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Mindfulness based task concentration training versus cognitive therapy for social anxiety disorder

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15/04/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/05/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/05/2011	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Mindfulness based task concentration training versus cognitive therapy for social anxiety disorder

Study objectives
This study compares mindfulness-based and task concentration training (MBTCT) with cognitive therapy (CT) for social anxiety disorder (SAD), in order to investigate:
1. Which approach is most effective in the short and longer term
2. Whether MBTCT has specific effects on attentional and CT specific effects of cognitive outcomes
3. Whether different mechanisms of change are involved in both approaches
4. Moderators of change within and across treatment modalities

Social Anxiety Disorder (SAD) is one of the anxiety disorders as classified by the Diagnostic and Statistical Manual of Mental Disorders as published by the American Psychiatric Association in 2000. People with SAD have a marked and persistent fear of one or more social or performance situations in which the person is exposed to unfamiliar people or to possible scrutiny by others. The individual fears that he or she will act in a way (or show anxiety symptoms) that will be humiliating or embarrassing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee Academic Hospital Maastricht, The Netherlands (Medisch Ethische Commissie academisch ziekenhuis Maastricht). Approved 29/03/2002 Ref no: MEC 02-008.3

Study design
A single centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Social Anxiety Disorder (SAD)

Interventions

1. Mindfulness based and task concentration training (MBTCT) consisting of first 5 sessions Mindfulness-base cognitive therapy (MBCT), almost identical to the MBCT sessions described by Segal et al. (2002)
2. Two modifications are made:
2.1. We delete any cognitive therapy in order to make the treatments as different as possible as to examine the effects of pure attention training with pure cognitive therapy
2.2. We remove the parts about depression and rephrased them into SAD
3. In session 6 and 7 task concentration training for SAD was added
4. In session 5 and 6 patients practice in-session and in their daily life how to focus attention outward rather than inward (task-focused versus self-focused), first in more neutral social situations, and then using the list of 5 difficult social situations that they formulate before treatment, their idiosyncratic situations (see outcome measures)
5. At the same time, they maintain daily mindfulness practice according to their own choice of combination of exercises learned (bodyscan, yoga, sitting meditation with awareness of the breath, body, sounds, thoughts).
6. They are instructed to apply the 3 minute breathing space before, during and after their 5 idiosyncratic difficult social situations
7. Session 8 follows roughly the original MBCT session 8
8. Cognitive therapy (CT):
8.1.The first sessions (5 in group and 6 in individual treatment) are focused on changing probability and cost ratings of idiosyncratic automatic thoughts about being disliked by others (e. g. others think I am stupid, annoying or think I am unlikeable)
8.2. Patients learn to apply highly structured techniques on their 5 idiosyncratic social situations that are formulated before treatment and on day-to-day situations
9. These techniques focus on either changing probability ratings:
9.1. With the brainstorm technique patients brainstorm about other ways people can view them next to their negative automatic thoughts and with the pie-method evaluate the probability of each of these views
9.2. With a cost scale, patients evaluate the cost of being negatively evaluated in perspective of other negative things people can think of each other (e.g., being a criminal, a bighead, lazy)
10. In the last 3 sessions behavioral experiments are used to test in day-to-day situations whether people indeed have such negative views about them, e.g. patients rate how many people look at them in a negative way when walking on the street, when taking their time to pay in the supermarket or respond negatively when saying their opinion or saying no to a request

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Assess general aspects of social anxiety:
1.1. Patients complete the subscale of the social phobia and anxiety inventory (SPAI, Turner, Beidel, Dancu, & Stanley, 1989; Dutch validation by Bögels and Reith, 1999)
1.2. The anxiety and avoidance of the social phobia subscales of the fear questionnaire (FQ, Marks & Mathews, 1979)
1.3. The subscale social sensitivity and distrust of the symptom checklist (SCL-90, Dutch validation Arrindell & Ettema, 1986)
1.4. The fear of negative evaluation scale (FNE-short, Leary, 1983)

