centrum Groningen

Laan van Nieuw Oost Indië 334
Den Haag 2593 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with major depressive disorder (DSM-IV) with at least two previous depressive episodes in the past five years.
Last episode was treated succesfully with an antidepressant and the patient is still using that antidepressant at an adequate dose (recommended minimum dose according to Farmacotherapeutisch Kompas.
Currently in remission according to DSM-IV criteria, for at least 8 weeks and no longer than 2 years.
A current score of <10 in the Hamilton Rating Scale for Depression (HRSD).;New addition on 30-7-2012
All included participants are able to particpate in the additional study with the exception of women with a current pregnancy or recent delivery (<6 months); in case of doubt the woman will not be included.

Exclusion criteria

* Bipolar I of bipolar II disorder (indicated by previous or current manic or hypomanic episode (DSM-IV)
* serious neurological or somatic disorder (including organic brain damage) as possible cause of depression
* alcohol or drug abuse during the last six months; alcohol or drug dependence during two years
* comorbid anxiety disorder, necessitating additional treatment
* ongoing or recent (<6 months) psychotherapy (CT, CBT, IPT, etcetera) with a frequency of more than two times a month.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2009
Enrollment:	276
Type:	Actual

Ethics review

Approved WMO Date:	28-04-2009
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)
Approved WMO Date:	22-11-2013
Application type:	Amendment
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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	NL24000.097.08
Other	NTR454