Title of the project: Cognitive Behavioral Therapy/ Metacognitive Therapy for Low Self Esteem

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Study protocol:

Metacognitive Therapy or Cognitive Behavioral Therapy for Low Self-Esteem: A pilot study.

In Norwegian:

”Effekten av metakognitiv terapi og kognitiv atferdsterapi i behandling av lav selvfølelse: En pilot-studie”

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In collaboration with:

Department of Psychology
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&

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SUMMARY

The association between low self-esteem and psychiatric disorders indicates that low self-esteem is an important transdiagnostic construct. People who report having a low self-esteem seem to experience more mental health problems and a reduction in quality of life.

There have been a few trials considering the effect of Cognitive Behavioural Therapy (CBT) for low self-esteem, however, there are few randomized controlled studies. Recently, Meta Cognitive Therapy (MCT) has been introduced as a new, specific treatment for MDD, showing promising and lasting results. This treatment approach also has proven more effective than CBT for GAD or worry disorder. So far, no study has examined MCT for low self-esteem in a randomized controlled trial.

For the present clinical trial, 20 patients with low self-esteem will be selected and distributed into two treatment conditions. The first group (n=10) will be treated with MCT, whereas the second group (n = 10) will be treated with CBT. The patients will be assessed with different outcome measures at pre-treatment, at the end of treatment, and at six months follow up. In addition, they will also be assessed weekly using various measures.

We aim in this study to (1) evaluate the accessibility and effectiveness of MCT and CBT in treating low self-esteem, (2) investigate the patterns of change and the mechanisms of action involved during treatment, and (3) examine the impact of meta-cognitions and neuropsychologial processes in the treatment response and any relapse prevention of low self-esteem.

STUDY ORGANISATION

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INTRODUCTION

Self-esteem reflects how people feel about themselves and is a multifaceted construct related to other psychological constructs such as self-image, self-concept, self-perception, self-confidence, self-acceptance, self-respect, and self-worth. Research suggests that self-esteem is related to psychological well-being and psychological problems (Sowislo &Orth, 2013). Healthy self-esteem has been described as holding a balanced view of oneself in which one recognizes and accepts human weaknesses and appreciates ones' strengths and good qualities (Fennell, 1997). Small, but significant, sex differences have been found, with lower levels of self-esteem among women (Kling et al., 1999). Findings from prospective studies suggest that self-esteem is relatively stable throughout life (Orth& Robins, 2014). It is generally believed that there are many benefits to having an accepting view of the self. It seems that high self-esteem is related to success and well-being in different areas of life such as relationships, work, and health (Orth & Robins, 2014), however directionality is debated.
Low self-esteem in adolescence, on the other hand, is associated with greater risk of mental health problems, substance dependence, and lower levels of life and relationship satisfaction in adulthood (Boden et al., 2008). However, the relationship between self-esteem and relevant outcomes (e.g., performance, interpersonal functioning, lifestyle, and happiness) is as mentioned not always straightforward (e.g., Baumeister et al., 2003).

The association between low self-esteem and psychiatric disorders (Zeigler-Hill, 2011) indicates that low self-esteem is an important transdiagnostic construct. The association between low self-esteem and symptoms of mental disorders may be bidirectional. A meta-analysis by Sowislo & Orth (2013) found that self-esteem predicted depression, whereas the direction was unclear for anxiety disorders. Self-esteem may represent a vulnerability to problems or disorders such as depression, social anxiety, eating disorder, and substance use (Vohs et al., 1999; Donnelly et al., 2008; Sowislo & Orth, 2013), but could also be the product of psychiatric disorders. Symptoms of depression for instance may reduce self-esteem in persons with mental disorders (Shahar & Davidson, 2003; Burwell and Shirk, 2006).

A prior study of the underlying mechanisms that predict self-esteem (Hagen et al., 2020) lends support to a metacognitive model to explain the relation between metacognitive processes and self-esteem. Results showed that metacognitive beliefs influence the degree of

brooding, which again is associated with low self-esteem. The current findings dovetail nicely with recent metacognitive approaches to understanding self-esteem by Kolubinski et al. (2019). Together these studies suggest that rumination, self-esteem, and depression are closely linked (Hagen et al., 2020; Kolubinski et al., 2016), and that rumination mediates the prospective effect of low self-esteem on depression (Kuster et al, 2012). Rumination is a perseverative coping strategy in response to negative automatic thoughts. It typically consists of repeatedly contemplating past mistakes, one's own shortcomings, negative mood, and pessimistic thoughts about the future (Wells, 2009).

