

# Evaluating the dissemination of evidence-based practices in substance use treatment: A cluster-randomized clinical trial of Colombo Plan's Innovative professional training model<sup>☆</sup>

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## ABSTRACT

The training of professionals who work in the treatment of substance use disorders is a fundamental aspect for the dissemination of evidence-based practices that ensure the quality of the treatment delivered to patients. Colombo Plan has developed a training model that allows effective, rapid, and scalable dissemination. However, this model does not have an empirical evaluation of its results to date. This project seeks to evaluate the dissemination model through a cluster-randomized clinical trial with a parallel superiority design, in which 27 treatment centers will be randomly assigned to training + action plan and technical advice, training only, or control without training, action plan or advice. The results of this study will inform public policy regarding substance use treatment at the national level and will help improve efforts by Colombo Plan at dissemination of evidence-based practices.

Substance use and substance use disorders (SUD) are associated with a series of negative consequences on physical and psychological health, as well as on a social and economic level. Approximately 296 million people (5.8 per cent of the global population aged 15–64) have used a drug in the last 12 months ([1]). Moreover, it has been estimated that SUDs account for about 1 % of the global burden of disease, although this is probably an underestimate [2]Rehm et al., 2015. A recent review of the epidemiological literature showed that the prevalence of binge drinking in the past 30 days was 18.4 % globally, whereas the prevalence of illicit drug use in the past year ranged from 0.35 % to 3.8 %. Additionally, disability-adjusted life years attributable to use were estimated at 85 million for alcohol and 27.8 million for illicit drugs worldwide [3]. Epidemiological data have also shown that levels of substance use tend to increase from early adolescence to a peak in early adulthood [4] Vergés et al., 2012; [5], with 15 % of cases of alcohol use disorder (AUD) already starting at age 18 [6] Glantz et al., 2020, so early diagnosis and treatment is crucial to reduce this burden of disease.

These indicators point to a serious public health problem, which must be addressed through a comprehensive strategy based on evidence that encompasses different levels, among which is the treatment of

people with problems associated with substance use. Treatment for SUDs has had remarkable growth in recent decades, with substantial advances in the knowledge of the factors that affect a good therapeutic outcome (e.g., Ref. [7]), as well as in the development of evidence-based interventions (e.g., Ref. [8–11]) that provide professionals with a broad set of effective therapeutic tools for work with their patients.

However, research has also shown that most of the time people accessing treatment do not receive evidence-based interventions [12, 13]. This is due to multiple reasons, including the lack of resources available in treatment centers, the lack of time to be able to implement an adequate intervention, and biases of therapists regarding the application of evidence-based therapies [14]. Nevertheless, one of the factors that certainly plays a fundamental role in this problem is the lack of access that professionals have to quality training in evidence-based interventions [15]. Given the cost and unavailability of such training, only a smaller percentage of professionals have the necessary competencies to deliver quality treatment, making it very difficult to build a network of treatment services that ensures quality throughout the territory, which represents a great challenge for public policy. This issue is particularly relevant in Latin American countries, where the diversity of

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treatment centers and contextual factors increases the inequalities in delivered services.

In this context, Colombo Plan, an international organization aimed at social development, through its Drug Advisory Programme, has generated the Universal Treatment Curriculum (UTC) designed to efficiently, massively, and rapidly transferring the most recent evidence on the treatment of SUDs. This model of dissemination involves the training of experts at the national level so that they are able to carry out the training of teams at the local level in physiology and pharmacology, treatment for SUDs, coexisting medical and mental disorders, basic counseling skills, intake, screening, assessment, treatment planning, case management, crisis intervention, and ethical considerations for addiction professionals.

The curriculum was developed by experts worldwide and has been translated into various languages, adapting to the cultural realities of different regions of the world, including Latin America. For rapid dissemination, it has adopted a training-of-trainers strategy, allowing experts at the local level to transfer the knowledge acquired in the territory in which they work. In addition, evaluation instruments have been developed that allow monitoring the learning of professionals who participate in the training. More recently, the training has been enhanced through a technical advice process involving separate meetings with each center and group meetings based on territorial proximity. The technical advice aims at helping professionals to implement their new skills within the particular context of their treatment centers, considering the available resources, and addressing implementation barriers. This component is thus capable of dealing with the previously mentioned diversity of realities faced by Latin American treatment centers.

