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

NCT:
CE2025/37

Informed Consent Form Main Experiment

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INFORMED CONSENT

Introduction

I, _____, have been invited to participate in the study entitled *"Efficacy of two group psychological interventions in university students with emotional symptoms: a randomized controlled trial with an idiographic approach."* This research is conducted by Mag. Mónica Larrosa from the University of Montevideo, under the supervision of Dr. Francisco J. Ruiz.

Purpose of the study

The purpose of this study is to evaluate the efficacy of two group-based psychological support programs, each consisting of 5 sessions, in university students presenting elevated emotional symptoms. Both programs are supported by prior empirical research. Participants will receive only one of them. Assignment to the program will be random. I understand that the information collected from my participation will be used exclusively for academic purposes.

Description of the procedure

This is a clinical research study involving two possible group interventions. The procedure includes the following phases:

1. Initial evaluation (online questionnaires on emotional symptoms and a brief sociodemographic questionnaire; eligibility will be determined based on responses).
2. Random assignment to one of the two group programs and installation of a mobile application to complete brief questionnaires.
3. Periodic assessments before, during, and after the intervention (participants will respond daily and weekly brief questions via their mobile phones for approximately 13 weeks).
4. Participation in the assigned group program (5 in-person sessions of approximately 90 minutes, once per week, led by psychologists trained in the corresponding approach).
5. Post-intervention and follow-up evaluations.

Some participants may be invited to a brief optional interview about their experience. Participation involves completing questionnaires and attending group sessions.

Use of collected data

I understand that the information collected from my participation will be used exclusively for academic purposes.

Compensation and benefits

Maintaining daily and weekly records over several weeks requires sustained effort. For this reason, a small compensation is planned for participation. The specific details will be clearly explained at the time of invitation and do not depend on the results obtained in the questionnaires, but rather on completing the scheduled assessments.

Additionally, after the study is completed, participants who wish to do so may be offered access to the other group program.

Risks and discomforts

Participation does not involve physical risks. However, some activities or questions may cause mild or temporary emotional discomfort when reflecting on personal experiences, both during assessments and group sessions. I may skip any question or withdraw at any time without providing a reason and without any negative consequences.

If responses indicate a high risk to my safety, a clinical safety protocol will be activated: a professional will contact me to assess the situation and guide me toward appropriate support services. This represents a necessary exception to confidentiality to protect my wellbeing.

Participation may also have positive effects, such as increased understanding of my emotional functioning or feeling more supported, although this cannot be guaranteed.

Confidentiality

I understand that any personal information included in the research results will be treated confidentially. I will be assigned a numeric code, and identifying data will be stored separately in a protected file accessible only to the principal investigator. Databases used for analysis will contain only coded data and will be stored in secure repositories with restricted access to the research team.

No publication will include my name unless I explicitly consent. Results will always be presented in aggregate form, without identifying information.

Because the intervention is conducted in a group format, all participants will be asked to commit to maintaining confidentiality regarding personal information shared during sessions.

This study complies with ethical and legal standards in Uruguay, including Law 18.331 on data protection, Decree 158/019, the University of Montevideo Code of Ethics, APA guidelines, and the Declaration of Helsinki.

Voluntary participation

Participation in this study is completely voluntary. I understand that I may withdraw my consent at any time without justification and without any academic or personal consequences. If I withdraw, I may request that my data not be used, unless they have already been included in aggregated analyses that cannot be modified.

Information

For further information about this study, I may contact the principal investigator:

Mag. Mónica Larrosa
Email: m.larrosa@um.edu.uy

I will receive a copy of this consent form for my records.

Consent

I voluntarily agree to participate in this study.

Participant signature: _____

Researcher signature: _____

Date: ____ / ____ / _____