Low self-esteem has previously been conceptualized based on the cognitive model proposed by Fennell (1997), where core schemas and automatic thoughts maintain a low self-esteem. Cognitive-behavioral therapy (CBT) interventions are aimed at cognitive restructuring in order to modify schemas about oneself and self-critical thoughts. CBT based on the cognitive model proposed by Fennell (1997) has shown promising results (Kolubinski et al., 2018). However, there are few clinical trials that have examined increasing low self-esteem, and only three have used a randomized controlled design (Brown et al., 2004; Waite et al., 2012; McElhinney et al., 2016).

The results of Hagen et al (2020) are potentially relevant for new clinical interventions in treating low self-esteem. Metacognitive therapy (MCT; Wells, 2009) based on the S-REF model, represent a different treatment approach. In this approach, low self-esteem is conceptualized as being maintained by rumination, worry and unhelpful coping strategies. These strategies are driven by metacognitions, and treatment seeks to challenge and change these metacognitions and to reduce rumination, worry and unhelpful coping strategies (Wells, 2009). If treatment is successful, it would create more adaptable styles to encounter negative thoughts and emotions and thereby reduce low self-esteem (Fahramand, 2014).

A meta-analysis by Normann & Morina (2018) showed that for depression and anxiety disorders, MCT had a better treatment outcome compared to CBT, and it would therefore be of interest to explore if these results are repeated when treating low self-esteem.

To sum up; there are a limited number of clinical studies on psychological treatment for low-self-esteem, and existing treatments given are largely based on cognitive therapy. Because both metacognitions and perseverant thinking could play a prominent role in low self-esteem,

a therapy such as MCT could be a promising new approach to treat such problems. To our knowledge no studies have so far examined the effectiveness of MCT in treating low self-esteem,or compared the effect of this treatment approach to the more established CBT model.

AIMS OF THE STUDY

The purpose of this pilot trial is to investigate the efficacy of MCT may be beneficial in treating low self-esteem, in comparison with CBT, which has some support as an intervention for low self-esteem. The outcome of this pilot trial is also specifically intended to inform the planning of any future randomized controlled studies.

RESEARCH QUESTIONS

Questions that will be addressed:

(1) Evaluate the accessibility and effectiveness of MCT and CBT in treating low self-esteem?
(2) Is change in metacognitions or cognitive content most predictive of treatment outcome?
(3) Is treatment change also associated with changes on neuropsychological measures?

STUDY DESIGN

We will use a multiple baseline single case design, involving 12 patients all of whom will either receive MCT or CBT and act as their own control. Such a design are recommended for preliminary evaluation of novel psychological interventions as they allow for examination of treatment-related changes within and between participants in small samples whilst allowing experimental control. Before commencing MCT or CBT, patients will complete baseline periods of three weeks, including three measurements. The baseline period will enable us to determine any possible effects of other factors such as history, maturation, statistical regression, or spontaneous remission, which may be responsible for symptom improvement. This design can increase confidence that any observable changes are likely to be attributable to the interventions. The therapy will take place at the out-patient clinic at the Department of

Psychology, NTNU, at the outpatient clinic at the Department of Psychology, UiO, at Metakognitiv Terapi Oslo and at Neeta Myrseth Parmar in Oslo.

ELIGIBLE CRITERIA

Inclusion criteria

Patients meeting all inclusion criteria listed below will be included in the study:

1. Signed written informed consent obtained prior to entry in the study.
2. Scores below 15 on the Rosenberg Self-esteem Scale (RSE)
3. 18 years or older.