However, even though the dissemination work through this curriculum has been developed for years, to date there is no empirical evaluation going beyond the learning of professionals and allowing for verification of the implementation of the acquired knowledge in their clinical practice. Moreover, the effect of the technical advice over and above the professional training needs to be tested to determine whether resources invested in this process are justified. Finally, the impact of training professionals is expected to be reflected not only in their clinical practice but also as improvements in the overall quality of the treatment centers and the clinical outcomes experienced by the patients.

## 1. Methods

The aim of the current protocol (preregistered in <https://osf.io/qkc3s>) is to evaluate the impact of a dissemination model of evidence-based practices for the treatment of SUDs through the training of professionals.

We have the following specific aims.

1. To assess the effectiveness of the dissemination model in improving therapists' knowledge of evidence-based techniques and their implementation in therapists' clinical practices.
2. To assess the impact of the dissemination model on the clinical outcomes experienced by the people served.
3. To evaluate the mediating effect of the change in knowledge and clinical practices of therapists on the association between the intervention and the clinical results of the people attended.
4. To evaluate the effect of adding an action plan and technical advice to the training delivered.
5. To evaluate the effectiveness of the dissemination model in improving the quality of treatment services at the level of treatment centers.

## 2. Design

The study involves a cluster-randomized clinical trial with a parallel superiority design, in which the treatment services (27 centers) will be

randomly selected (with replacement in case they do not complete the baseline data collection process) from a population of centers in the departments of Antioquia and Valle del Cauca, as well as the Capital District of Bogotá in Colombia and will be randomly assigned to three possible conditions, according to the scheme shown in Fig. 1.

Thus, 9 health services for the treatment of people who consume psychoactive substances will be assigned to the training condition + action plan and technical advice, 9 health services will be assigned to the training condition (where an action plan will not be implemented in order to assess the sufficiency of the training alone) and 9 health services will be assigned to the control condition without training (where the training will be delivered after the follow-up evaluation, so that it will not have any effect in study results).

The random assignment by cluster, in this case at the level of the health services, was selected for practical reasons, as well as to avoid contamination between treatment conditions within the same center. The random assignment allows us to infer that the changes observed in the quality of treatment services, knowledge and clinical practices of the therapists, and clinical results in the people attended, are actually due to training (and technical advice) and not to other contextual variables that may influence the treatment processes.

First, we hypothesize that the therapists from health services in the training + action plan and technical advice condition will present a greater knowledge of evidence-based techniques and better implementation of these techniques throughout time than the therapists in the training-only condition, who in turn will present better indicators than the therapists in the control condition without training. Second, we hypothesize that the quality of treatment services will be improved in centers assigned to training + action plan and technical advice condition compared to centers in the training-only condition, which in turn will be better than those in the control condition. Third, we hypothesize that the consumption and functioning trajectories of patients attended will be better in the centers assigned to the training + action plan and technical advice condition, compared to patients attended to in health services assigned to the training-only condition, which in turn will present better trajectories than the patients in health services assigned to the control condition without training. Finally, we hypothesize that the differences in clinical results observed in patients treated in the three conditions will be mediated by differences between the therapists in relation to their knowledge and implementation of evidence-based techniques.

