

**Effects of an ACT-based Psychological Treatment in Patients with
Chronic Kidney Disease**

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Study Protocol and Statistical Analysis Plan

Study Protocol:

- Objective: To study the effectiveness of an intervention based on Acceptance and Commitment Therapy (ACT), applied in CKD patients with high levels of depressive symptomatology.
- Design: randomized clinical trial
- Methods:
After being informed about the study, all CKD patients giving written informed consent will be assessed to determine eligibility for study entry. Patients who meet eligibility requirements will be assessed through a structured interview and standardized questionnaires and randomly assigned to two conditions, intervention group and control group (waiting list).

Participants assigned intervention group will immediately receive psychological intervention consisting in an 8-session individual face to-face ACT-based treatment. The participants will be assessed through self-report instruments before and after treatment and at 3 months follow-up.

Patients assigned to control group condition will remain on the waiting list and will receive the intervention after 5 months.

- Intervention protocol

Session 1: Introducing therapy, establishing the therapeutic alliance, reframing the problem. Introducing values clarification. Therapeutic methods. Therapeutic methods: metaphor of the two climbers, functional analysis.

Session 2: Values clarification, commitment to action. Therapeutic methods: garden metaphor, funeral exercise.

Session 3: Discriminating control as a problem, introducing acceptance, commitment to action. Therapeutic methods: metaphor of contemplating the waves from the beach, introduction to defusion training.

Session 4: Awareness of body sensations, exposure to anxiety, depressive mood and other emotional barriers. Therapeutic methods: Defusion training (body scan, emotional monitoring, valuable actions in presence of emotion/physical sensations).

Session 5. Learning to observe thoughts as thoughts. Acceptance. Therapeutic methods: leaves on a stream exercise, mindfulness.

Session 6. Acceptance as choice. Therapeutic methods: defusion training, invitation to choose acting in the presence of emotions, thoughts or physical sensations.

Session 7. Establishing the perspective of the "self as a context". Therapeutic methods: exercise of the three circles of the self, chessboard metaphor.

Session 8. Relapse prevention. Therapeutic methods: metaphor of falling off the bike, mindfulness.

Statistical Analysis Plan (SAP):

The results will be analysed through non-parametric techniques (comparisons of pre, post and follow-up group means). An analysis of variance will be performed to determine the specific weight of each independent variable, as well as the possible interaction between them. The statistical approach of Jacobson and Truax (1991) will be used to estimate the clinical significance of the effect.