

Efficacy of a positive parental practices promotion program in families of Chilean pre-school children

Submission date 20/02/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/03/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/10/2018	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

It is generally considered that children's experiences can help to shape their development. There is a lot of evidence that suggests that early parenting interventions (programs) can significantly enhance parenting skills, as well as parent-child relationships and child wellbeing. A growing number of children show signs of behavioral problems at home and at school. Many studies have shown that this problem behavior in young children can get worse with age, and so it is important that behavioral problems are addressed early on to ensure healthy childhood development. Parenting interventions have been proven to be very successful at improving child behavior. The most effective of these programs are shown to teach parents how to stimulate and encourage good behaviour and appropriately deal with bad behaviors, while avoiding being overly punitive (inflicting punishment) and harsh. This study is looking at a new parenting intervention called the Day UdeC Program, which has been designed at the University of Concepción. The aim of this study is to test whether the Day UdeC Program can help to improve parenting practices and parent-child relationships.

Who can participate?

Families with pre-school age children (between 2 and 6) who attend educational centres in Concepcion, Chile.

What does the study involve?

Educational centres are randomly allocated to one of two groups. Parents/guardians of children who attend educational centres in the first group take part in the Day UdeC Program. This involves attending six, weekly sessions which last for around two hours. In these sessions, parents/guardians are taught skills to strengthen their relationship with their children and learn positive discipline strategies (helping the child to develop a conscience so that they behave properly in a loving and supportive way). Those in the second group do not take part in the Day UdeC Program during the study period, but are able to attend the program after all of the study assessments have been completed. At the start of the study and then again after the program ends (8-9 weeks), participants in both groups complete a number of questionnaires in order to test their parenting skills as well as their overall mood.

What are the possible benefits and risks of participating?

Participants may benefit from being able to improve their parenting skills. There are no risks involved with taking part in this study.

Where is the study run from?

Educational centers (public and subsidized schools, and centers from JUNJI and Integra Foundation) in Concepcion (Chile)

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

March 2015 to October 2016

Who is funding the study?

National Commission for Scientific and Technological Research FONDEF Program Ideas (Chile)

Who is the main contact?

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Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ID14I10058

Study information

Scientific Title

Assessment of a parenting practices promotion program focused on prevention and early intervention of behavioral problems in Chilean preschool children: a cluster randomized trial

Study objectives

1. Participants receiving the parental training program will present less frequency of inconsistent parental practices and less frequency of harsh and punitive practices than participants assigned to the control group
2. Participants receiving the parental training program will present more frequency of positive parental practices than participants assigned to the control group. They will also have higher satisfaction degrees with the parental role
3. Participants receiving the parental training program will show more frequency of positive interactions in the observational assessment of a ludic interaction with their child than participants assigned to the control group
4. Participants' children receiving the parental training program will present less frequency of externalized behavior than children's participants assigned to the control group
5. The lower frequency of externalized behavior in children of participants assigned to the experimental group will be mediated by the greater positive parental practices and the lower negative practices that participants assigned to that condition will present

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the University of Concepción, 01/06/2013

Study design

Multi-centre cluster randomised interventional 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

Parental practices

Interventions

Families who are interested in participating sign informed consent stating that they are willing to comply with the study assessments and workshops. A limit of invitations will be set in order to evaluate between 16 and 18 participants per center. The participating educational centres are then randomised to one of two groups.

Intervention group: Centers will receive the day to Day UdeC Program. The program is implemented in six, two hour sessions, and is delivered to the guardians of the child (mothers, fathers or other caregivers). Sessions take place weekly, with the exception is the sixth session which will be held fifteen days after the fifth session. The program also considers two sessions of 2 hours with the educational personnel from the centers. The first of them will be carried out before the beginning of the sessions including the families and the second one, at convenience. The duration of the whole application of the program is approximately two months. The program is designed to develop skills to strengthen the relationship with the children, create a stable and predictable media for them and implement positive discipline strategies.

Control group: Participants in this group do not receive the Day UdeC program during the study period. These participants are given access to the program after the follow up measures are collected.

Following the intervention period (8-9 weeks) participants in both groups are assessed in order to record frequency of inconsistent and punitive parental practices and the increase of positive parental practices using questionnaires.