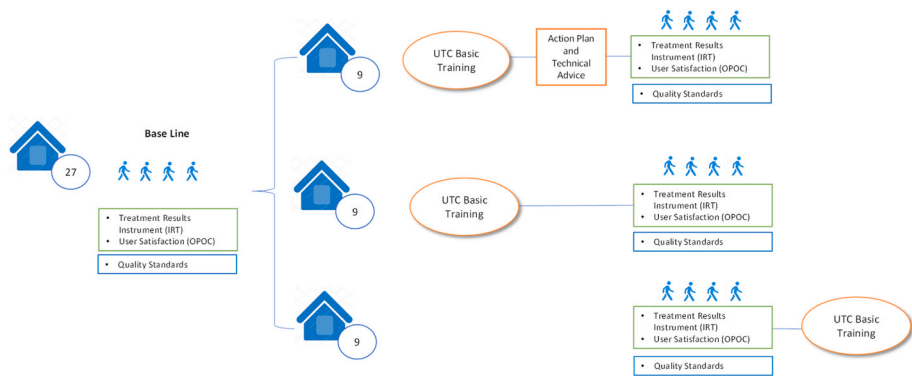
### 2.1. Variables

We developed a multi-level measurement strategy that includes three units of analysis related to the improvement of 1) health service processes for people with psychoactive substance use (treatment center level, where randomization will be performed), 2) therapists' knowledge and clinical practice (level of professionals, nested within treatment centers), and 3) health and quality of life in the people attended (level of patients, nested within professionals).

**Training.** The Universal Treatment Curriculum (UTC) in its basic component is made up of 8 courses, developed by experts in the field, that aim to improve the knowledge, skills, and competencies of the participants, as well as promote evidence-based practice to improve the provision of services and treatment outcomes.

The training will be provided in face-to-face mode (with the possibility of hybrid training) with a duration of 5 months. Each UTC course will be taught by a pair of national trainers who will be trained and certified by Colombo Plan. The courses have been designed to favor the voluntary participation of the professionals, incorporating measures that help to maintain the workflow of both the therapists and the treatment services (e.g., facilities for hybrid execution of the courses, spaced and non-intensive courses that prevent people from being away from their workplaces for long periods). Table 1 briefly describes the contents of each course.

As mentioned in the Introduction, the UTC is culturally adapted. To



**Fig. 1.** Schematic presentation of the study design. 27 centers will be randomly assigned to study conditions.

**Table 1**  
Universal treatment curriculum.

Course Title	Description
1. Physiology and Pharmacology for Professionals	Aimed at understanding the physiology of addiction as a brain disease; it describes the pharmacology of psychoactive substances.
2. Treatment for Substance Use Disorders: Continuing Care for Addiction Professionals	Aimed at providing a conceptual basis on the organization of services necessary for the treatment of substance use disorders. Provides an overview of recovery and recovery management, stages of change, principles of effective treatment, treatment components, and evidence-based practices.
3. Common Co-Occurring Mental and Medical Disorders: An Overview for Addiction Professionals	Aimed at providing an overview of the relationship between co-occurring mental and medical disorders and treatment problems related to substance use disorders.
4. Basic Counseling Skills for Addiction Professionals	Aimed at providing an overview of the helping relationship and provides opportunities to practice basic counseling skills including skills in motivational interviewing, group counseling, and implementation of psychoeducation sessions.
5. Intake, Screening, Assessment, Treatment Planning, and Documentation for Addiction Professionals	Aimed at developing skills on how to conduct intake, screening, and assessment processes, treatment planning, and documentation.
6. Case Management for Addiction Professionals	Oriented to provide an overview of case management with substance use disorders and provides the opportunity to practice skills required for case management.
7. Crisis Intervention for Addiction Professionals	Oriented towards understanding the concept of crisis as part of life and provides guidelines for intervention, including suicide risk management. It also addresses ways counselors can avoid personal crisis situations, providing counselor self-care information and exercises.
8. Ethics for Addiction Professionals	Aimed at addressing professional conduct and ethical behavior in the treatment of substance use disorders that covers confidentiality, ethical principles, and professional codes of ethics. It also covers the importance of supervision as part of ethical practice. Participants also have the opportunity to learn and practice using an ethical decision-making model through case study analysis.

ensure a culturally sensitive and relevant training process, we will employ the following strategies: a) Incorporation of trainers with specific cultural knowledge (the trainers responsible for implementing the UTC will be professionals with validated experience in treating people with SUD in Colombia); b) Contextual preparation prior to training (before training, the coordinating team and trainers will meet with local government professionals to understand the political and health context of the country; and c) Adaptation of terminology and content (to maximize effectiveness, we will avoid the use of technical terminology, idioms or cultural references that may be unknown or misinterpreted by participants, and trainers will be required to use examples adapted to the local context and accessible language).

