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

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Statistical Analysis Plan for
Metacognitive Therapy or Cognitive Behavioral Therapy for Low Self-Esteem

In this study, patients with low self-esteem will be treated with metacognitive therapy (MCT) or cognitive behavioral therapy (CBT). The main aims are 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 design

This is a controlled trial with two parallel treatment arms: MCT (n = 10) and CBT (n = 10). Treatment consist of eight weeks of therapy. Participants will be assessed using multiple baseline measurements and follow-up points: baseline (three consecutive weeks prior to treatment start), post-treatment, and at six-month follow-up. In addition, some measures are conducted weekly throughout the treatment.

Outcome Measures

Primary Outcome

The Rosenberg Self-Esteem Scale (RSES) is measured before treatment (three baseline time points), during treatment (eight time points), post-treatment and at six-months. The primary outcome is change in RSES.

Secondary Outcomes

Generalized Anxiety Disorder-7 (GAD-7) and Patient Health Questionnaire-9 (PHQ-9), measured at the same time points as the primary outcome. The secondary outcomes are change in GAD-7 and PHQ-9.

Other Outcomes

In addition, we evaluate change in the following outcomes:

Questionnaires. The following questionnaires are conducted at baseline 3 (pre-treatment), post-treatment, and at 6 months follow-up: Repetitive Thinking Questionnaire (RSCQ), Ruminative Response Scale (RRS), Penn State Worry

Questionnaire (PSWQ) Meta-Cognitions Questionnaire-30 (MCQ-30), Automatic Thoughts Questionnaire (ATQ), Inventory of Interpersonal Problems-64 (IIP-64), and Behavior Rating Inventory of Executive Function (BRIEF).

Neuropsychological tests. Participants complete three tests from the Cambridge Neuropsychological Test Automated Battery at baseline 3 (pre-treatment), post-treatment, and at 6 months follow-up. The tests are Intra-Extra Dimensional Set Shift (IED), Spatial Working Memory (SWM), Rapid Visual Information Processing (RVP), and One Touch Stockings of Cambridge (OTS).

Statistical Analyses

Primary Analysis

A linear mixed model (LMM) is used to predict self-esteem. The model includes fixed effects for time, treatment, and their interaction, and random intercept and slope for participants. Fixed and interaction effects examines the overall changes and the differences between CBT and MCT. Random intercepts and slopes allow participants to start at different baseline self-esteem levels and follow unique trajectories. This approach improves accuracy over standard regression by modeling individual variation. The outcome variable was specified as follows: T0 = mean of baseline RSES; T2-9 = RSES at week 1-8 of treatment; T10 = RSES at post-treatment; T11 = RSES 6-month follow-up. We will conduct the analysis in R using the lme4 package with the following specifications: *rses ~ time* treatment + (1 + time | participant)*. Missing data are managed using restricted maximum likelihood, in line with an intention-to-treat approach. To compare MCT vs. CBT at each time point, estimated marginal means and effect sizes will be computed using the emmeans package in R. Per-protocol analyses are conducted for participants who completes at least six treatment sessions.

Secondary Analyses

We will use LMM to examine change in PHQ-9 (*phq-9 ~ time* treatment + (1 + time | participant)* and GAD-7 (*gad-7 ~ time* treatment + (1 + time | participant)*, with time points corresponding to the primary analysis.