

Effectiveness of a school model for the integral prevention of risk behaviors: a cluster-randomised trial

Submission date 31/10/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/11/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/11/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Multiple component interventions have proved to reduce the severity or the development of risk factors that can lead to problems in childhood and adolescence. It has been found that school programs that involve families and the community are more effective than programs that target only the children. The main aim of this study is to assess the effectiveness of the simultaneous administration of two interventions, both aimed at the reduction of children problematic behavior, one through the enhancement of social skills among children, and the other through the improvement of the parenting skills of their caregivers. The second aim is to find out whether the effect of the interventions persists 3 and 7 months after the interventions.

Who participated?

Children, their caregivers and their teachers from four public primary school of Mexico City

What does the study involve?

Participating schools are randomly allocated to one of four interventions. The Huellitas intervention aims at the development of social skills in children and is administered by trained teachers. The CAPAS-Mx intervention focuses on the reduction of children's problematic behavior through the training of their caregiver's parenting skills. The simultaneous intervention (Huellitas-CAPAS-Mx) consists of the administration of both programs in the same school. The fourth school is put on a waiting list and receives both interventions 3 months after the interventions are finished in the other schools. Caregivers' parenting skills and their children's conduct behavior are social skills are assessed at the start of the study and 12, 24 and 36 weeks later.

What are the possible benefits of participating?

Caregivers have the opportunity to learn and practice different positive parenting strategies under the guidance of trained professionals. Children can benefit from learning new social skills that can improve their school and family interactions. Teachers are able to guide their students, reducing problems in the classroom. Caregivers, teachers and children can improve their mental health. The social benefit is high if actions are taken at critical stages of development.

Where is the study run from?

Ramon de la Fuente Muñiz National Institute of Psychiatry, México City (México)

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

November 2014 to February 2017

Who is funding the study?

The National Council for Science and Technology (CONACyT) (Mexico)

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

EP15016.0 (internal number)/Grant No.PDCPN-2014-248428 (sponsor number)

Study information

Scientific Title

A four-arm, cluster-randomised study to evaluate the effectiveness of a multicomponent intervention to prevent risk behaviors in Mexican students through the development of social skills in children and positive parenting in their caregivers

Study objectives

The multicomponent intervention will have a greater effect at reducing behavioral problems and increasing social skills in children and the positive parenting strategies of their caregivers vs. individual interventions.

The null hypothesis is that the multicomponent intervention will not have significant differences when compared with the individual interventions.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Ramón de la Fuente Muñiz National Institute of Psychiatry (Mexico), 30/03/2015, ref: EP15016.0

Study design

Randomized four-arm multisite controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Conduct disorders prevention

Interventions

The four participating schools were randomly assigned to four conditions:

1. Dejando Huellitas en tu vida (Huellitas) (Making trails in your life)/Huellitas): a social skills program for children, administered by supervised trained teachers in 12 weekly sessions (60 minutes each). The main topics are:
 - 1.1. Personal aspects of the child, such as expressing and respecting each other's emotions and opinions
 - 1.2. Prevention of abuse and maltreatment
 - 1.3. Their relationships in their school and family environments
 - 1.4. Equity, non-discrimination and self acceptance
2. Criando con Amor, Promoviendo Armonía y Superación en México (CAPAS-MX) (Raising Children with Love, Promoting Harmony and Self-Improvement/CAPAS-MX): a parenting intervention program to reduce children problematic behavior. Parents were trained by

supervised professionals in 12 weekly sessions (90 minutes each) in which caregivers learned:

- 2.1. Positive involvement
- 2.2. Promoting the development of new skills
- 2.3. Effective discipline
- 2.4. Monitoring
- 2.5. Problem solving

3. Huellitas-CAPAS-Mx: the simultaneous implementation of both interventions previously described

4. Control group: a waiting list group that took both interventions 3 months after the interventions were ended in the other experimental conditions.