**Action Plan and Technical Advice.** Treatment centers for people who consume psychoactive substances in the training condition + action plan and technical advice will receive support for the implementation of evidence-based clinical practices in the context in which they operate, considering both the physical and human resources available.

Implementation of this action plan will be monitored through a technical advisory process with periodic meetings in which the implementation barriers that arise in each treatment center will be addressed. The process will include both individual meetings with each center, and extended meetings with the treatment centers grouped by territory. It will be carried out by an expert in implementation sciences and evidence-based treatment interventions, and its design will be flexible by recognizing the unique reality of each health service participating in the study.

## 2.2. Population and sample

Given the multi-level measurement strategy, the population included will be professionals of each treatment center and patients receiving treatment, with prior informed consent.

The inclusion criteria for treatment centers will be.

- Treatment centers with authorization from the national health agencies to provide treatment for SUDs.
- Treatment centers with professionals who are certified to provide treatment for people with psychoactive substance use.
- Treatment centers with at least three professionals interested in receiving training.
- Treatment centers that perform at least five patient admissions per month, on average.
- Treatment centers that accept and sign the commitment letter to participate in the study.

The exclusion criteria for treatment centers will be.

- Treatment centers that do not have an internet connection as part of their infrastructure.

- Treatment centers that do not serve adults (people 18 years or older).

The study sample will be comprised of 27 treatment centers selected through simple probabilistic sampling, among centers that meet inclusion criteria. Subsequently, 9 centers will be randomly assigned to the training condition + action plan and technical advice, 9 centers will be randomly assigned to the training-only condition, and 9 centers will be randomly assigned to the control condition without training.

The participation of approximately 108 health professionals is expected, with an average of 4 people for each treatment center who will be trained in the application of evaluation instruments and a minimum of 3 people to participate in UTC training, who can be the same or different from those in charge of the evaluation. The treatment teams will include professionals in medicine with or without specialization, professionals in nursing, psychology, social work, occupational therapy, and other specializations that allow for the treatment of people who consume psychoactive substances.

We estimate that at baseline at least 800 patients will enroll in the study, with a sample dropout rate of 20 % expected at 3 months and 40 % at 6 months. After training, we expect a similar number of participants and same dropout rates. All individuals admitted to treatment during a predetermined 7-month period will be invited to participate in the study. Therapists at each center will be in charge of evaluation of the respective inclusion criteria for treatment access.

We conducted a power analysis using Optimal Design. We estimate that, with 9 clusters per group and 4 professionals per cluster, we will be able to detect a large effect size ( $\delta = 0.8$ ), for the comparison of changes in knowledge and practices, assuming an ICC of 0.05–0.10, with 0.05 type I error, achieving 80 % statistical power. In addition, we estimate that, with 36 professionals per group and approximately 7 patients per professional, we will be able to detect a medium effect size ( $\delta = 0.5$ ), for the comparison of changes in clinical outcomes, assuming an ICC of 0.05–0.10, with 0.05 type I error, achieving 95 % statistical power.

### 2.3. Measures

Measurement instruments are organized according to the three units of analysis mentioned previously.

**Treatment Centers.** At baseline, information will be collected to characterize each center based on the following variables: authorization for their operation, location, modality (outpatient/residential), population served (adults/adolescents/both), inclusion criteria and severity of the population in treatment, administrative dependence (public/private), type of health service, years of operation, care capacity, number of admissions per month, number of sessions per patient, internet connection, human resources (number of professionals, type of professionals, average years of experience, average length of stay, type of training).

To evaluate the outcome variables, an evaluation of quality standards will be conducted, allowing to determine whether improvements are incorporated in the management and design of the treatment program, based on the training provided. This evaluation will be based on the application of the instrument Key Quality Standards for the appraisal of drug treatment services coordinated by UNODC and WHO [16], which will be adapted to the local context through a commission of national experts.

**Professionals.** Professionals at each center will be characterized based on the following variables: age, gender, training (career, years of study, academic degree, specific training in addictions), and experience (years of experience, years of experience in addictions, years of work in the center).

