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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

Submission date	Recruitment status	[X] Prospectively registered
16/08/2021	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
07/09/2021	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
20/08/2021	Mental and Behavioural Disorders	[ ] 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?
1. Ruben David Castañeda Torres, ruben@mentte.org
2. Maria Esparza Lopez, maria@mentte.org

Contact information

Type(s)
Public

Contact name
Mr Ruben David Castañeda Torres

Contact details
Placeres 1043, Colonia: Campo De Polo Chapalita
Guadalajara
Mexico
44500
+52 (0)33 1525 7406
ruben@mentte.org

Type(s)

Public

Contact name
Miss Maria Esparza Lopez

Contact details
Placeres 1043, Colonia: Campo De Polo Chapalita
Guadalajara
Mexico
44500
+52 (0)33 1525 7406
maria@mentte.org

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Prevention

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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
Guadalajara
Mexico
44500

Sponsor information

Organisation
New York University

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

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