

Identifying Moderators of Treatment Effectiveness in CBT and EFT

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Objective: The current study will explore the interaction between these two client characteristics, treatment response and treatment outcome in CBT and EFT, to determine whether patients* pre-treatment affect regulation capacity and level of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45403

Source

ToetsingOnline

Brief title

Treatment Effectiveness Study

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym

anxiety, mood disorder

Health condition

depressieve stemmingsstoornissen en afwijkingen

Research involving

Human

Sponsors and support

Primary sponsor: Ontario Institute for Studies in Education

Source(s) of monetary or material Support: Beide behandelingen worden regulier gefinancierd door de zorgverzekering.

Intervention

Keyword: cognitive behavrioal therapy (CBT), depression, emotion-focused therapy, generalized anxiety disorder

Outcome measures

Primary outcome

Beck Depression Inventory (BDI). This self-report inventory assesses symptoms of depression (Beck et al., 1996; Brouwer et al., 2013; Cole et al., 2003; Kjærgaard et al., 2014; Wang & Gorenstein, 2013; Dutch version: Van der Does, A. J. W., 2002).

State-Trait Anxiety Inventory (STAI). This is a self-report measure assessing how respondents feel in general (Spielberger, 1983; Spielberger et al., 1989; Barnes et al., 2002; Dutch version: van der Ploeg, H. M., 1980).

Difficulties in Emotion Regulation Scale (DERS). This scale provides an assessment of emotion dysregulation Gratz & Roemer, 2004; Dutch version: Neumann, A., van Lier, Pol A. C., Gratz, K. L., & Koot, H. M., 2010).

Attachment Style Questionnaire (ASQ). The ASQ is a 40-item self-report questionnaire assessing five styles of adult attachment: one securely attached style, confidence (in self and others), and four insecurely attached styles,

discomfort with closeness, need for approval, preoccupation with relationships, and relationships as secondary (to achievement) (Feeney, Noller, & Hanrahan, 1994; Dutch Version: van Oudenhoven, J. P., Hofstra, J., & Bakker, W., 2003).

Secondary outcome

General Outcome Measures

Outcome Questionnaire-45.2 (OQ-45.2). This self-report measure provides an index of mental health functioning and most items, the subscales, and the Total Score are sensitive to the effects of interventions while remaining stable in untreated individuals (Lambert et al, 2013; Dutch version: Amble, I., Gude, T., Stubdal, S., Oktedalen, T., Skjorten, A. M., Andersen, B. J., . . . Wampold, B. E., 2014).

Rosenberg Self-esteem Inventory (RSE). The RSE is a 10-item self-report questionnaire, rated 1-5, used to measure self-esteem (Rosenberg, 1965; Dutch version: Franck, E., de Raedt, R., Barbez, C., & Rosseel, Y., 2008).

Secondary Outcome Measure for MDD

Dysfunctional Attitudes Scale (DAS). The DAS is a 17-item, self-report inventory, rated 1 to 7, developed to identify pervasive negative attitudes toward self, outside world, and future that may relate to or cause depression (Weissman & Beck, 1978; Dutch version: Raes, F., Hermans, D., Van den Broeck, K., & Eelen, P., 2005).

Secondary Outcome Measure for GAD

Penn State Worry Questionnaire (PSWQ). This is a self-report measure designed to measure the trait of worry (Meyer et al., 1990; Dutch version: van der Heiden, C., Muris, P., Bos, A. E., & van der Molen, H. T., 2010).

Beck Anxiety Inventory (BAI). The BAI is a 21-item self-report inventory assessing severity of anxiety in adults focusing on somatic symptoms (Beck, Epstein, Brown, & Steer, 1988; Dutch version: Muntingh, A.D.T., van der Feltz-Cornelis, C.M., van Marwijk, H.W.J., Spinhoven, P., Penninx, B.W.J.H., van Balkom, A.J.L.M., 2011).

