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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

Registration date
22/11/2017

Overall study status
Completed

Last Edited
20/11/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomized four-arm multisite controlled trial

Study type(s)
Prevention

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(s)
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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Sex
All

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
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Sponsor information

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

ROR
https://ror.org/059ex5q34

Funder(s)

Funder type
Government

Funder Name
Consejo Nacional de Ciencia y Tecnología

Alternative Name(s)
Secretariat of Science, Humanities, Technology, and Innovation, SECIHTI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Mexico

Results and Publications

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