Intervention Type

Behavioural

Primary outcome measure

Reduction of frequency of inconsistent and punitive parental practices and the increase of positive parental practices are measured using at Alabama's Questionnaire adapted to pre-schoolers CAP Pr-20 and from the List of Severe Discipline Practices at baseline and post-intervention (8-9 weeks).

Secondary outcome measures

1. Parental satisfaction is measured using at Parental Evaluation Scale post-intervention (8-9 weeks)
2. Reduction of depressive parental symptoms are measured using at depressive scale from Inventario de Problemas Conductuales y Socioemocionales post-intervention (8-9 weeks)
3. Reduction of externalized behaviours are measured using at Eyeberg Child Behavior Inventory baseline and post-intervention (8-9 weeks)

Overall study start date

01/03/2015

Completion date

30/10/2016

Eligibility

Key inclusion criteria

Families with preschool age children (aged 2 to 6 years) currently attending educational centers (public and private subsidized schools, and centers from JUNJI and Integra Foundation) in Concepción, Chile.

Participant type(s)

Healthy volunteer

Age group

Mixed

Sex

Both

Target number of participants

The trial considers a minimum of 300 participants. A minimum of 18 clusters will be included (17 participants by cluster).

Key exclusion criteria

Families with children diagnosed with:

1. Intellectual disability (severe and profound)
2. Generalized developmental disorder

Date of first enrolment

20/03/2016

Date of final enrolment

30/04/2016

Locations**Countries of recruitment**

Chile

Study participating centre**Lafkeen**

Galvarino 1121
San Pedro de la Paz
Chile
4130000

Study participating centre**Los Pinos**

Escocia con Italia s/n
Chiguayante
Chile
4100000

Study participating centre

El Porvenir

Calle 2 esquina calle 3 s/n

Porvenir

Chiguayante

Chile

4100000

Study participating centre

Juan Pablo II

Toltén 1284

Valle Nonguén

Concepción

Chile

4130000

Study participating centre

Diego Portales

Dalcahue esquina Aisén s/n

Población Diego Portales

Talcahuano

Chile

4260000

Study participating centre

Leonera

Los Andes esquina Escocia S/N

Chiguayante

Chile

4030000

Study participating centre

La Gloria

Pasaje Malalcahuello 540

Población La Gloria

Talcahuano

Chile

4260000

Study participating centre
Nuestra Señora de las Nieves
Avenida 5 De Octubre 375 Boca Sur
San Pedro de la Paz
Chile
4260000

Study participating centre
Brisas del Mar
Esperanza 640 Población 18 de Septiembre
Tomé
Chile
4160000

Study participating centre
Escuela Penco
Maitén 297
Penco
Chile
4150000

Study participating centre
Escuela Los Conquistadores
Cochrane 40
Penco
Chile
4150000

Study participating centre
Escuela Almirante Jorge Montt
Lorenzo Riveros, N° 338
Penco
Chile
4150000

Study participating centre
Escuela República Italia
Roberto Ovalle 2

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Study participating centre
Escuela Isla de Pascua
Las Heras 485
Penco
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Study participating centre
Escuela Los Libertadores
Los Yaganes 290
Hualqui
Chile
4180000

Study participating centre
Escuela Thompson Matthews
Juan Manuel Vacle, 430
Lota Alto
Chile
4190000

Study participating centre
Colegio María Inmaculada
General Cruz N° 250
Concepción
Chile
4030000

Study participating centre
Colegio Guillermo Velasco
Maipú N°1150
Tomé
Chile
4160000

Study participating centre**Clegio San Pedro**

Lautaro 431, del BíoBío
Coronel
Chile
4190000

Study participating centre**Escuela Santa Teresita**

Yugoeslavia 1464
Hualpén
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Sponsor information

Organisation

University of Concepción

Sponsor details

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Concepción
Chile
4030000

Sponsor type

University/education

Website

www.udec.cl

ROR

<https://ror.org/0460jpj73>

Funder(s)

Funder type

Research organisation

Funder Name

National Commission for Scientific and Technological Research FONDEF Program Ideas
(Comisión Nacional de Investigación Científica y Tecnológica Programa FONDEF Ideas)

Results and Publications

Publication and dissemination plan

Planned publication of study results in a peer reviewed journal.

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/09/2018		Yes	No