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Randomized controlled trial comparing the therapeutic effect and change processes in Cognitive Behavioral Therapy and Emotion-Focused Therapy for depression.

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Randomized controlled trial comparing the therapeutic effect and change processes in Cognitive Behavioral Therapy and Emotion-Focused Therapy for depression.

A collaboration between the Norwegian Institute of Emotion Focused Therapy (NIEFT), Institute for Psychological counselling (IPR) and Department of Clinical Psychology, University of Bergen).

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Project period: 1.1.2021 – 12.31.2030

Introduction and background

Depression is a widespread mental disorder which can result in severe impairment and reduced quality of life for those affected. Cognitive behavioral therapy (CBT) is the approach with strongest empirical support, and is often recommended as treatment for depression, as in the NICE Guidelines for Depression (National Institute for Health and Care excellence, 2009). However, research indicates that not all patients respond to CBT (Lambert, 2011), indicating a need to expand the range of available evidence-based psychotherapies, and mapping the mechanisms of change in existing treatments (Dimidjian & Hollon, 2010; Kazdin, 2009).

Emotion focused therapy (EFT) is one promising treatment for depression with empirical support for its efficacy (Elliot et al. 1990; Goldman, Greenberg & Angus, 2006; Greenberg & Watson, 1998; Watson et al. 2003). A previous study found equal outcome in CBT and Process-Experiential treatment/EFT for depression (Watson et al; 2003), but more studies are needed to replicate these findings across cultural contexts. The main aim of this study is to investigate whether there are significant differences in the therapeutic effect of EFT compared to that of CBT for patients with moderate and major depressive disorder in a Norwegian outpatient setting.

Although several psychotherapeutic approaches have shown efficacy in the treatment of depression, no psychotherapeutic interventions is beneficial for all patients (Lambert, 2011). There is a need for research that investigates what treatments works for whom, based on patient characteristics and preferences (Blatt, 2008; Nilsson et al., 2007; Roth & Fonagy, 1996). The present study will investigate whether patient characteristics moderate treatment outcome, both within and between treatment conditions. In addition, qualitative interviews will be conducted to get a deeper understanding of what clients find helpful and challenging within the CBT and EFT condition, and to explore the experience of patients who drop-out of the treatment process.

In order to further develop psychotherapeutic treatments and increase their effectiveness, there is a need to identify processes that are related to good and poor outcome (Kazdin, 2011). Processoutcome studies are commonly used for this purpose (Rice & Greenberg, 1984; Watson, 2018). The present study will investigate and compare characteristics of psychotherapy processes in both the CBT and EFT conditions and how these are related to outcome.

Study design and Method

The study will be conducted as a randomized controlled trial (RCT) in order to compare the efficacy of EFT to CBT. RCT's are considered the gold standard for efficacy studies (Kendall, 2018). Participants will be recruited from the Norwegian mental health program "Return to work", a publicly funded

treatment program where patients with common mental health issues receives outpatient psychotherapeutic treatment to reduce and prevent sick leave.

The present study will address the following research hypothesis and questions:

1. EFT and CBT will not result in significantly different outcome in the treatment of patients with moderate and major depressive disorder.
2. Patient characteristics (severity of depression, emotional coping, rumination/worry, adverse childhood experiences and clients' initial ability to make sense of their experience) will moderate treatment outcome for both conditions.
3. Will therapeutic processes (therapeutic alliance, therapist empathy, clients' ability to make sense of their experience and emotional processing) mediate treatment outcome equally for both conditions?
4. What do patients in both conditions describe as helpful and unhelpful aspects of treatment?
5. How do patients in both conditions describe their own change or lack or change after treatment?
6. How do patients that choose to drop out of treatment describe the processes leading to that decision?

Enrollment		
A) Number of participants	B) Source of recruitment	C) Description of participants

N = 112 (56 in each condition). If the publicly funded program "Return to work" is continued within the organization Institutt for Psykologisk rådgivning in 2022, and the local ethics committee (REK) approves, the number of participants will be increased in order to increase the statistical power of the study. Based on previous studies (Watson et al, 2003; Stiegler, Molde & Schanche, 2017), estimated sample size is sufficient to investigate significant differences between conditions . An effect size (Cohen's d) on the primary outcome measure is approximately 0.50 (moderate). Power analysis show that there is a 32 % probability of detecting significant results given that there is an actual large difference between the conditions. The calculations	The government funded mental health program «Return to work». Based on the current number of referrals to this program, we expect to recruit at least 112 participants during the recruitment phase. If, for unknown reasons, we are faced with difficulties in the recruitment of participants, the backup solution will be to supply participants from the ordinary intake of self-referred patients to Institutt for Psykologisk rådgivning.	Adults 18 years and older with symptoms of moderate or major depression referred by their general practitioner for participation in the program "Return to work".
are taken from Howell (2013). An estimated drop out rate of 20 % implies that we will need to recruit 112 patients for this study. Fifty-six randomized to the EFT condition and fifty-six to the CBT condition. We will use both frequentist and Bayesian to analyze the data. We will use Linear Mixed Models to estimate the effect of the interventions, and structural equation modelling to analyze moderating and mediating factors. As we expect that there will be no significant difference between the conditions, we will utilize Bayesian statistical procedures to get a more nuanced picture		

of the data, which might help us to draw some more conclusions out of the data.		