Post-Session Measures

Client Task Specific Change Measure * Revised (CTSC-R). The CTSC-R is a 12-item client self-report measure of client change (Greenberg, Rice, & Watson, 1996; Watson, Greenberg, Rice & Gordon, 1999).

Working Alliance Inventory-Short Form (WAI-S). The WAI-S (Tracey & Kokotovic, 1989; Dutch version: Stinckens, N., Ulburghs, A., & Claes, L., 2009) is a 12-item self-report questionnaire, rated 1 to 7, derived from Bordin's (1979) conceptualization of the working alliance consisting of agreement on tasks and goals, as well as the therapeutic bond.

Barrett-Lennard Relationship Inventory (BLRI). This is a self-report measure used to rate Rogers* relationship conditions (Barrett-Lennard, 1962, 1978; Dutch version: Leitaer, 1976).

Study description

Background summary

Rationale: MDD and GAD are major health problems that seriously compromise functioning with high social and economic costs (Chisholm et al., 2016; Greenberg et al., 2015; Revicki et al., 2012; Wittchen et al., 2011). Effective treatment of these disorders has a direct potential benefit of reducing health care expenses (Chisholm et al., 2016). While a number of treatments are effective in the treatment of these disorders, some patients, up to 5% to 10%, deteriorate in treatment in both clinical trials and routine care (Hansen et al., 2002; Lambert & Ogles, 2004). Researchers have suggested the need to identify specific moderators of patients* treatment response. Two client characteristics that have been shown to be important in treatment outcomes are affect regulation and attachment insecurity (McBride, Atkinson, Quilty & Bagby, 2006; Mennin et al, 2009).

Study objective

Objective: The current study will explore the interaction between these two client characteristics, treatment response and treatment outcome in CBT and EFT, to determine whether patients* pre-treatment affect regulation capacity and level of attachment insecurity interact with treatment type to influence outcome.

Study design

This study will investigate the aptitude by treatment interaction using HLM and a parallel study design.

To assess the role of patients* affect regulation capacity and attachment insecurity as moderators of treatment response in CBT and EFT for MDD & GAD, hierarchical linear mixed models (HLM) will be conducted using patients BDI and STAI-T scores respectively. It is expected that there will be no differences in outcome overall between CBT & EFT for MDD or GAD, but it is expected that patients with higher DERS scores indicating greater problems regulating affect and or higher attachment insecurity on the ASQ will do better in EFT than CBT.

Intervention

Intervention

Emotion Focused Psychotherapy (EFT; Elliott, Watson, Goldman & Greenberg, 2004; Greenberg & Watson, 2006; Watson & Greenberg; 2017) and Cognitive Behavioral Therapy (CBT; Beck & Emery, 1985) are the two treatment interventions based on the relevant treatment manuals for each approach.

Study burden and risks

There are no additional psychological or physical risks associated with participating in the study beyond those that would be expected from engaging in treatment as usual. Some participants may experience some distress and fatigue answering questions about their psychological functioning. Patients will have the support of their therapist to address these issues as well as the option to withdraw from the research at any time and remain in treatment or request an alternative treatment. Overall, it is expected that participants will benefit from treatment and that the study will provide valuable information to guide treatment delivery for those suffering from GAD and MDD to enhance treatment effectiveness.

Contacts

Public

Ontario Institute for Studies in Education

Bloor Street West Toronto 252
Toronto M5S 1V6
CA

Scientific

Ontario Institute for Studies in Education

Bloor Street West Toronto 252
Toronto M5S 1V6
CA

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients diagnosed with MDD or GAD between the ages of 18-65.

Exclusion criteria

Patients diagnosed with psychosis, addictions, at risk of suicide, mentally retarded, or diagnosed with cluster A and severe Cluster B personality disorders.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2018
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date: 29-05-2017
Application type: First submission
Review commission: METC Maxima Medisch Centrum (Veldhoven)

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	NL59481.015.16