

INFORMED CONSENT

Study Title: Efficacy of a Short-Term Emotion-Focused Therapy Intervention for Self-Criticism Compared with a Cognitive-Behavioral Gold Standard: A Randomized Controlled Trial

(original working title: “Emotions, Self-Criticism and Therapeutic Outcomes: Bridging the Gaps through an Emotion-Focused Therapy Approach”)

Ethics Approval:

Approved by the Ethics and Deontology Committee of the University of Maia on 18 June 2024 – Approval No. 214/2024

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INFORMED, FREE AND CLEAR CONSENT

[In accordance with the Declaration of Helsinki, the Oviedo Convention, and the General Data Protection Regulation of the European Union]

Please read the following information carefully. If you believe that anything is incorrect or unclear, do not hesitate to ask for further clarification. If you agree with the information provided below, please indicate your consent at the end of this document.

Study title:

Final Title: Efficacy of a Short-Term Emotion-Focused Therapy Intervention for Self-Criticism Compared With a Cognitive-Behavioral Gold Standard: A Randomized Controlled Trial

[Initial title: “Emotions, Self-Criticism and Therapeutic Outcomes: Bridging the Gaps through an Emotion-Focused Therapy Approach”]

Funding:

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Context:

The promoting institution of this study is the University of Maia, through its Psychotherapy Research Laboratory, affiliated with the Psychology Center of the University of Porto. The principal investigator responsible for this project and study is Professor João Salgado, PhD.

Study description and procedures:

Self-criticism is a form of negative self-treatment that often leads to a decrease in mental health and an increase in psychological distress. The main objective of this study is to comparatively evaluate the effectiveness of two brief individual interventions targeting self-criticism, through the application of two specific tasks: (1) two-chair dialogue and (2) cognitive restructuring. Specifically, the impact of each intervention on mental health and well-being levels will be assessed in an adult population with moderate to high levels of self-criticism.

Individuals interested in participating will be asked to complete an initial set of questionnaires to determine whether they meet the eligibility criteria for inclusion in

the study. Participants who do not meet the criteria will be duly informed of their ineligibility and will receive an email explaining the reasons for exclusion. If exclusion is due to a situation considered to involve increased mental health risk, the participant will be contacted and provided with alternative referral options. At any time, participants may contact the research team for clarification of any questions.

After the initial screening, each selected participant will be randomly assigned to one of two approaches, on the basis of which six psychological support sessions will be conducted: (1) Emotion-Focused Therapy or (2) Cognitive-Behavioral Therapy. All participants will be invited to attend the scheduled intervention sessions, which will be conducted online. The intervention consists of six weekly individual sessions, led by psychologists with specific training in each approach, with an approximate duration of 60 minutes per session. Before each session, a few minutes will be allocated to completing brief online questionnaires. Follow-up assessments will be conducted one week, one month, and three months after the end of the intervention to monitor therapeutic gains, using a new set of questionnaires at each time point. Both assessment moments and intervention sessions will take place online.

Data collection, storage, and protection:

When a participant expresses willingness to take part in the study, an alphanumeric code is assigned to ensure data confidentiality. This code will serve as the participant's identifier and will be known only to the contact management officer and the principal investigator. It will be securely stored at the Psychotherapy Research Laboratory of the University of Maia. All other data collected will be stored as follows, with access restricted to the research team:

- Questionnaire responses and the alphanumeric code will be stored in one database, while sociodemographic data will be stored in a separate database.
- The databases will be encrypted and stored in a secure cloud environment, following security protocols guaranteed by the IT services of the University of Maia / Maiêutica.
- Access to the database containing sociodemographic data will be password-protected and limited to the Principal Investigator and the person responsible for contact management, thus protecting participants' identities while ensuring that data destruction can be carried out if requested.
- After appropriate data cleaning, anonymized databases containing no identifying information (e.g., email, age, sex, profession) may be made available to the scientific community. Identifying information will be securely

stored until the conclusion of the study and will be destroyed after the end of the research if so requested.

Confidentiality:

This study guarantees the confidentiality of the information provided and the protection of participants' identities. The collected data will be used solely for research, supervision, and training purposes within the scope of this study, unless the participant also authorizes its use in other contexts. Only the researchers involved in this study will have access to questionnaire data and intervention sessions. Confidentiality may be exceptionally breached during the assessment phase and/or treatment if a situation of risk to the participant or others is identified, namely in cases of high risk of harm to oneself or others. Such situations will always be discussed and managed in collaboration with the participants.

Confidentiality and session recording:

Psychological support sessions will be audio- and video-recorded by the psychologist responsible for each intervention within the research team. Video data will be processed in an anonymized manner, meaning that no personal identifying information will be disclosed, and no information will be shared without the participant's explicit authorization. All video data collected will be destroyed after analysis, unless the participant authorizes its use for further analyses.

Right to withdraw:

Participation in this study is entirely voluntary. All participants have the right to withdraw or discontinue their participation at any time, without any negative consequences.

Right to object:

Participants may, at any time, exercise their right to object (i.e., withdraw consent for data collection and use) and/or request the destruction of their data.

Other rights:

After completion of the project, and upon request, participants may be provided with a summary of the main study findings. Any participant has the right to lodge a complaint with the Portuguese Data Protection Authority (Comissão Nacional de Proteção de Dados) if they believe that their data have not been properly handled.

Acknowledgements:

On behalf of the entire research team, we thank you in advance for reading this document and, should you decide to participate, we sincerely appreciate your

contribution to advancing knowledge in the field of well-being and mental health promotion.

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