As mediating (or possibly moderating) variables, attitudes towards evidence-based practice (measured using the Spanish version of the Evidence Based Practice Attitude Scale; [17] Aarons et al. al., 2010 [18]) and Willingness to Change (measured through the TCU Organizational

Readiness for Change scale [19]) will be assessed.

The outcome variables at this level (and primary outcome variables of the study) will be the possible changes in knowledge and practices after the UTC training, which will be measured through a UTC Pre and Post Test Instrument (included in the training strategy in the UTC Curriculum). In addition, the incorporation of new therapeutic practices of the professionals of the services participating in the study will be measured through the application of a check list of practices contained in the UTC training.

**Patients.** People receiving treatment at each center will be characterized according to the following variables: age, gender, education, ethnic identity, type of referral, and number of previous treatments.

As dependent variables, the level of substance use will be measured through questions of frequency and quantity of use reported through the Instrument for Evaluation of Treatment Results (IRT). This was developed by a group of experts based on the TOP (Treatment Outcome Profile) instrument, developed by the National Agency for the Treatment of Substance Abuse of England (NTA). The IRT instrument was subjected to a piloting process in which 10 countries including Colombia participated, its linguistic adaptation was carried out and an application manual was created at the regional and local level. It evaluates the level of consumption of psychoactive substances, the state of mental and physical health, occupational situation, violation of the social norm, significant relationships, and satisfaction with life in the last 4 weeks.

In addition, the level of satisfaction with treatment will be evaluated through the Ontario Questionnaire on Perception of Mental Health and Addiction Care (OPOC-MHA), self-administered by patients at the end of the treatment or 3 months after starting treatment [20]. This instrument presents adequate psychometric properties in the population aged 12 years and over in treatment for the consumption of alcohol and other psychoactive substances. Specifically, the instrument has shown adequate factorial validity and internal consistency in each of its domains (Cronbach's  $\alpha > .7$ ) after its application in the reference population in the validation process carried out in Chile in 2017 [21] SENDA-MyDO, 2017.

Likewise, as a possible mediating variable, a variable related to the treatment plan received will be recorded, through a discharge form, at the time of treatment termination, measured as the percentage of weekly sessions in relation to those prescribed from the initial assessment.

Finally, as an additional dependent variable, the percentage of sufficient retention (patients who remain in treatment for at least 90 days), and the total percentage of dropouts and therapeutic discharges per therapist and per center will be recorded, a record that will be conducted by each center administrative staff.

### 2.4. Procedure

Prior to beginning of the study, a person from the research team in charge of monitoring and logistics will coordinate with each treatment center to examine their registration methods and standardize the procedure for collecting information so that it is not disruptive to the normal operation of the center. In addition, a 2-day face-to-face training workshop will be held in which information regarding the study will be delivered and the participants will be trained in conducting the interviews, as well as in the characteristics and application strategy of each of the instruments involved.

To ensure data quality, constant monitoring will be carried out and feedback will be provided to each treatment center, including a bi-monthly report prepared by the field research team. Further, treatment centers will receive incentives for their participation and adequate implementation of data collection procedures, including access to professional training and official certification of their participation in the study.

Random assignment will be carried out using a computer-generated randomization sequence with a maximally tolerated imbalance of 3 using the big stick method. It is possible that, given the heterogeneity of



treatment centers, this process might need to take into account heterogeneity in the number of people attended, ratio of people attended per therapist, treatment modality (outpatient or residential), type of health service (public or private), among others. Thus, after selecting the final sample of centers that will participate in the study, the attributes with more variability and that could have the greatest impact on clinical results will be selected to be stratified across conditions.

We estimate that the time to obtain the baseline (before training) will be 13 months, a period that will make it possible to follow patients attended up to 6 months after entering treatment. This will allow for an intra-center comparison in addition to the inter-center comparison provided by the parallel design with control group.

The therapists at each center will not be blind to the treatment condition, but the patients attended will be blind because both the therapists and the administrative team will be instructed not to provide this information to the patients. At the end of the study, they will be asked if they knew what condition their treatment center had been assigned to.

