ISRCTN23894653 https://doi.org/10.1186/ISRCTN23894653

A small randomised controlled trial on ST-MBCT + TAU versus COMET + TAU for patients with a personality disorder

Submission date
31/08/2017

Recruitment status
No longer recruiting

Registration date
13/09/2017

Overall study status
Completed

Last Edited
27/09/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
There are long waiting lists in mental health care. In particular patients with personality disorders have to wait for a long period. Personality disorders are conditions in which an individual differs significantly from an average person in terms of how they think, perceive, feel or relate to others. Studying time-limited therapy interventions for example as a first step intervention in the treatment of patients with a personality disorder is an important step to help patients earlier. Most research on the treatment of personality disorders focuses on long-term treatments. Little is known of the effectiveness of time-limited therapies. Even less is known about what patient variables predict or moderate/mediate a positive or worse outcome. The two time-limited therapies in this study are widely used in the Netherlands as part of treating personality disorders. This study aims to find out more on the effectiveness of both treatments and to look for factors which predict what works best for which patient.

Who can participate?
Outpatients with a personality disorder aged 18-65

What does the study involve?
Participants fill in self-reports on their mental health and have an interview with a researcher who formally diagnoses them. Participants are than randomly allocated to one of two types of therapy. They participate in 8 weeks of group therapy of 1.5 hours per session. Participants are assessed again directly after the last therapy session and one month later.

What are the possible benefits and risks of participating?
The possible benefits are increased self-esteem and/or more awareness of one's pitfalls which enables one to either not step in to the pitfall or more easily step out of it. The risks are that the patient is confronted with painful feelings of the realization that he/she has a mental disorder.

Where is the study run from?
GGZ Delfland (Netherlands)

When is study starting and how long is it expected to run for?
February 2012 to July 2014

How long will the trial be recruiting participants for?
GGZ Delfland (Netherlands)

Who is the main contact?
Mr M. F. Van Vreeswijk

Contact information

Type(s)
Scientific

Contact name
Mr M. F. van Vreeswijk

Contact details
Noordeinde 27A
Delft
Netherlands
2611 KG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
METC-nr. : 11-124. Dossier : NL37067.098.11.

Study information

Scientific Title
A small randomised controlled trial on ST-MBCT + TAU versus COMET + TAU for patients with a personality disorder: effectiveness, predictors and mediators of outcome

Study objectives
Given the awareness/acceptance oriented approach of SMT, it is hypothesized that patients following SMT will show greater reduction in general distress after treatment than patients following COMET. Moreover, it is hypothesized that patients following COMET will improve more on self-esteem and that patients following SMT will improve more regarding mindfulness skills, schemas and modes. Finally, the aim of this study is to explore possible predictors, moderators and mediating mechanisms. It is expected that in both treatment conditions schemas and modes at pre-treatment will predict reductions in global psychological distress and that a schema change will at least co-occur with changes in global psychological distress.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee Zuid-Holland (METC-ZWH: The Netherlands), 07/02/2012, METC-nr: 11-124, File-NR: NL37067.098.11

Study design
Interventional single-centre parallel-groups single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Outpatients with personality disorder(s)

Interventions
For this pilot study, a parallel-groups randomized single-blind trial was used. Randomization to the condition SMT or COMET was performed by GraphPad software (http://www.graphpad.com /quickcalcs/randomize1.cfm). Signed informed consent was obtained after full explanation of the procedures and of both therapies before the first assessment and randomization. Each patient was screened by means of the Mini-International Psychiatric Interview-Plus (M.I.N.I.-Plus, Sheehan, & Lecrubier et al., 1997, 1998; Bohnen, de Winter & Hoenkamp, 2011) and the Structured Clinical Interview of DSM-IV Disorders II (SCID-II, First, Spitzer, Gibbon, Williams, & Benjamin, 1997; Weertman, Arntz, & Kerkhofs, 2000). After inclusion, the patients filled in five self-report questionnaires before the start of the group training, directly after the last session of the group training of two months and one month after finishing the group training.

