Official Title:
Group-Based Acceptance and Commitment Therapy Versus Active Control in University Students With Emotional Symptoms

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Study Protocol

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1. Official Title

Efficacy of a Group-Based Acceptance and Commitment Therapy Protocol Compared to an Active Control in University Students With Emotional Symptoms: a Randomized Controlled Trial With an Ideographic Approach.

2. Scientific Background and Rationale

Emotional disorders such as anxiety and depression are highly prevalent among university students, representing a major public health concern. These conditions frequently co-occur and share transdiagnostic processes, particularly repetitive negative thinking (RNT) and psychological inflexibility.

Acceptance and Commitment Therapy (ACT) is a process-based intervention that targets these mechanisms by promoting psychological flexibility. Evidence supports its efficacy across emotional disorders and student populations, particularly in group formats.

However, most clinical trials rely on retrospective self-report measures, which may fail to capture dynamic psychological change. Ecological Momentary Assessment (EMA) enables real-time, repeated measurement of symptoms and psychological processes, improving ecological validity and sensitivity to change.

To date, no randomized controlled trial has integrated:

- ➔ Group-based ACT
- ➔ An active control condition (non-directive therapy)
- ➔ Daily and weekly EMA in a university population in Latin America.

This study aims to address this gap and provide both clinical and methodological contributions.

3. Objectives

Primary Objective

To evaluate whether a group-based ACT intervention is more effective than a non-directive supportive therapy (NDT) in reducing emotional symptoms (depression and anxiety).

Secondary Objectives

1. To assess changes in:
    - Psychological flexibility
    - Repetitive negative thinking
    - Meaning in life
2. To examine trajectories of change using EMA (daily and weekly).
3. To compare the sensitivity of EMA versus traditional pre–post measures.

4. To explore participants' subjective experience of change.

4. Study Design

➔ Type: Randomized controlled trial
➔ Design: Parallel-group
➔ Allocation ratio: 1:1
➔ Blinding: Outcome assessors and data analysts blinded

5. Methods

5.1 Participants

University students aged 18–28 years will be recruited from universities in Montevideo, Uruguay.

Inclusion Criteria

- PHQ-9 ≥ 8 and/or GAD-7 ≥ 8
- Willingness to participate in group intervention and EMA assessment

Exclusion Criteria

➔ Current suicide risk
➔ Psychotic disorders
➔ Substance abuse
➔ Clinical conditions requiring immediate specialized care

5.2 Interventions

Experimental Group (ACT)

Participants will receive a manualized group-based ACT intervention:

➔ 5 weekly sessions
➔ 90 minutes per session
➔ Focus on:
- Acceptance
- Cognitive defusion
- Values clarification
- Committed action

Control Group (NDT)

Participants will receive a non-directive supportive group therapy:

➔ Same duration and format (5 weekly sessions - 90 minutes per session)
➔ Focus on:
- Empathy
- Emotional validation
- Active listening
➔ No structured therapeutic techniques

5.3 Outcomes

Primary Outcomes

➔ Change in emotional symptoms measured by the Patient Health Questionnaire-4 (PHQ-4)

Secondary Outcomes

➔ Change in psychological flexibility and inflexibility measured by the Flexible and Inflexible Behavior Questionnaire (CCFI)
➔ Change in repetitive negative thinking measured by the Repetitive Negative Thinking Questionnaire-3 (RNT-3)
➔ Change in anxiety symptoms measured by the Generalized Anxiety Disorder-7 (GAD-7 total score)
➔ Change in depressive symptoms measured by the Patient Health Questionnaire-9 (PHQ-9 total score)
➔ Change in sense of purpose in life measured by the Purpose in Life Test (PIL-Test total score)
➔ Perceived change and intervention acceptability

- Measures:

EMA Measures

➔ Daily: PHQ-4, CCFI, RNT-3
➔ Weekly: PHQ-4, CCFI, RNT-3

Pre-post-follow-up Measures:

➔ PHQ-9
➔ GARD-7
➔ PIL-Test

Qualitative Outcomes

➔ Post-intervention semi-structured interviews

5.4 Procedure

➔ Screening and baseline assessment (Week 1)

- ➔ Baseline EMA period (Weeks 2–5)
- ➔ Intervention phase (Weeks 6–10)
- ➔ Post-treatment assessment (Week 11)
- ➔ Follow-up assessments (Weeks 15 and 23)

EMA data will be collected continuously throughout the study using a mobile application.

5.5 Randomization

Participants will be randomly assigned (1:1) to ACT or NDT using a computer-generated random sequence.

6. Ethical Considerations and Amendments

This study has been submitted for approval to an institutional Human Subjects Protection Review Board.

All protocol amendments approved by the ethics committee prior to submission and applicable to all trial sites are incorporated into this protocol.

Any future modifications to:

- ➔ study design
- ➔ eligibility criteria
- ➔ outcomes
- ➔ analyses

will be:

1. Approved by the ethics committee before implementation
2. Documented with justification and date
3. Updated in the trial registry when applicable

Participant safety procedures include risk assessment for suicidality and referral protocols when necessary.

7. Data Management

All participant data will be de-identified and stored securely. Only the research team will have access to identifiable data. Data sharing will follow ethical and regulatory standards.