

# A randomized controlled trial of a group-based mindfulness intervention, mentoring and services as usual for improving the behavioral, social and emotional outcomes of young adults on probation

<b>Submission date</b> 16/08/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/09/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 20/08/2021	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Mexico has experienced a significant increase in crime and violence in recent years, which has negatively affected the security and economic growth of the country, with a particularly detrimental effect on young people. Young people are the main perpetrators of violence; they are victims, aggressors and inheritors of the social and economic consequences of this scourge. In response to these dynamics, it is important to develop evidence-based prevention initiatives that effectively mitigate the criminal and violent behavior of young people previously incarcerated and currently on probation, who are responsible for a significant part of the violence in Mexico. This study focuses on the effects of mindfulness-based intervention and case management on improving the lives of young people who are on probation in Mexico. There is a growing body of evidence suggesting that interventions based on contemplative practices lead to a number of positive psychological outcomes, such as improved cognitive performance and emotional regulation, including changes in brain structure and activity. Mindfulness can be defined as an ability to focus attention on the present and without prejudice; in which, each thought, feeling or sensation is recognized and accepted as it is, without any elaboration. It implies a state of consciousness that incorporates self-awareness and attention with the main characteristic of being open, receptive and without prejudice. At present, there is a considerable body of studies that have identified favorable repercussions of mindfulness-based training on behavior. For example, it has been postulated that such approaches are associated with lower levels of anxiety, greater regulation of emotions, and more adaptive responses to stressful situations. Recently, some studies have proposed mindfulness as a method that can improve executive functioning. Mindfulness training can be a tool that improves inhibitory control and therefore contributes to better control of emotions. Moreover, it is postulated that the fundamental functions of a case manager are to assess client's needs, to develop a service plan, as well as the connection of the client with the appropriate services and the monitoring of the client's progress, in addition to defending the

client's needs can support young people to gain access to key education and occupational goals. As such, case management can also potentially support young people on probation and prevent recidivism.

However, we do not know the effects of mindfulness on key outcomes for young people on probation nor do we know the effects of case management plus mindfulness on these outcomes. This study is the first to evaluate these interventions for this population in Mexico.

**Who can participate?**

People between the ages of 15-29 years who are on probation in Mexico

**What does the study involve?**

This study involves being involved in either a mindfulness group or case management plus a mindfulness group for 10 weeks. Participants will also complete assessments before and after the intervention.

**What are the possible benefits and risks of participating?**

There may be direct benefits of participating. Participants may learn skills that have been shown to support emotions, cognitions and behavior. Participants may also advance their education and obtain meaningful employment. The risks are discomfort completing the assessments, as they ask about sensitive topics (e.g., substance use).

**Where is the study run from?**

New York University (USA)

**When is the study starting and how long is it expected to run for?**

February 2020 to August 2023

**Who is funding the study?**

United States Agency for International Development (USA)

**Who is the main contact?**

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## Contact information

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

ET032021-317

## Study information

**Scientific Title**

A randomized controlled trial comparing the effects of mindfulness-alone compared to mindfulness plus case management on cognitive, emotional and behavioral outcomes of young people in conflict with the law

**Study objectives**

1. The mindfulness training program improves cognitive, emotional, and behavioral outcomes.
2. The case management program together with mindfulness training has a greater effect on improving cognitive, emotional, and behavioral outcomes compared to mindfulness training alone.
3. Young people who do not receive any type of support or accompaniment do not improve on cognitive, emotional, and behavioral outcomes.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 10/05/2021, Universidad De Guadalajara Centro Universitario De Ciencias Biológicas Y Agropecuarias Instituto De Neurociencias Comité De Ética (Francisco de Quevedo 180 Colonia Arcos de Vallarta C.P. 44130. Guadalajara, Jalisco, México; +52 (0)1 33 3777 1150 Ext. 33350; +52 (0)1 33 3818 0740; ineuro@cencar.udg.mx), ref: ET032021-317

**Study design**

Randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Community

**Study type(s)**

Prevention

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Lack of impulse control among youth in conflict with the law that may lead to impulsive behavior and the commitment of criminal and administrative offenses

**Interventions**

This is a randomized controlled design of two interventions (mindfulness-alone and mindfulness plus case management). A third group (control group) will be identified through local referrals and will be used for comparison. Allocation to the experimental groups will be done on a 1:1 basis via predetermined assignment based on a random number sequence.

**1. Mindfulness training:**

A group-based, 10-session intervention consisting of didactics, modeling, and role-plays to develop mindfulness. Homework is assigned between sessions for the implementation of skills. Young people in conflict with the law receive group training in mindfulness (Free Mind Protocol of Mentte CEDAT).

**2. Case management + mindfulness training:**

Case management includes one-to-one supportive assistance to support educational and occupational attainment. Young people will receive an accompaniment and follow-up process bringing educational and work opportunities.

**3. Services as usual control condition:**

Young people in conflict with the law who are supervised by the justice system utilizing services as usual.

**Intervention Type**

Behavioural

**Primary outcome measure**

Impulse control measured using the Stroop and Stop Signal assessment at baseline and post-intervention (10 weeks)

**Secondary outcome measures**

1. Self-reported crime measured by self-report at post-intervention
2. Educational and occupational attainment measured by self-report at post-intervention
3. Aggression and anger measured by the anger-aggression toolbox self-report at post-intervention
4. Mindfulness measured by the Five Facet Mindfulness Questionnaire at post-intervention
5. Empathy measured by the Basic Empathy Scale and the Multidimensional Prosocial Behavior Scale at post-intervention
6. Self-efficacy measured by the General Perceived Efficacy Scale at post-intervention
7. Substance use measured by the DUDIT and AUDIT and post-intervention

**Overall study start date**

01/02/2020

**Completion date**

30/08/2023

## Eligibility

**Key inclusion criteria**

The participants come from two different origins depending on the assigned intervention condition:

1. 1,000 young people in conflict with the law from 27 municipalities in the states of Jalisco, Chihuahua and Nuevo León that are members of the Mentte CEDAT program
2. 100 young people in conflict with the law who are supervised by the justice system

**Participant type(s)**

Other

**Age group**

Mixed

**Sex**

Both

**Target number of participants**

1100

**Key exclusion criteria**

Does not meet the inclusion criteria

**Date of first enrolment**

01/09/2022

**Date of final enrolment**

01/05/2023

## Locations

**Countries of recruitment**

Mexico

**Study participating centre****Mentte CEDAT**

Placeres 1043, Colonia: Campo De Polo Chapalita  
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44500

## Sponsor information

**Organisation**

New York University

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**Sponsor type**

University/education

**Website**

<http://www.nyu.edu/>

**ROR**

<https://ror.org/0190ak572>

## Funder(s)

**Funder type**

Government

**Funder Name**

United States Agency for International Development

**Alternative Name(s)**

U.S. Agency for International Development, Agency for International Development, USAID

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United States of America

## Results and Publications

**Publication and dissemination plan**

1. The study protocol will be available - not yet finalized for submission
2. Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

01/05/2024

**Individual participant data (IPD) sharing plan**

This data is from a high-risk/sensitive/vulnerable population (young adults - including minors - who are on recent probation due to criminal conviction) and as such, all precautions are being taken to provide security to the data including limiting access. The researchers will be holding the data at Mentee CEDAT.

**IPD sharing plan summary**

Not expected to be made available