Schema Mindfulness Training (SMT)
The used SMT-protocol, written by van Vreeswijk et al. (2014), consists of eight group sessions of 90 minutes, once a week. The structure of the training is as follows: session one: psycho-education on schemas, modes and basic mindfulness exercises; session two: more mindfulness for the environment; session three: mindfulness for respiration and painful memories; session four: mindfulness to schema coping; session five: mindful allowing and accepting what is; session six: mindfulness to schemas facts or fiction; session seven: mindful taking care of yourself by the Healthy adult and the Happy child (Young et al., 2011); session eight: schema mindfulness and the future.

COMET
A negative self-image is a problem common to many psychiatric disorders (Appelo & Korrelboom, 2005) and to various types of personality disorders as well (Beck, Freeman & Associates, 1990). Korrelboom (2011) has written a protocol to positively correct a dysfunctional self-image using counter-conditioning by positive verbalisations (Lange et al., 1998), imaginations (Segal, Gemar & Williams, 1999), attitude and facial expression (Camras, Holland, & Patterson, 1993) and music (Van der Does, 2002). Previous research has shown that COMET has a positive effect on the self-image (Korrelboom, Huijbregts, de Jong, & Daansen, 2009; Korrelboom, Marissen, & van Assendelft, 2011) of both patients with personality disorders and eating disorders and that it can effectively be used in a group format (e.g. Martens, Korrelboom, & Huijbregts, 2009; ; Ekkers et al., 2011). The protocol consists of eight group sessions of 90 minutes, once a week. The structure of the treatment/training is as follows: session one: naming the negative self-image and naming the opposite image; session two: explaining the opposite image with examples; session three: exercising to feel the opposite image using imaginations and positive verbalisations; session four: exercising to feel the opposite image using imaginations, positive verbalisations, attitude and facial expression; session five: exercising to feel the opposite image using imaginations, positive verbalisations, attitude, facial expression and music; session six: exercising with building a stable positive self-image; session seven: exercising First-Aid measure for negative self-image; session eight: the future.

Two therapists treated four closed groups of patients with SMT and two other therapists treated four closed groups of patients with COMET at GGZ Delfland. All the therapists have had a post-doctoral training of 2-4 years after a master graduation in psychology to become a licensed mental health care professional. The therapists of the SMT condition all had training in Schema therapy of at least four days. The therapists in the COMET-condition where trained by Kees Korrelboom, developer of the COMET-program. The therapists had previous therapy experience in respectively SMT and COMET. There was no supervision nor video or audio taping to assess treatment adherence. During the group treatment patients were allowed to have a medical consult from a psychiatrist if necessary.

Intervention Type
Behavioural

Primary outcome measure
General psychological distress assessed using the Symptom Checklist-90 (SCL-90; Dutch version by Arrindell & Ettema, 1986). The SCL-90 is a 90-item self-report questionnaire which measures the following complaints: Agoraphobia, Anxiety, Depression, Somatic complaints, Insufficiency of thinking and doing, Interpersonal sensitivity, Hostility, Sleeping problems. The sum score represents a Global Severity Index. The Dutch version is reliable (Cronbach's alpha 0.97 by total score) and valid (Arrindell & Ettema, 1986). In this study the Cronbach's alpha for the total score was 0.88. We used the Global severity index (GSI) as primary outcome.

Method of measurement:
Questionnaire (self-assessment)

Timepoints:
T1: Before the start of the therapy
T2: Directly after the last therapy session
T3: One month after T2

Secondary outcome measures

1. Mindfulness assessed with the Mindfulness Attention Awareness Scale (MAAS, Brown & Ryan, 2003; Dutch version by Schroevers, Nyklíček, & Topman, 2008). The MAAS is a 15-item self-report questionnaire which represents the frequency of everyday mindfulness experiences. Previous studies found a one-factor structure. Cronbach's alpha ranged between .82 - .87 (Carlson & Brown, 2005; Brown & Ryan, 2003). The Dutch version is reliable (Cronbach's alpha 0.81) and valid (Schroevers, Nyklíček, & Topman, 2008). In this study the Cronbach's alpha was 0.86. This study used the sum score of the MAAS as an index of mindfulness

2. Self-esteem assessed using the Rosenberg Self-Esteem Scale (RSES, Rosenberg, 1965; Dutch version by Franck, de Raedt, Barbez, & Rosseel, 2008). The RSES is a 10-item self-report questionnaire assessing the degree of self-esteem. The Dutch version of the RSES is reliable (Cronbach's alpha 0.86) and valid (Franck, de Raedt, Barbez, & Rosseel, 2008). The Cronbach's alpha in this study was 0.87. This study used the sum score of RSES as a measure of self-esteem.

