Participant information & Consent

PARTICIPATION INFORMATION:

Meta-Cognitive Therapy Versus Cognitive Behavioural Therapy for Depression

You are hereby invited to participate in a scientific research trial at CEKTOS. Before you decide whether you would want to participate in the trial, you need to fully understand what the study is about and why we conduct this trial. We would therefore ask you to read this participant information thoroughly.

You will receive an invitation to an interview where the participant information will be thoroughly elaborated, and where you can ask any questions you may have. You are welcome to bring a family member, friend or an acquaintance for the interview.

If you decide to participate in the trial, we will ask you to sign a consent form. Remember that you are entitled to time of consideration before you decide whether to sign the statement.

We are working towards optimizing our treatment of depression. Psychotherapy as usual at CEKTOS include cognitive behavioural therapy which has proven effective in several Danish and international studies.

Cognitive therapy is primarily concerned with changing negative thoughts and beliefs in regard to one self, others and the world, using restructuring and Socratic dialogue, ie a special interview technique that intends to challenge the way of thinking. In addition, there are several behaviour-oriented methods working towards increasing the feeling of enjoyment and activity levels using homework tasks.

Meta-cognitive therapy is primarily concerned with changing and increases the clients meta-cognitive control using awareness training and *detached mindfulness*, i.e. the client learns to separate himself from his thoughts and minimize rumination and worry.

We would like to ask you if you want to participate in a study that intends to clarify which of the two forms of therapy that is best.

If you choose to participate in the trial, you will be invited to an initial interview and then randomly referred to the psychologist Pia Callesen to receive either traditional cognitive therapy or meta-cognitive therapy. All research participants will receive active treatment. You will be asked to fill in various questionnaires and participate in short interviews throughout the course of treatment, and 3 and 6 months after completion. This will take about 5-10 min. per. session and additionally 1.5 hr. before the course, after 6 sessions as well as 3 and 6 months after ended treatment. This is necessary to measure the impact of therapy and your learning outcome of the course. In addition, the session will be recorded on video. Both questionnaires and video will be handled with 100% confidentiality and kept safely locked away. The course of therapy will last up to 24 sessions. You may at any time and without reason withdraw your consent. There can always be the possibility of unpredictable risks and impacts associated with your participation in biomedical research, but this study does not include blood tests, pharmaceuticals and the like, and according to our experience, a possible risk will be extremely small.

Your participation in the trial may make it easier to determine which treatment will be the most appropriate to choose for future clients.

There shall be no remuneration for participation in the study, and we can not pay any transportation fees.

The person responsible for the study, Pia Callesen, is engaged in a self-funded doctorate, and this trial is part of the process. Pia Callesen has no independent economic interests in or the results of the study

If you have questions about the above please do not hesitate to contact the project manager Pia Callesen directly on tel. 22 68 42 81 or e-mail: pia.callesen@cektos.dk