2. All these questionnaires possess satisfactory psychometric qualities.
3. The level idiosyncratic social anxiety of the patients is composed out of the anxiety and avoidance ratings (scale 0-8) of participants' idiosyncratic main phobia (e.g., talking to unfamiliar people) of the FQ, a severity rating (scale 0-8) of the idiosyncratic target complaint that the participant formulates (e.g., feeling insecure) and avoidance and anxiety ratings on a Visual Analogue Scale (VAS) of five constructed target situations (e.g., I say something to an unfamiliar person and I feel that I blush)
4. These target situations are carefully formulated by the therapist and patient in two pre treatment sessions
5. General psychopathology is measured with the SCL-90 subscales generalised anxiety, agoraphobia, depression, somatisation, obsessive-compulsivity, sleeping problems, and other problems, and the subscales agoraphobia and blood/Injury of the FQ
6. The clinical significant change is determined with the ratings on the social phobia subscale of the SPAI.
7. Patients scoring below 89 are considered social anxiety free and a score of 89 or higher represent still suffering from social anxiety
8. This cut-off point was based on data of Bögels and Reith (1999) in which a score above 88 corresponded with 91% correct diagnoses of SAD

Secondary outcome measures

1 .Patients characteristics are assessed at pre-assessment:
1.1. Sex
1.2. Age
1.3. Education level
1.4. Marital status
1.5. Job status
1.6. Medication use
1.7. Past treatment
1.8. Duration of complaints.
2. Axis I and Axis II diagnoses are determined at pre-assessment with the Structured Clinical Interview for DSM-IV Axis I and II disorders (SCID-I, First, Spitzer, Gibbon, &Williams, 1996; SCID II).
3. The following attention measures are assessed:
3.1. State self-focused attention is measured with the SelfFocused Attention (SFA) scale (Bögels, Alberts, & De Jong, 1997), which consists of the subscales SFA on Arousal (item example: In the presence of other people, Im constantly focusing on ... whether my heart is beating) and SFA on Performance (item example: In the presence of other people, Im constantly focusing on ... how well I take part in the conversation)
3.2. Factor-analysis confirmed the existence of two factors, as well as a reliable total score (Bögels et al., 1997). The subscales Public and Private Self-Consciousness of the Self Consciousness Scale (SCS, Fenigstein, Scheier, & Buss, 1975, Dutch validation Bögels, Alberts, & de Jong, 1996) are administered to assess a dispositional tendency to be aware of oneself, privately or publicly
4. Cognitions related to social anxiety are measured with:
4.1. The Social Phobic Belief scale (SPB), a 15 item questionnaire measuring the conviction of negative beliefs related to social phobia, that is, negative assumptions about the self, the others, as well as conditional beliefs (Bögels, unpublished). The reliability and discriminant validity of the SPB has been demonstrated in previous research (e.g., Voncken, Bögels, & De Vries, 2004).
4.2. The probability and cost ratings of the negative automatic thought (e.g. these people do not like me) that are part of the formulated target situations

5. We measure the view of self, using the self subscale of the Self-Other-Ideal Questionnaire (Miskimins, Wilson, Nicolas-Braucht, & Berry, 1971). This questionnaire measures 15 aspects of functioning, which seem relevant to social anxiety, such as:
5.1. Smart and skilled
5.2. Physically attractive
5.3. Friendly and warm
6. Patients rate each item on a VAS in which 0 represents the most negative and 100 the most positive outcome. This scale is shown to be reliable (Bögels, Sijbers and Voncken, 2006)

Overall study start date
29/03/2002

Completion date
01/08/2008

Eligibility

Key inclusion criteria
1. Patients that are referred for treatment to the community mental health centre in Maastricht
2. Fulfilled the criteria of a primary diagnosis of SAD using the Structured Clinical Interview for the DSM-III-R (SCID, Spitzer & Williams, 1985) by trained clinical interviewers

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
90: 48% male; 52% female

Key exclusion criteria
1. Other severe psychiatric problems that might interfere with treatment
2. Current substance dependence
3. Psychotic disorder
4. Suicidal behavior
5. Borderline personality disorder
6. Having received (cognitive) behavioral treatment for SAD in the preceding 6 months

Date of first enrolment
29/03/2002

Date of final enrolment
01/08/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
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Sponsor information

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University/education

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ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
University/education

Funder Name
Maastricht University (The Netherlands)

Alternative Name(s)

Maastricht University, UM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		01/01/2006		Yes	No
Other publications		01/01/2006		Yes	No