Exclusion criteria

Patients presenting with any of the following will not be included in the study:

1. Psychosis
2. Bipolar type 1
3. Current suicide intent
4. PTSD
5. Cluster A or cluster B personality disorder
6. Substance dependence

MEASURES

A battery of measures will be administered at multiple baseline (pre-treatment), at post-treatment (at 8 weeks) and at six months follow-up. These measures include a combination of self-report instruments, neuropsycholoigal tests, and assessor administered ratings. All patients must sign a written consent for participating before they will be included. The instruments to be included are as follows:

Assessment of patients:

I. Symptom measures (self-report):

1. Rosenberg Self-esteem Scale (RSE; Rosenberg, 1965)
2. Robson Self-Concept Questionnaire (RSCQ; Robson, 1989).
3. Ruminative Response Scale (RRS; Nolem-Hoksema & Morrow, 1991)

4. Penn State Worry Questionnaire (PSWQ; Meyer, Miller, Metzger & Borkovec, 1990)
5. Metacognitions Questionnaire-30 (MCQ-30; Wells & Cartwright-Hatton, 2004)
6. Automatic Thoughts Questionnaire-8 (ATQ-8, Netemeyer et al, 2002)
7. Patient Health Questionnaire -9 (PHQ-9; Spitzer, Kroenke & Williams, 1999)
8. Generalized Anxiety Disorder-7 (GAD-7; Spitzer, Kroenke, Williams & Lowe; 2006)
9. Inventory for Interpersonal Problems (IPP-64, Horowitz et al, 1988)

II: Neuropsychological measures:

1. Behavior Rating Inventory of Executive Function – Adult Version (Roth et al, 2005)
2. CANTAB: Intra-Extra Dimensional Set Shift (CANTAB, 2009)
3. CANTAB: Spatial Working Memory (CANTAB, 2009)
4. CANTAB: Rapid Visual Information Processing (CANTAB, 2009)
5. CANTAB: One Touch Stockings of Cambridge (CANTAB, 2009)

THERAPISTS COMPETENCE AND SUPERVISION

The four therapists have received training and are licenced in either meta-cognitive therapy or cognitive behavioral therapy. The supervision of the therapists will take place biweekly, where the CBT group and metacognitive group will meet up to discuss their patients and supervise each other. All therapists will receive equal amount of collegial supervision and support during the study period.

TREATMENT

The meta-cognitive treatment program is based on Wells's metacognitive therapy (Wells, 2013). The patients receiving meta-cognitive therapy will be treated for 8 sessions, with weekly session of 45-60 minutes duration. A detailed description of the content of each MCT-session could be found in appendix A in the study protocol. The CBT is based on the treatment manual written by Fennell (1997). The patients receiving CBT will be treated for 8 sessions, with weekly session of 45-60 minutes duration. A detailed description of the content of each CBT- session could be found in appendix B in the study protocol.

TREATMENT CONDITIONS AND ADHERENCE

The treatment will be administered according to the originators published treatment manuals for MCT and CBT as described above under treatment. Using checklists session-by-session will ensure adherence of the therapy (see appendix A and B for a further description for this)

SCHEDULE OF ASSESSMENTS

See appendix C for a further description related to the schedule of assessments.

PROCEDURE

1. All patients referred to the study will be asked to fill out the Rosenberg Self-esteem Scale in order to participate in the trial. A RSE score below 15 will result in a further assessment in order to examine whether they fulfil the inclusion and exlusion criteria. If they fulfill these criteria the participants be asked to take place in the study.
2. Patients will be distributed to one of the two treatment conditions (MCT or CBT)
3. Patients will be asked to self-rate symptoms on a battery of self-report questionnaires three times before start of therapy (multiple baseline for three weeks).
4. Patients will be assessed at neuropsychological tests after the multiple baseline (before start of therapy).
5. Meta-cognitive therapy will be given to patients in group 1, while patients in group 2 will receive CBT.
6. The patients will be assessed prior to treatment, at post-treatment at 8 weeks, and at six months follow-up.

GENERAL CRITERIA FOR RECOVERY/IMPROVEMENT

The criteria for improvement and recovery will be estimated based on the primary outcome measure on RSE. Other outcome measures will include: Reduction of symptoms of anxiety and depression as measured by self-report questionnaires, in addition to a reduction in worry and rumination.

PRIMARY EFFICACY VARIABLES

The primary efficacy variables would be related to change in self-esteem at post-treatment and by six months follow-up.

SECONDARY EFFICACY VARIABLES

The secondary efficacy would be related to symptom measures of anxiety, depression, rumination, worry, metacognitions, cognitive content and interpersonal problems at post-treatment and by six months follow up.

ANALYSIS OF EFFICACY DATA

A comparison between the two groups of patients will be conducted at post-treatment and at six months follow up. The null hypothesis is assumed. A within group analyses will be conducted in order to estimate effect sizes and significant clinical change estimates.