3. Schemas assessed with the Young Schema Questionnaire, (YSQ; Young & Brown, 1994; Dutch version by Rijkeboer, 2005). The YSQ is a 205-item self-report questionnaire which represents sixteen dysfunctional schema's: Abandonment/ Instability, Mistrust/Abuse, Emotional Deprivation and Social Isolation/Alienation (schema domain 1: Disconnection and Rejection); Dependence/Incompetence, Enmeshment/ Undeveloped Self and Failure (schema domain 2: Impaired Autonomy and Performance); Entitlement/ Grandiosity and Insufficient Self-control /Self-discipline (schema domain 3: Impaired Limits); Subjugation and Selfsacrifice/ Approval Seeking/Recognition Seeking (schema domain 4: Other Directedness); and Emotional Inhibition and Unrelenting Standards/Hypercriticalness (schema domain 5: Overvigilance and Inhibition). The Dutch version of the YSQ is reliable (Cronbach's alpha ranging .76 - .95) and valid (Rijkeboer & van den Bergh, 2006). For the purpose of this study the trialists used the five schema domains.

4. Schema modes assessed with the Schema Mode Inventory-I (SMI-I; Young et al., 2007). The SMI-I is a 118-item self-report questionnaire which represents fourteen modes divided over four domains: Vulnerable child, Angry child, Enraged child, Impulsive child, Undisciplined child (child mode domain), Compliant surrenderer, Detached protector, Detached self-soother, Self-aggrendizer, Bully/Attack mode (coping mode domain), Punitive parent, Demanding parent (parent mode domain), Happy child and Healthy adult (healthy mode domain). The Dutch version of the SMI-I is reliable (Cronbach's alpha ranging between .79 - .96) and valid (Lobbestael, van Vreeswijk, Spinhoven, Schouten, & Arntz, 2010). For the purpose of this study the trialists used the four mode domains.

Method of measurement:
Questionnaire (self-assessment)

Timepoints:
T1: Before the start of the therapy
T2: Directly after the last therapy session
T3: One month after T2

Overall study start date
08/02/2012

Completion date
01/07/2014

Eligibility

Key inclusion criteria
1. Patients (male or female) with a main diagnosis on Axis II, meaning one or more cluster A, B, C personality disorders or a personality disorder NOS
2. Aged 18 to 65 years
3. Patients were allowed to have a diagnosis on Axis I other than the exclusion criteria

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
58

Key exclusion criteria
1. Acute psychosis
2. Addiction of such severity that clinical detoxification was indicated
3. Severe suicidality for which hospitalisation was necessary
4. Untreated ADHD, bipolar I disorder and an IQ lower than 80
5. Patients were not allowed to have had Schema therapy or COMET in the past 12 months

Date of first enrolment
01/03/2012

Date of final enrolment
01/07/2017

Locations

Countries of recruitment
Netherlands

Study participating centre
GGZ Delfland
Jorisweg 2
Delft
Netherlands
2612 GA

Sponsor information

Organisation
GGZ Delfland

Sponsor details
Sint Jorisweg 2
Delft
Netherlands
2612 GA

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04c0z9s56

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
GGZ Delfland

Results and Publications

Publication and dissemination plan
It is the intention to publish the outcome of this study in the form of an article in a English psychology/psychiatry journal.

Intention to publish date
01/01/2018

Individual participant data (IPD) sharing plan
The SPSS-data file, which includes SES, mental health diagnosis and the primary and secondary outcome measures, can be obtained from M. F. van Vreeswijk. The data will become available after publication in an international scientific journal and is available for researchers who want to do a meta-analysis. It will be available for 5 years unless the journal regulations ask for a

longer period of time. Anonymisation on the data is done according to the rules of the Medical Ethical Committee of which the trialists have obtained permission to do this study. This METC works on the basis of international ruling (e.g. Helsinki agreement).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		22/01/2019	22/01/2019	No	No
Results article	results	01/05/2020	27/09/2019	Yes	No