Patients eligible for the program who based on the referral from their general practitioner present with depression as an issue will be contacted by phone and given verbal information about the study. Patients who are interested in participating, will also receive written information, and will be given one week to consider participating. For patients who consent to be evaluated for participation, a meeting will be scheduled to evaluate their eligibility for the study. Screening will be conducted by members of the research team who are not participating as therapist in the project.

Screening/selection of participants		
A) Pre-screening	B) Clinical screening	C) Criteria for participation
By phone: Inclusion: 1) Eligible for the Return to work program based on referral from GP. 2) Symptoms of depression as described in the referral. 3) Interest in participating in the study. Exclusion: 1) Not interested in taking part in the research study.	- Mini – International neuropsychiatric interview (M.I.N.I., version 6.0.0). - Structured Clinical Interview for DSM-IV (SCID-II). - Hamilton	1) INCLUSION: i) Moderate or major depressive episode as primary diagnosis 2) EXCLUSION i) Serious mental illness (schizophrenia, severe bipolar disorder, recent or current psychotic episode) or intellectual disability. ii) Severe alcohol or drug abuse, last 12 months. iii) Suicidality last 6 months iv) Severe medical issues v) If the participant is on antidepressive medication, the dosage must have been stable for more than 4 weeks, and the participant must consent to staying on the same dosage for the duration of the treatment. vi) The participant is currently in another treatment for depression
		vii) Severe Borderline or narcissistic personality disorder

Patients not eligible for the study will be referred back to standard treatment within the Return to Work program. Patients included in the study will be randomly allocated to one of the two treatment

conditions. An independent researcher will carry out the randomization procedure. In both conditions, the patients will receive 14-18 session of individual therapy, the same number of sessions as standard treatment in the program.

Patients are blinded to the study conditions. No information about study design or the type of intervention is given to the patients, except that they will be told that both treatments focus on learning to cope with negative thoughts and feelings.

Randomization	
EFT	CBT
14-18 sessions individual therapy EFT intervention N=56	14-18 sessions individual therapy CBT intervention N=56

Pre-treatment self-report measures
Primary symptoms: 1. Beck Depression Inventory, BDI-II Secondary symptoms: 2. Beck Anxiety Inventory, BAI 3. Repetitive Eating Questionnaire, REP(EAT)-Q Interpersonal functioning: 4. Inventory of Interpersonal problems, IIP Cognitive and emotional and cognitive functioning: 5. The Acceptance and Action Questionnaire, AAQ-2 6. Emotion Approach Coping Scale 7. Penn State Worry Questionaire Relationship to self: 8. Self-Compassion Scale, SCS Other measures: 9. Adverse Childhood experiences, ACEs 10. Quality of life questionnaire

Mid-, post-treatment and follow up (3, 6 and 12 months)	
A) Self report measures	B) Post-treatment qualitative interviews
Measures of primary symptoms: Primary symptoms: 1. Beck Depression Inventory, BDI-II Secondary symptoms: 2. Beck Anxiety Inventory, BAI 3. Repetitive Eating Questionnaire, REP(EAT)-Q	15 participants from each condition (N=30). Up to 12 participants who drop out of treatment will be selected to undergo a qualitative interview.

Interpersonal functioning: 4. Inventory of Interpersonal problems, IIP Cognitive and emotional functioning: 5. The Acceptance and Action Questionnaire, AAQ-2 emotional and cognitive functioning: 11. The Acceptance and Action Questionnaire, AAQ-2 12. Emotion Approach Coping Scale 13. Penn State Worry Questionaire Relationship to self: 6. Self-Compassion Scale, SCS Other measures: 7. Quality of life questionnaire	

Process measure for each session
Self-report measures: 1. Beck Depression Inventory, BDI-II 2. Working Alliance Inventory - short version, WAI 3. The Acceptance and Action Questionnaire, AAQ-2 Video-observed process measures: 1. Measure of Expressed Empathy (MEE), Watson, 1999. 2. The Experiencing Scale, Klein et al., 1969. 3. Classification of Affective-Meaning States (CAMS)

To study changes in psychotherapeutic processes we need access to the patient's verbal and nonverbal expression. All therapy sessions will be video-recorded. Observation and rating of video recorded therapy sessions are the most reliable method to control for therapist adherence to the method.

Competence and adherence measures	
EFT	CBT
1. Working alliance Inventory, WAI 2. Person-Centered & Experiential Psychotherapy Scale—EFT supplement	1. Working alliance Inventory, WAI 2. Cognitive Therapy Adherence and Competence Scale

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