DROP-OUT RATE

A treatment dropout will be defined as any patient receiving less than three sessions. If the patient withdraws from the trial with less than three sessions, he or she will be defined as a dropout patient and will not be included in the statistical analyses. Results from the study will be based on per protocol completers.

PATIENT POPULATION FOR ANALYSIS

The per protocol completed treatment patients (PP patients) consist of all patients who completed treatment or received at least six sessions as prescribed in the protocol.

TERMINATION OF THE STUDY AND PATIENT SAFETY

In accordance with the Helsinki Declaration, patients have the right to withdraw from the trial at any time for any reason. Additionally, any patient may be discontinued from the study at any time if the investigator feels it is in the best interest of the patient. Patients may be discontinued for the following reasons:

1. By request of the patients or investigator whether for health risks or other reasons.
2. By severe adverse experience that may place the patient at risk.
3. Severe non-compliance with therapy, protocol deviations or behaviour putting the patient himself at risk.
4. Intercurrent illness.

If the participants experience negative adverse effects under or after treatment (which is not expected), the therapist treating the patient would refer the participant for suitable psychological treatment.

VARIATIONS TO THE PROTOCOL

Variations or violations to the protocol are prohibited unless where the patient is in a situation of hazard. In case of deviations from protocol the nature and rationale for the deviation must be documented. The comment should be signed and dated by the investigator. The primary investigators (Roger Hagen and Leif Edward Ottesen Kennair) will decide whether the violation of the treatment condition disqualify the collected data.

COMPLIANCE WITH GOOD CLINICAL PRACTICE (GCP)

The study will be conducted in compliance with good clinical practice (GCP), including the recent version of the declaration of Helsinki (2000) and the laws and regulations of Norway.

CONFIDENTIALITY AND PATIENT DATA

All patient data collected for the purpose of the study should be handled by the investigator and his staff with precautions, to ensure the safe confidentiality of the patients and related data. Confidentiality of the patients is based on the laws and regulations by national health authorities and the declaration of Helsinki. The patients' confidentiality will be secured in any presentation of the study. The data and identity of the participant will be securely saved in a secure database at the University of Oslo (TSD), to Norwegian law and regulations. On request the national health regulatory authority will be granted access to the study patient's journal.

ETHICAL ASPECTS

The study will be conducted in accordance with the principles outlined in the "Helsinki declaration" (5th version, 2000). Patients will be informed and asked to sign a written consent before they participate in the study. It will be clearly stated for the patient that participation is absolutely voluntarily and confidential, and that the patient may withdraw from participation in the trial at whenever point he or she chooses.

APPROVAL FROM ETHICAL COMMITTEE

The study will be submitted for the Norwegian Ethical Committee (REK) and Norwegian Center for Research Data (NSD) in order to get approval from these before the study starts.

PUBLICATION AND DISSEMINATION OF THE RESULTS

Publications based on the data from this study proceed from the group headed by the primary investigators, with specification of the participating clinics and contacts. Authors of the publications will be those who actively participate in producing the protocol, compiling the results and writing the articles.

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Appendix A: Metacognitive therapy manual for low self esteem

Session 1

- Review CAS-1 and generate case formulation based on the generic model
- Socialize to the model
- Identify and label rumination and worry episodes (increase meta awareness)

. Introduce rationale of attention training.

- Practice attention training (use sounds in the room - 5 minutes)
- Homework: ATT practice in everyday settings

Session 2

- Review homework and CAS-1, especially related to rumination and worry time and beliefs related to uncontrollability
- Introduce and practice detached mindfulness
- Introduce rumination and worry postponement as an experiment to modify uncontrollability belief
- ATT practice
- Homework: ATT + form, apply DM to triggers, rumination and worry postponement.

Session 3

- Review homework and CAS-1, especially related to rumination and worry time and beliefs related to uncontrollability
- Identify triggers for rumination and worry and practice DM (compare active rumination to DM and postponed rumination in session)
- Challenge uncontrollability metacognitions (verbally and experientially)
- Explore unhelpful coping (avoidance and activity levels) and threat monitoring
- ATT practice

· Homework: ATT, apply DM to triggers, rumination and worry postponement, increase activity levels.