Patients' assessments will begin at the time of admission to treatment and then three and six months after admission, regardless of their status at the time (i.e., therapeutic discharge, abandonment, in treatment, other). Patients who are no longer in treatment will be contacted by the field research team to conduct the assessment and encourage continued participation in the study.

## 2.5. Statistical analyses

Using the data obtained during baseline, we will characterize the treatment centers, professionals, and patients, and estimate internal consistency using Cronbach's alpha and the Omega coefficient to verify the reliability of the measurement instruments and their adequacy for use in the Colombian population. As initial evidence of validity, the correlation between the variables will be estimated to establish if the association between them corresponds to what is theoretically expected.

Differences between the groups in variables at the level of treatment center, health professionals, and patients attended will be evaluated with ANOVA for continuous variables and chi-square for categorical variables. Variables with statistically significant differences will be included in the analyses as covariates and possible moderators. Additionally, modality (outpatient/residential) and human resources of the centers, previous training and experience and attitudes towards evidence-based practice of professionals, and age, gender and education of the patients, will be tested as *a priori* moderators. To test the main hypotheses of the study (see the Design section), hierarchical linear models (HLM) will be estimated using Mplus v8.11 ([22] Muthén & Muthén, 2017). The analysis will include four levels: within-patients (level 1, which looks at change in patients over time), between-patients (level 2, through which the effect of the intervention on patients is examined), therapists (level 3, through which the effect of the intervention on therapists is examined) and treatment centers (level 4, which allows controlling for effects at the level of the treatment centers in which therapists are nested, given the diversity of treatment centers mentioned in the Introduction). The analysis makes it possible to estimate a change parameter across repeated measures, examining whether the change parameter differs by condition, controlling for covariates. HLM allows good handling of missing data (analyses will be performed to assess that Missing at Random assumptions are met) by considering all participants (including those who dropped out of the study) in the analyses. Therefore, these analyses will be performed according to the intention-to-treat principle. Moreover, HLM is suited to analyze different types of data, including binary, nominal, and ordinal outcomes [23], thus providing the flexibility needed for the analysis of the various outcomes mentioned in the Measures section. To determine if changes in the indicators of consumption of psychoactive substances and functioning of patients attended are mediated by the changes in knowledge and implementation at the level of the therapists, a

mediation analysis with bootstrapping will be carried out to estimate asymmetric confidence intervals. Given that this is a superiority design, one-tailed tests will be used.

The researcher in charge of statistical analyses will be blind to the treatment condition, since the database will code the groups numerically, without disclosing the meaning of this coding to the analyst.

## 3. Expected benefits

Regardless of the confirmation of study hypotheses, we expect that the current study will improve the coordination and experience-sharing among treatment centers and between them and national agencies. The study procedures will help centers to incorporate mechanisms for monitoring and measurement that can be sustained in time. Although the current study will not examine long-term effects of the training model, each center will be able to assess the sustainability of improvements over the years. Moreover, our instruments will provide a measurement framework that will serve as a foundation for each center to include new measures that are aligned to their future goals.

## CRedit authorship contribution statement

**Alvaro Vergés:** Writing – review & editing, Writing – original draft, Methodology, Conceptualization. **Rodrigo Portilla Huidobro:** Writing – review & editing, Project administration, Methodology, Funding acquisition, Conceptualization. **Marta Oliva:** Writing – review & editing, Resources, Project administration, Funding acquisition. **Víctor Landa:** Writing – review & editing, Project administration, Methodology, Investigation.

## Ethical considerations

In accordance with ethical and legal standards, the research team will carry out a reserved and protected handling of the data. Both therapists and patients will sign an informed consent, given that both will be considered as participants in the study. Researchers will emphasize that participation is voluntary and that participants may withdraw from the study at any time they wish, without their refusal to participate affecting their condition as workers (in the case of therapists) or their access to services (in the case of patients). The data collected will not include the names of the participants and only general demographic information will be gathered. The data will be stored on a cloud service in an encrypted folder. Therapists and center directors will be informed that comparative information will not be provided by therapist, since the objective of the study is not to evaluate the effectiveness of individual therapists. However, the overall results of the study will be shared with the centers, including interested therapists and patients.

## Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

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