The training of both teachers and caregivers was performed by professionals that supervised the fidelity of the interventions. Assessments were made prior and after the interventions. As for the experimental conditions, schools, participants, teaching staff and assessment supervisors, and the statistical analyst were blinded throughout the study, until the pre-test was completed. It all started with an assessment of the caregivers about their parenting skills and their children's conduct behavior. Then the kids were assessed about their social skills. They were measured at baseline and then three times again: 12, 24 and 36 weeks after randomization.

Intervention Type

Behavioural

Primary outcome measure

Children's problematic behavior, measured with the Child Behavior Checklist for Ages 6-18 (CBCL /6-18; Achenbach & Rescorla, 2001). A self-report questionnaire completed by caregivers.

Measured at baseline with three follow-up assessments: one post-treatment assessment at the end of the 12 weeks treatment phase, a first follow-up assessment at 24 weeks after randomization (Follow-Up 1) and a second follow-up (Follow-up 2) 36 weeks after randomization.

Secondary outcome measures

1. Children's social skills, measured with the Social Skills Questionnaire for Girls and Boys (Villatoro et al., 2011), which measures resistance to social pressure, assertiveness, autonomy, mediation, self acceptance, self image, bullying, tolerance to failure, consistency in activities, and persistence.
2. Parenting practices (Amador 2014): five different scales were used to inquire about positive involvement, promoting development of new skills, effective discipline, supervision, and problem solving

Measured at baseline with three follow-up assessments: one post-treatment assessment at the end of the 12 weeks treatment phase, a first follow-up assessment at 24 weeks after randomization (Follow-Up 1) and a second follow-up (Follow-up 2) 36 weeks after randomization.

Overall study start date

24/11/2014

Completion date

03/02/2017

Eligibility

Key inclusion criteria

For caregivers (parent or person who spends the most time taking care of the child):

1. At least 18 years old
2. Spend time with the child on a regular basis
3. Accept to participate
4. Complete the pre-test assessment

For children:

1. In 2nd, 4th or 5th grade of primary school
2. Have an authorization by the legal caregiver to participate in the study
3. Accept to participate
4. At least one of his/her caregivers accepts to participate in the study
5. Complete the pre-test assessment

Participant type(s)

Mixed

Age group

Mixed

Lower age limit

18 Years

Sex

Both

Target number of participants

378 in 4 clusters (n = 103, 110, 82, 83)

Key exclusion criteria

Does not meet the inclusion criteria

Date of first enrolment

01/12/2015

Date of final enrolment

26/01/2016

Locations

Countries of recruitment

Mexico

Study participating centre

Ramon de la Fuente Muñiz National Institute of Psychiatry

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Sponsor information

Organisation

National Council for Science and Technology (CONACYT) of Mexico, through the PDCPN-2014-248428 project

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Funder type

Government

Funder Name

Consejo Nacional de Ciencia y Tecnología

Alternative Name(s)

Consejo Nacional de Ciencia y Tecnología, National Council of Humanities, Sciences and Technologies, Mexican National Council of Science and Technology, National Council for Science and Technology (CONACyT), National Council of Science and Technology, Mexico, Conahcyt

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Mexico

Results and Publications

Publication and dissemination plan

Once the first paper is published the protocol and other information about the study will be available at <http://www.uade.inpsiquiatria.edu.mx/>

Expected publications:

1. Two original articles are going to be submitted to peer reviewed journals
2. Two bachelor's degree thesis
3. Three master's degree thesis
4. 5 posters at the Annual Reunion of Research at the National Institute of Psychiatry Ramón de la Fuente Muñiz
5. 2 posters at the Inter-American Psychology Conference
6. 1 oral presentation of the results at a prestigious scientific congress or academic meeting

Dissemination plan:

1. 1 scientific dissemination article
2. 5 dissemination videos in social media
3. 1 meeting with decision makers

Intention to publish date

02/02/2018

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date