

Effectiveness of a Group Intervention Based on Acceptance and Commitment Therapy to Address Problematic Chemsex Through a Randomized Clinical Trial (ChemACT)

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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 patients with problematic sexualized use of drugs with high levels of hypersexuality.
- Design: randomized clinical trial
- Methods:

After being informed about the study, all 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 group on line 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: metaphor "the gym of the mind", metaphor "the garden" functional analysis, behavioral experiments.
- Session 2: Discriminating control as a problem, creative hopelessness, introducing acceptance, sustaining work on committed actions. Therapeutic methods: metaphor "the hungry tiger", exercise "don't think about...".
- Session 3: Values clarification, identifying barriers related to values work, promoting defusion and increasing awareness of private events (craving/urge discrimination training), commitment to action. Therapeutic methods: funeral exercise, defusion exercise: exposure to a complete sequence of an episode of 'out of control' behavior.
- Session 4: Working on barriers, promoting defusion with thoughts related to practicing chemsex (learning to observe thoughts as thoughts). Therapeutic methods: metaphor of "the street with shops", defusion exercise of "putting thoughts on billboards".

- Session 5. Acceptance as a choice. Therapeutic methods: metaphor of "the toll booth or choosing which train to take", defusion training, invitation to choose acting in the presence of emotions, thoughts or physical sensations.
- Session 6. Reinforcing creative hopelessness, establishing the perspective of the "self as a context". Therapeutic methods: metaphor "walking the path", exercise of the observing self.
- Session 7. Acceptance, exposure with response prevention to the most aversive private events. Therapeutic methods: exercise "choosing to pay the toll for a fuller life", invitation to choose acting in the presence of aversive private events.
- Session 8. Relapse prevention. Therapeutic methods: metaphor of "falling off the bike", imaginal exposure to potential situations that discriminate inflexible behavior.

Statistical Analysis Plan (SAP):

The demographic and clinical characteristics of the participants in each treatment group will be described, using measures of central tendency (mean, median) and dispersion (standard deviation, range). 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. A comparative analysis will be conducted between the treatment groups using appropriate statistical tests (Student's t-test or Wilcoxon signed-rank test for continuous data, or chi-square test for categorical data). The statistical approach of Jacobson and Truax (1991) will be used to estimate the clinical significance of the effect.