Session 4

· Review homework and CAS-1, especially related to rumination and worry time, beliefs related to uncontrollability, and unhelpful coping strategies

· Check that rumination and worry postponement and detached mindfulness is being applied to at least 75 % of the triggers, and that rumination and worry episodes last no longer than 2 minutes

· Challenge unhelpful coping and threat monitoring using experiments in the session

· ATT practice

· Homework: ATT, apply DM to triggers, rumination and worry postponement and ban unhelpful coping and threat monitoring + plan activities

Session 5

· Review homework and CAS-1, especially related to rumination and worry time, positive beliefs, and the use of unhelpful coping

· Check the DM is widely applied to triggers

· Challenge positive beliefs about rumination and worry and other CAS activities such as threat monitoring

· Review unhelpful coping and threat monitoring and suggest other way to cope with triggers

· ATT practice

· Homework: ATT, apply DM to triggers, rumination and worry postponement + plan activities

Session 6

· Review homework and CAS-1, especially related to rumination and worry time, positive beliefs, and the use of unhelpful coping

· Explore and challenge negative beliefs about feelings and low self esteem (danger/blocking beliefs)

· ATT practice, increased difficulty

· Homework: ATT, widen application of rumination and worry postponement, and reduce unhelpful coping and threat monitoring, maintain increased activity levels

Session 7

· Review homework and CAS-1, check for residual beliefs, unhelpful coping and threat monitoring

· Begin work on therapy blueprint

· Challenge residual beliefs

· Explore and challenge (?) fear of fallback

· ATT practice

· Homework: ATT, finish writing the therapy blueprint (Old plan/new plan), implement new plan

Session 8

· Review homework and CAS-1

· Finish the new plan & summarize therapy

. Challenge residual beliefs

· Discuss likely future triggers how the new plan should be implemented in the future

· Homework: Implement the new plan

Appendix B: Cognitive behavioural therapy for low self-esteem

Session 1

Review Rosenberg

Generate case formulation based on CBT-model for low self-esteem

Socialize to the model

Identifying anxious predictions and negative automatic thoughts

Identifying self-critical thoughts

Identifying the bottom line

Homework: Recognize trigger situations where anxious predictions (NAT) or self-critical thoughts appear.

Session 2

Review Rosenberg

Review homework

Testing anxious predictions:

Identifying trigger situations where anxious predictions (NAT) appear.

Questioning NAT through Cognitive diamond and ABCD-model

Formulating more realistic thoughts

Homework: Behavioral experiments addressing avoidance and safety seeking behaviors

Session 3

Review Rosenberg

Review homework

Working with self-criticism:

Identifying trigger situations where self-critical thoughts appear.

Questioning self-critical thoughts through cost-benefit analysis and ABCD-model

Formulating more realistic and kinder thoughts

Homework: Behavioral experiments treating oneself as if worthy of respect and affection

Session 4

Review Rosenberg

Review homework

Identifying and questioning cognitive distortions

Formulating more realistic thinking patterns.

Homework: Behavioral experiments questioning cognitive distortions

Session 5

Review Rosenberg

Review homework

Identifying and questioning rules of living

Formulating more realistic and helpful standards and rules

Homework: Behavioral experiments trying out a more realistic rules of living

Session 6

Review Rosenberg

Review homework

Directing attention to qualities, assets, strengths, skills

Homework: Gathering data to support new perspective

Session 7

Review Rosenberg

Review homework

Questioning the bottom line

Creating a new self-representation, a balanced view

Homework: Behavioral experiments trying out a balanced view

Session 8

Review Rosenberg

Review homework

Summarize therapy and formulate a new plan

Homework: Implement the new plan

Appendix C: Schedules of assessments

Week	Entry	BS1	BS 2	BS3 (Pre)	S1	S2	S3	S4	S5	S6	S7	S8	Post	6 m FU
Inclusion/exclusion criteria	X													
Informed consent)		X												
Socio-demographics		X												
RSE		X	X	X	X	X	X	X	X	X	X	X	X	X
RSCQ				X									X	X
RRS				X									X	X
PSWQ				X									X	X
MCQ-30				X									X	X
ATQ				X									X	X
PHQ-9		X	X	X	X	X	X	X	X	X	X	X	X	X
GAD 7		X	X	X	X	X	X	X	X	X	X	X	X	X
IIP-64				X									X	X
BRIEF				X									X	X
C-IED				X									X	X
C-SWM				X									X	X
C-SST				X									X	X

Note. Abbreviations: BS = Baseline, S= Session, Post= Post-treatment; FU= follow-up